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OMB/RECORDS MANAGEMENT DIVISION
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ROLL NUMBER

DESCRIPTION

1332

2005 HOUSE INDUSTRY, BUSINESS AND LABOR

HB 1332

2005 HOUSE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. HB 1332

House Industry, Business and Labor Committee

☐ Conference Committee

Hearing Date Monday, January 25, 2005

Tape Number	Side A	Side B	Meter #
1	X		0-end
1		X	0-end

Committee Clerk Signature

Minutes:

Chairman Keiser: Opened the hearing on HB 1332. All committee members were present.

Representative N. Johnson: Appeared in support of HB 1332 and provided written testimony (SEE ATTACHED TESTIMONY).

Dr. Patricia Hill, Executive Vice-president, North Dakota Pharmacist Association: Appeared in support of HB 1332 and provided written testimony (SEE ATTACHED TESTIMONY).

Representative Ekstrom: Is there a typical estimate of what kind of extra dollars we may be expecting.

Dr. Pat Hill: My colleagues can answer that. The pharmacy industry in ND has had a good relation ship with BCBS and the fact that BCBS owns a PBM, would not necessarily jeopardize that relationship, the pharmacies that are being paid by Prime Therapeutics are at a level that will put some of the pharmacies in ND out of business.

Steve Irsfeld, Rph, Dickinson: Appeared in support of HB 1332 and provided written testimony (SEE ATTACHED TESTIMONY).

Tony Welder, Pharmacy Owner, 40 years, Bismarck: Appeared in support of HB 1332 and provided written testimony (SEE ATTACHED TESTIMONY).

David Olig, Pharmacist, Fargo: Appeared in support of HB 1332. The bill protects ND purchases that's the most important part, why are we in favor of this bill? Because what is going on is wrong. PBM's are garnishing these discounts based on volume, PBM's have no volume, they don't own any inventory. All of the rebates are earned by ND PERS, or any other purchasing group, all of the rebates should be there. How can they have profitability if they don't have inventory? Could we not start our own PBM? We are looking at a nonprofit PBM that has a maximum retention rebate of 3 1/2%. PBM's never save us a dime, they have added a layer of cost.

Terry Christensen, Pharmacist, Bismarck: Appeared in support of HB 1332, I'm going to give an example of what I had happen about a week ago, a prescription that I had filled for a woman, who had insurance plan administered through a PBM, her husband had brought the prescription in and I had filled it, this time it came back as a non-formulary prescription, CO-pay came out as $105.00 the employer a self funded plan, ended up paying $5.00 of course he didn't like that so I changed it to one of there formulary drugs, co-pay came back as $60.00 for the customer, and the employer would of paid $67.00, so I took it to the employer and showed him this, I said why is your plan sponsor recommending you use a formulary drug that is going to cost you more money, I think you need to call express-script and ask them why? And He did and they wouldn't answer

him. You as employers would want to know why the formulary drug the preferred drug, is going to cost you more?

Gary Boehler, Executive VP Pharmacy Operations, Thrifty White Drug: Appeared in support of HB 1332. One of the recurring themes that I hear, is that when my PBM comes to me, they tell me that my rates, because we had a good year last year, are only going to rise by 8%, 10%, 12%, 14%. And then when I go back and I did a little analysis last week, on the inflation of our retail of the last 4 years, they have actually dropped between Dec. of 2000-2001, our rate of inflation for all the prescriptions we filled, was 7.8%. The following year it dropped 6.9%, then ending Dec. 2003, we were at 4.4%, and for the year just ended Dec. 31, we were 2.4%, and that's the retail inflation that we saw. From a cost perspective, the manufacturers of the industry state, that inflation runs somewhere on the cost of goods, between 3% and 5%, and that will vary year to year depending on the number of new drugs that come out particularly the single source brand, If our health plans and sponsors are being charged double digit increases on an annual basis, yet the rate of inflation is somewhere between 4% and 5% and let's just call it 5%, that leaves a spread of 5, 7, 8, 9, or 10% or more, the question that should be posed to all of us is where is that additional increase that the plan sponsors are being charged, going? It's not going to the community pharmacy, because our reimbursement have declined for the last 14 years, I've been in pharmacy operations for 23 years and a pharmacist for 35 years, so I've seen all of this evolved since I graduated from college. Somewhere in the middle that money is being kept. The second thing I would like to talk about is generic vs. brand utilization, the rebates from the drug manufacturer comes to the PBM's for the brand name drugs, not for the generic. The real focus is on the brand name drugs, the single source drugs. Lack of transparency by the PBM's pushes

up the cost of prescription drugs for planned sponsors because of kick backs received from the drug manufactures who then in turn continue to raise prices to hold their profit lines up at that 18% to 20%, and until that model is broken, we will be 2 years from now, 4 years from now, 10 years from now and we will be preaching and talking the same issues.

Chuck Johnson, General Council, ND Insurance Department: Appeared in support of HB 1332 and provided written testimony (SEE ATTACHED TESTIMONY).

Linda Wurtz, Associate State Director for Advocacy and Communication for AARP: Appeared in support of HB 1332 and provided written testimony (SEE ATTACHED TESTIMONY).

Cal Rolfson, Legislative Consultant, Pharmaceutical Research & Manufactures of America: Appeared in support of bill and provided a written statement (SEE ATTACHED TESTIMONY).

Vernon Rowen, VP, State Government Affairs, Express Scripts: We are the nations third largest PBM providing services for about 50,000,000 Americans across the country, we have a very limited business here in North Dakota. This is a very bad piece of legislation and very poor public policy. PBM's have not increased drug costs, its well proven that PBM's have reduced drug costs. We make about 1.5% profit margin on revenues we receive, in return numerous studies show that consistently that PBM's deliver about a 25%-30% savings on prices of drugs based on compared to a cash paying customer would pay. Employers understand how PBM's work. We are in the center of the hub of prescription drug delivery system today, there are about 60 PBM's that compete across the country.

Rod St. Aubyn, Blue Cross Blue Shield of North Dakota: Appeared in opposition of HB 1332 and provided written testimony. The worst part of this is that no one has been able to prove that a problem exists in ND.

David Lassen, Senior Director, Care Management, Prime Therapeutics: Appeared in opposition of HB 1332, and provided written statement (SEE ATTACHED TESTIMONY).

Representative Thorpe: Does BCBS own any part of Prime Therapeutics?

David Lassen: Yes they own a portion of Prime.

Representative Johnson: 9 BCBS's own Prime Therapeutics, and that they can request Prime Therapeutics to do an audit, so its saying that the company that owns the company can ask the company to do an audit? Which means its not valuable to anything, am I understanding that right?

David Lassen: Yes of course that is right.

Representative Keiser: Does Prime receive rebates?

David Lassen: Does Prime receive rebates, yes they do.

Representative Keiser: If that is true, do you see any conflict of interest in your contractual relationship with the blues and the rebating?

David Lassen: Prime right now is working with all BCBS plans to eliminate rebate revenues. and move to a different pricing law.

Representative Kasper: Who currently right now has advantage to the rebates?

David Lassen: BCBS, we pass it back to them, they pass it back to the members.

Patrick Ward, Partner, Zuger, Kirmis and Smith, Medco Health Solutions, Inc.: Appeared in opposition of HB 1332 and provided a written statement (SEE ATTACHED TESTIMONY).

2005 HOUSE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. HB 1332

House Industry, Business and Labor Committee

❑ Conference Committee

Hearing Date 1-26-05

Tape Number	Side A	Side B	Meter #
4	xx		0.0--18.9

Committee Clerk Signature Pam Dever

Minutes: **Chair Keiser:** HB 1332 is very complicated and will require many subcommittee meetings. Don't get frustrated.

Rep. Amerman: I believe there is a problem out there. I don't know if this bill solves it. Why weren't there any employees at the hearing? Confuses me. Are the employers just asking the pharmaceutical to bring this forward?

Rep. N. Johnson: I met with pharmacists afterwards. They said most employers don't understand. They just look at the bottom line. Are they getting this amount of coverage and this amount of premium. It's not visible. They can't find out what kind of a deal the drug companies are giving them the PBM's. That's why there were no employers in here.

Rep. Ekstrom: All the employers sponsored the bill. I think they know there is a problem and they can't get at it. They can't see it. There are suits all over the country and big ones.

Rep. Clark: In the beginning of testimony, I thought this would be an open and shut case. The more we heard, it is very obvious this is complicated and problems do exist.

Rep. Ekstrom: I was wondering if Attorney General could help with some clarity for us with rebates, etc. and legal contracts.

Chair Keiser: If we form a subcommittee, we need to get both parties together. We need to identify what the issues are and how to better address them. This bill does not do that. If you want to vote on this bill the way it is, that's fine. I don't support it.

Rep. Vigesaa: I thought what the pharmacists brought up what was what the bill brought up. All of the employers are major companies.

Chair Keiser: What drives me crazy is that the PBM's unilaterally decides to charge 3 cents to fill a Rx to a pharmacy. The judge rules against us, penalizes us, and we change it to 10 cents. We do we not recover the penalty. You are not suppose to make money off of that kind of judgment. It's suppose to be a penalty that stops the action. And here they go unilaterally to 10 cents and have the pharmacies have to pay it and they bill the BLUE's for it.

Rep. Thorpe: I move a DO NOT PASS on HB 1332. Rep. Clark: I second.

Rep. N. Johnson: I am going to vote no on this motion because I feel it need to be dealt with further.

Rep. Ekstrom: I , too, will resist this motion. I don't think we have talked about this enough.

Rep. Thorpe: I withdraw my motion. Rep. Clark: I withdraw my motion.

Chair Keiser: BLUE's has a monopoly, that's a given. We need to have a subcommittee. That committee will be in charge of coming up with a good bill. The two entities are so far apart. Is there any common ground? Both sides are anxious. They may be willing to sit down and talk. The following will be on the subcommittee: Rep. Kasper, Rep. Vigesaa, Rep. Dosch, Rep. Thorpe, and Rep. Amerman. Rep. Kasper will chair. Adjourned.

2005 HOUSE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. HB 1332 sub

House Industry, Business and Labor Committee

❑ Conference Committee

Hearing Date 2-2-05

Tape Number	Side A	Side B	Meter #
1	x		0-end
1		x	0-4.5

Committee Clerk Signature Judy Rourke

Minutes:

Chairman Kasper: called the subcommittee on HB 1332 or order.

I would like each side to give a brief overview on why you like or don't like the bill, this is my third session, and is by far one of the most difficult bills that I have heard, I think both sides of the issue have given a very good presentation. That is one of the reasons that the sub committee has to deal with it and come out with a bill that is in the best interest of the state and is fair to the opposing sides that have the issues here before us.

Dave Olig, Pharmacist, Fargo: Provided a written statement (SEE ATTACHED TESTIMONY). One of the things we need to talk about is transparency, is required because it's about the people who are purchasing health care, that is the major issue.

We are dealing with something we call a spread, PBM's retaining manufacturers

rebates, this is a very difficult complex situation. Average wholesale prices are established by manufacturers, those numbers are manipulated by mail order pharmacies, and they establish a new average whole sale price if you look up Celebrex that start at $3.14 up to $8.00 per pill those prices are for one reason and that is to bill the planned sponsor. They are spreading out these prices based on Average wholesale price and it doesn't say whose. There is an average wholesale price the original one being established by the manufacturer for original packets. When a mail order pharmacy decides to buy 55,000 capsules and they repackage them and give them a new number when they do that they assign a new average wholesale price to it, that price is what the spread ends up being. There was a study at Creighton University they were assumed to be non partial third party, they took a look at 400,000 prescriptions in that 400,000 prescriptions, they said that spread between average wholesale price adjustment totaled conservatively more then $6,000,000.00 in over charges. Key word is conservatively. I pay one match price and they have plan incredible discrepancies **Peter Harty, VP Government Affairs, Medco Health Solutions one of the 3 large PBM's:** I took out of what Olig just said is the reason you don't need this bill, he gave you an example of an employer in that state what that employer was unable to get what that employer wanted from that PBM , what they do they went after the market place and got themselves a new PBM that gave them what it was that they were looking for in terms of the PBM services. Didn't need a statute,

didn't need regulations, didn't need a law to say this is the way your going to do it and yet they got exactly what they wanted. You don't need this law because the market place is working. There is about 60 PBM's engaged in the market place. I do want to touch at the market place in which we work vigorous competition amongst us in the business. I don't think that this state or any other state wants to interfere with that competition, I don't think that my colleagues and our legal department are a client contract, if you see one client contract you've seen one client contract, there is no one size fits all that works in this environment every payer has different issues. I do want to say that we are a 4 profit company and I'm not ashamed of that I'm not ashamed of the fact that just like every other private sector of business, we mark up our goods and services in order to return a profit back to our shareholders. How many businesses have to disclose to their customers what their revenue streams are what their mark up is, I will tell you that our net income after taxes is 1.2%, I will point you to our financial statement submitted to the FTC certified and audited, my CEO faces personal criminal liability if those numbers are not correct and it is 1.2%. Our gross market is 4.4% 1.2% is net. How many payers have come here to say, help us to negociate with PBM's, how many, none, I don't know that there are any payers that say they need the states help.

Representative Kasper: Do you do a lot of business in North Dakota? And is that through your

own contracts with the employer, or through insurance companies.

Peter Harty: We have somewhere in the order of 40-50,000 lines here, some with employers and some with insurance companies, in terms of what we have here in the state of North Dakota.

Representative Kasper: Over all what is the size of your company in the U.S.

Peter Harty: We have about 60,000,000 covered lives that we have across the country.

Representative Kasper: And are you the largest PBM?

Peter Harty: I think that CareMart is slightly larger in terms of covered lives.

Representative Kasper: Do you always work through insurance companies or the employer, or do you provided services to pharmacists?

Peter Harty: We contract with employers and through insurance companies.

Representative Kasper: And the theory because of your large size, your able to negociate with the drug manufacturer to purchase at a lower price which is passed on to the consumers that use your services?

Peter Harty: That is correct.

Representative Kasper: When you negociate with the drug companies you might be able to negociate a different pricing schedule then one of your PBM competitors, depending on the volume and who is doing the better negotiating?

Peter Harty: That is absolutely correct we have no idea what deal they are able to cut with the manufacturer and they have no idea what kind of a deal we are able to cut.

Rod St. Aubyn, Blue Cross Blue Shield of ND: That is one of the issues about

disclosure, you start disclosing that then all of the rates that have been negotiate with manufacturers that ends up being no further negotiations because everyone can see what every one else is doing.

Lauren Baldwin, CareMart: Once generic products come on to the market place the rebate or discount from the manufacturer are eliminated because everybody drops there prices.

Representative Kasper: I would think as a drug ages from year to year and more utilized the and the time goes by where the drug companies are able to recover some of there research costs, the theory would be as time goes on the drug would become lower priced is that a correct assumption or not?

Peter Harty: I think that would be a good theory. There is competition, there is not a generic on all drugs, and until there is the price might not drop.

Representative Kasper: Once this drug price is set is the tendency of the manufacturer is to raise the price if the competition bares it? Or until a generic comes on board or is it to hold the price level, or do you begin to see a reduction in pricing as time goes on?

Peter Harty: The manufacturer decides what price they want to put on it when they first bring the drug to market, and what the market can bare.

Representative Kasper: As time goes on what does the market do on these drugs?

Dave Olig: What you tend to see is what they call "me too" 17%-18% spread, the prices everyone of those discounts get added back to the price as we see discount given to Express Scripts the AWP goes up again and I pay the higher price and the bill price ends up being the

new AWP based on the discount given to PBM's, it's a pay to play scenario, the issue is how much of a spread is there between AWP and what the discount is and how much is given back to the planned sponsor, who buys the product, PBM's don't buy a thing, they don't own anything, they don't own any drugs, the planned sponsor does they pay for the products, I pay for the products, these people pay claims, the question winds up being What percentage of that discount based on the volume the planned sponsors earn by buying these medications? That is excess cost and that is the issue there is a huge spread.

Representative Kasper: If there is in fact competition in the market place, why aren't drug prices going down when we are seeing a 15% to 20% per year cost escalation, where is the savings to the consumer if there is competition?

Representative Dosch: How many PBM's do business in North Dakota?

Dave Olig: Probably about 30, it ends up being the big "3" CareMart PCS ExpressScripts, Medco, and Prime Therapeutics and after that it is everybody else.

Representative Dosch: Your trying to tell us your saving us a lot of money because of your quantity buying but yet when we have double digit increases in our drug prices year after year, where am I saving money?

Representative Kasper: There really is no relationship between the average whole sale price and the price that is paid is there? They could be totally different, the wholesale price is just a price that is plugged in some place where somebody decides that is the price that were going to talk about.

Lauren Baldwin: I believe so.

Representative Kasper: That would be a spread, would it not be?

Peter Harty: That's a benchmark.

Representative Dosch: How can the local pharmacies ever compete with that? If what you are telling me is truly correct, how does the local pharmacy compete with that?

Representative Kasper: Peter, you keep talking about the employers are knowledgeable, that may be in the real world can hire a Hewellet, or a Mercer, but in the real world here in ND, we are trying to focus on the North Dakota problem, not the St. Louis, MO. problem, we are mostly small business, the only thing they know is that my prices are going up and my premiums are going up and its getting to the point that I'm getting strangled, and I can't afford to pay the premiums, we are trying to address this cost escalation in the market place if there is competition, so we can try to do the right thing with this bill.

Representative Dosch: Dave, when we talk about transparency, how does that effect you?

Dave Olig: I am just as concerned as the average employer, I'm looking at a 3% gross.

Pat Ward, Zuger, Kirmis and Smith: This bill came up in other states and they did a through study and what the FTC said is that there is vigorous competition between this PBMs and if these disclosure requirements are in this bill it actually is going to decrease the competition and causing the consumers to pay more not less. And nobody is talking about the problem that the pharmacists have, I don't think it does. They are talking about that PBM's are not saving money there have been other studies. Mail service pharmacy saves money not as much as the PBM's and that the retail pharmacy is the place that you are going to save the least money on drugs, these are things that have been studied and looked at if there is a problem in ND, I don't think that we have enough information, I'm suggesting that if you guys think that something needs to be done here in ND my idea would be to convert this to a study bill and have someone take this time and come

to the right conclusion, I don't think a legislative committee can make this decision, my recommendation would be please don't do it, its probably unconstitutional, I think you don't want to go there, I think that you may be concerned that there is problem, but if there is lets study it and find out.

Dr. Patricia Hill, Pharmacist: the disclosure issue, the fact of the matter is, in the handout that you have today it was brought up last week, we have provided you with the name and telephone number of the attorney in S.D. that actually crafted that legislation and according to his own words that bill was crafted to very much address the judges comments that came out of the injunction, and it was crafted to accommodate all of the concerns about fiduciary, responsibilities and disclosure and trade secrets, you have his name and phone number he is in the middle of his session, but he will take calls from the committee members, if you need to speak to him about that because he understands your concerns and he is in a position to alleviate that. The other issue is that there are in fact employers interested in this.

Representative Thorpe: The bill is asking for transparency, what is fair for one, should be fair to all.

Meeting adjourned.

2005 HOUSE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. 1332 sub

House Industry, Business and Labor Committee

☐ Conference Committee

Hearing Date 2-8-05

Tape Number	Side A	Side B	Meter #
1	x		0-32.8

Committee Clerk Signature Jodey Reuter

Minutes:

Chairman Kasper: Called the subcommittee to order on HB 1332. All members were present.

Representative Vigesaa: Have both sides come up with any compromises on the direction with this bill?

Rod St. Aubyn, Blue Cross Blue Shield: Pat Ward will offer an amendment that will turn this bill into a study, so we can work on this in the interim.

Dr. Patricia Hill: We are actually proposing an amendment with the Insurance Commissioner in the morning. It might be beneficial to have the bill provide a little bit more oversight by the Insurance Department to provide that expertise to ND employers and that would require a fiscal note so that the insurance department could retain that expertise. If you do consider a study at some point I would like to share some information that might influence whether you want to

study it further or whether you want to take on some savings with our ND public employees program. I had visited with **Larry Kuker, Director of Employees Benefits for the state of SD** and their transparency bill which ours duplicates, is HB 1311 and was in place of July 1st of last year, and so when they did their RFPs for their state employees group you could only participate if you complied with state law, which included transparency, he reported to me that 13 PBMs actually participated with the RFP of the one they choose is Prescription Connections that is out of California and did not previously do business in South Dakota, they are a smaller entity and serve about 5 million consumers, by simply switching to that PBM they initially saved $800,000.00 from what they had been paying previously in addition to that, the savings they now project for the first year, in terms of receiving !00% of the Rebates, that they had not be receiving before, is 1/4 million dollars for the biennium it will be close to 1 ½ millions dollars that theyhad never seen before in addition to the $800,00.00.

Vern Rowen, Express Scripts: The state of SD did not need to pass that law for the state employee program to fit those requirements in place, but whoever bid on that contract had the ability to do that before they passed the law. You don't need a law to do that, you can use your market place of competition as your purchasing clout to demand those things from the people who provide the services to you.

Kathy Allen, Benefit Program, ND, PERS: We just put out the bid last year for our plan, we did include questions Pharmacy Benefit Manager, one of the

questions that we did ask in our proposal is if we would be allowed to unbundle which means to carve out the prescription drug benefit, and of course that answer, in the case of our plan and we only received one bid and that was from BCBS of ND. They indicated that "no" we could not carve that benefit out. There for in the contracts that we are looking at for the next 6 years would be the Pharmacy Benefits Managers Prime Therapeutic, and they have the Dakota RX network and that is the network that we are with BCBS and contracted for. Currently we do participate in their rebate program, generally what we get is the average wholesale price minus 10%, for independents and for the few chains we have in the state it is average wholesale is 12%, the dispensing fees range are different between urban and rural, for brands it could range anywhere between $4.25 to $5.00 a script and for generic it could range between $5.00 to $5.75 a script.

Representative Dosch: BCBS or the ND Pers are not receiving any percentage of the discount negotiate right now?

Tom Christanson, BCBS of ND: Prime Therapeutics on our behalf contracts with the ND Pharmacists. In the reimbursement rate there is an ingredient cost of the drug that needs to be remembursed and then there is a professional servicre fee and that ingredient cost of the drug is an estimated cost that is based on the AWP and then a discount is taken off of that. The other part of $4.25-$6.75 is the dispensing or professional fee that reimburses the pharmacists for the services that they provide.

Representative Dosch: I understand that but my question is, is any of the

discount being passed on to ND PERS?

Tom Christenson: They would take the full advantage of that part of it, if that is what we are talking about. That is the rebate part of it, Prime Therapeutics negotiate on our behalf, they retain a percentage of that as an administrative fee for negotiating the rebate, and supporting our formulary efforts.

Representative Dosch: Is that common that BCBS does not allow the carving out of the drug benefits portion of that contract, is that typically what happens, or have you in the past been able to negociate with others then Prime for example?

]Kathy Allen: We have not been in a position to negociate with other firms, we are a fully insured plan and as such the Pharmacy Manager that BCBS uses for all of its clients is the same one that PERS has been using.

Representative Kasper: If I'm understanding this correctly is you signed a 6 year contract and when you asked if you could carve out the PBM you were told NO so in other words it was a take it or leave it from the BCBS perspective to ND PERS?

Kathy Allen: That is correct.

Representative Kasper: When we get into transparency, my first question is, are you totally 100% transparent with PERS contract so they are able to see all of the discounts and rebates that the PBM is receiving and they know what percentage they are receiving and what percentage is being kept by the PBM?

Tom Christenson: They are aware of the percentage that is being retained and the

remainder has passed on that is provided in a written form and with payments. There is no purchase that goes on from the manufacturer it actually is a rebate or refund and what it is passed on is the utilization that is made, so this AWP minus 12 or 10 is what the pharmacy is being reimbursed, in addition to that act additional discounts are bargained for.

Representative Kasper: And are you disclosing 100% of the information from your discounts from the drug manufacturers to the various customers?

Tom Christenson: I can't answer that question one way or the other.

Representative Kasper: How does a PBM feel about a mail order?

Tom Christenson: right now we have contracts with 2 mail order facilities, one is Wal-Greens the other is Prime Mail, which is with Prime Therapeutics.

Representative Kasper: Are there different pricing structures with mail order as opposed to local pharmacists?

Tom Christenson: With Generic drugs there is a different pricing, on the retail side generic costs ingredient costs are reimbursed. The mail order side that is AWP minus 35 % the top 10 utilized drugs are MAC. The difference between AWP and mac is mac is kind of a blended AWP in a way, with generics unlike a single source brand drug, which would have its own AWP, generics, there could be multiple manufacturers of the same products, each with its own price, and also the ability of pharmacies to purchase those drugs is generally quite competitive because of the different products that are out there, to come up with an estimate

of what that ingredient cost is a MAC (Maximum Allowable Cost) price is employed it looks at the AWP prices that are out on various generics, its generally probably a discount of more in the neighbor hood of AWP minus 50% to 60%, again because of the ability of the extra competition and the ability of pharmacies to purchase those drugs.

Representative Dosch: We are looking at the total cost of the prescription, who ends up paying that dispensing fee? Do you charge more on a normal walk-in business, but on mail order there is no dispensing fee as far as the consumer is concerned, do you recover the cost on the consumer or not?

Answer: I don't know who answers this. The contract with the PBM sets out our reimbursement and that would be the pricing billed to the plan 5the patient is going to pay the co pay, what that means is that they established the MAC and we have different MACS for different PBMs the numbers are different from one PBM to another. So we are set up with a MAC, plus a fee that determines retail.

Representative Kasper: Here is the question that has been bothering me, Tom, you said you don't have the drugs, your just the record keeper, pharmacies are dispensing the drugs, there is income coming in here but you don't have the drugs, you have the drugs and your getting paid, so the pharmacy does not get there drugs through the PBM do you? So the question is how are we getting any discounts per volume through the PBM when they are reimbursing you that has nothing to do with your cost, and they are not getting the volume discount be

cause you are buying your drugs some other place, how are you making any money when your reimbursement could be lower then what your actual cost was, and how do you drive the discounts from the manufacturers?

Tom Christenson: It is based on the drug formulary, a list of preferred drugs so to speak.

Representative Kasper: Where are the drugs? Let me clarify what I think you said..... your going to get a credit, for Lipitor (example) because its on your formulary from the manufacturereven if it was bought in one place and dispensed in another, so what you are doing is keeping track paper wise, your negotiating with the drug companies and your saying that we are going to drive your product because you are on our formulary, so it doesn't matter who dispenses it because of the fact that it is on your formulary, your getting the discount and then they buy it based on their price and they make their money on their spread, and you make your money on your discounts and rebates?

Tom Christenson: That is correct. The discounts that we are able to negociate are separate things.

Representative Kasper: So all of this coming because a consumer is using a drug and a doctor is prescribing a drug.

Tom Christenson: Yes

Representative Kasper: So what percentage of all of these rebates and discounts end up to the benefit to the employer or the consumer?

Tom Christenson: Except for what may be retained by the PBM, everything

Representative Kasper: What percentage?

Tom Christenson: I think that is probably proprietary information.

Representative Kasper: And that is the problem isn't it you just hit it right on the nose. The proprietary concern where the employer and the consumer is not getting the information, and they are the ones paying the price, and that is why prices keep on going up. In the PBM there is no competition.

Representative Kasper: We will reconvene tomorrow.

Hearing adjourned.

2005 HOUSE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. HB 1332 sub

House Industry, Business and Labor Committee

❑ Conference Committee

Hearing Date 2-9-05

Tape Number	Side A	Side B	Meter #
1	x		0-37.1

Committee Clerk Signature Joan Burke

Minutes:

Chairman Kasper: reconvened the sub committee on HB 1332

Sparb Collin: When it comes to the relationship with the PBM, PERS right now is under a fully insured rate with BCBS, what that means that unlike a self funded plan, we don't bid out various components we have a contract with BCBS and part of the contract of BCBS, they bring along the Pharmacy Benefits Management, we don't independently bid for that.We go out every 6 years on a bid, and one of the questions we ask is.... describe how drug rebates will be returned to PERS as part of the accounting process. Drug rebates for ND PERS account are identified by Prime Therapeutics are netted against ND PERS claims expenses. So that is the guidance we have. Now last session you authorized us part of this general accounting and auditing function, so that we can become a little more pro active in these things. So one of the questions that internal audit

asked as we started to look into some of these processes that were starting out....

1. this question came up in July of this year, questions that we ask BCBS about documentation about preform rebates, and that is just a generic name for Prime Therapeutics contracts" is it possible to get a report or some type of support documentation for performed rebates for both bienniums"? And what it tells for one quarter we had about 53,000 participants the gross amount of the rebate was $336,996.45, there was a 8% administrative charge, which is $26,863.49, the net amount is $310,132.00 that would come back to PERS. We also as part of our arrangement we fund the clinical outreach program of BCBS, and as you know is one of the issues today is that pharmacy companies send out a lot of pharmacy representatives to encourage doctors to use there prescriptions. We see that marketing that goes on TV as well. The net amount in that quarter is $291,000.00 that comes back to PERS. We are still in the process of our internal auditor to continue to work on that.

Representative Kasper: Is this a report that BCBS gave to you, or that you did internally?

Sparb Collin: BCBS gave this to us in response to the question that we asked on the back up report.

Representative Kasper: And this was the entire documentation they gave you? No cover letter or anything?

Sparb Collin: That was for one quarter, I guess I never asked for a cover letter I

just asked our auditor what we had gotten this term for the back ground report. We may have the authority to go in and audit those numbers in more detail.

Representative Dosch: Sparb, you never done an audit of BCBS up to this point?

Sparb Collin: On this specific subject, no we have not.

Peter Harty, VP, Government Affairs and Policy, Medco Health Solutions which is a PBM:

As I indicated last week, this piece of legislature is not necessary and that the market place where PBM's compete vigorously for business has evolved over the last couple of years, the same issues that are being talked about in this room for the last 2 weeks are things that benefit managers and employers of health plans talk about amongst themselves. The same news paper articles the same questions, the same concerns, the folks that do this stuff every day for a living manage the benefits of the employer, manage the benefits of the health plan, they know what questions to be asked. They know the answers they are looking for, and they understand how to use the competitive process to get to the results that they want to get to. We don't contract with the 50, 200, 250 employer, they don't deal with us, they don't carve out the benefits, they go to BCBS or somebody else that we call an agragator its somebody that takes all these lines from these small employers and they have thousands lives that they turn around and negociate with us. So we not taking advantage of the small employer who doesn't know what sort of questions sophisticated health care purchaser who know how to contract.

Dr. Patricia Hill, VP, Pharmacist Association: The ultimate goal is to address

the rising cost of prescription medications. In a variety of conversations in and out of this committee, there has been visiting about S.D., whether or not this looks like S.D.'s bill, I can tell you that they are very similar, the language on the fiduciary issue is very much like S.D. I have that language if you would like to see it. In terms 0of vigorous competition, we talked about that in two separate meetings, you heard yesterday that when our state employees put out bids they got one, I'm not sure that qualifies for vigorous competition. Another piece of information that you would be interested in because its been brought up on several occasions in the past as a point of reference, is that in the fact in the state of Maine, it was the first state to consider this type of legislation, an injunction has been filed, and you might find some relief in knowing that the judge ruled last week, that, that injunction is to be lifted, and that many of the points that you have heard about and been discussed in this committee and the concerns that go along with that law suit have actually been ruled in favor of the state of Maine as of Last Friday, I do have a press release that came out of the state of Maine.

Representative Amerman: We have to make a decision in this committee.

Representative Dosch: This is the disclosure report that the state is getting, and the comment that was made is, that the ND PERS is just kind of beginning to understand this whole process and the questions that need to be asked, so when you talk about the educated consumer out there, if ND PERS is just beginning to understand this I really have problems with any othersmall employer group being able to understand this. The fact that they received one bid and that was from

BCBS, and that did not allow the unbundling of the Pharmacy Benefits, I have a little bit of difficulty understanding where this vigorous competition is in the state of N.D.

Hearing adjourned.

2005 HOUSE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. HB 1332 (sub)

House Industry, Business and Labor Committee

☐ Conference Committee

Hearing Date 2-14-05

Tape Number	Side A	Side B	Meter #
1	x		19.2-end
1		x	0-21.5
2		x	0-end

Committee Clerk Signature Joan Rensch

Minutes:

Chairman Kasper: Reconvened on HB 1332.

Chuck Johnson, General Counsel, North Dakota Insurance Department: I'm trying to come up with some wording that would be agreeable to committee, chairman, commissioner, and interested parties, you all have a set of the amendments and the chairman asked for all of the amendments into a bill and so my assistant did that and maybe the sub committee can look through that, page one is just a simple change of the title. Page 2, there is a addition number 3 is see identified information that changes HIPPA requirement.

Chairman Kasper: What does this exactly do to them.

Chuck Johnson: It protects information that is considered so be private and personal and privileged. Page 3, we have taken out part of the pharmacy benefits management that includes mail service pharmacy and then later on it takes out

certain patient compliance. If Blue Cross Blue Shield contracting with a PBM, whatever it is, if it decides its going to hire people in house to do the prescription management program, not relying on any body else, they are going to be negotiating drug purchases with drug companies themselves. SO they are going to be doing everything that a PBM does, but they are going to be doing it with there own people, in house, taking all the benefits of it, doing all the work involved with it, assuming all the risk of running a program like that, if they do that for themselves, they are not impacting anybody, they certainly impacting their policy holders, but that's a relationship between themselves and their insurers. The other relationship that your dealing with here is the relationship between insurance companies and prescription benefits management because that is a totally different relationship. So with this bill you are trying to regulate that information, your trying to make those PBM's licensed to we have some review and oversight over them. That is fine with respect to a third party that's offering this kind of service, but when you have an insurance company just doing the in house work of deciding which drugs they will allow, how much they are going to pay the pharmacist. There isn't a concern to regulate an insurance company that is doing work for itself as it is for a third party that is doing work for insurance companies.

Representative Kasper: And what is the reason you don't want to know what is going on there?

Chuck Johnson: Any of those dealings would be regulated by insurance law.

Representative Kasper: What about the transparency in 26 21, and what would happen to the discounts and rebates, if they were subject to 26 21 only?

Chuck Johnson: Any discounts or rebates would flow right back to the insurance company, there is no danger that there is a third party in between your insurance company and the manufacturer that is going to be keeping part of those, those moneys that come back in they are considered income or reduction of expenses for the insurance companies, the insurance company bases his rates on its cost and expenses.

Representative Kasper: We have also allowed under statute for that entity to form as the words are saying here "when the health carrier or its subsidiary" and we have allowed Blue Cross or Meridian to form separate subsidiary that are underneath their holding company, so theoretically this part of the bill would allow separate subsidiary which would be a PBM to do what it wishes with the drugs and there would be no transparency in that PBM?

Chuck Johnson: I would there would be transparency, if you have a subsidiary it is totally controlled by Blue Cross and the benefits of the subsidiary in the way of profits gets flowed back to Blue Cross Blue Shield.

Representative Kasper: So this exemption, would Blue Cross then have to take those rebates and discounts and provide it to the benefit of the insured or employers?

Chuck Johnson: Any discounts that the Blues receive and they would get

factored into rate calculation so as the expenses are reduced and rates would be lowered because of it.

Representative Vigesaa: In this particular case Blue Cross Blue Shield has a relationship with Prime Therapeutics so how do we separate those 2 in this section are Prime Therapeutics still considered a PBM and then Blue Cross is not?

Chuck Johnson: Right, whether Prime Therapeutics is a PBM, the Blue Cross Blue Shield owns a minor part of that I understand, what ever profits are distributed from Prime Therapeutics back to Blue Cross Blue Shield, they don't really have control over it because they are only one of several owners, those profits or any distribution from Prime Therapeutics will go back to Blue Cross Blue Shield and that would be considered to be income it would eventually flow own to the rate payers. There is a little difference between a subsidiary and then this affiliate or Prime Therapeutics, they are a part owner of Prime Therapeutics.

Rod St. Aubyn, Blue Cross Blue Shield of North Dakota: We have no intention on doing any of this, the whole concept of that though is in the South Dakota law, if you are, for example we process all of our claims for everything else, for hospitals chiropractors, that is just what we do that is our business, it just so happens that on the pharmaceutical that we contract out because we don't have that purchasing power of the addition PBM. We have no interest in doing that it would cost us more. SO our members would end up paying more. All we are saying that if you were to do it in house, there is no contract between this hidden

PBM and us, and that would be fully regulated by the insurance commissioner. IF here was an entity that wanted to do that I don't envision us ever doing that I not sure about "or its subsidiary", I think that is just language. If we ever were to do that it doesn't make sense that we would have to register as a PBM and an Insurer, there is non contractual between a contract with ourselves.

Representative Kasper: So this wouldn't influence the current PBM arrangement that was subject to the transparency.

Rod St. Aubyn: Absolutely not, because we do not own this other entity, Prime Therapeutics, we are just a part owner, you would have to fully own.

Dr. Patricia Hill: This is our concern only because the attorney who wrote this text in South Dakota told me when we first started on this that this text specifically exempted Blue Cross, because at Blue Cross they don't have the situation that we have, in other words Blue Cross in South Dakota doesn't comprise the same percentage of the market that we have here, so they purposely exempted those folks, based on his legal opinion.

Chuck Johnson: On page 4, we struck out definition of "proprietary information, trade secret information definition number 8 refers to rebate noted its not a definition of rebate, it just notes that rebate includes a lot of things, as I understand it wants to make sure that what ever kind of benefits that flows back from the PBM to the Insurance company gets included in the disclosure.
We eliminated the section relating to the duties. Page 6, on the disclosure information, the disclosure is to the insurance department, and the insurer has the

right to audit, the insurance department would have the right to audit the insurer and the PBM books. The disclosure sections were taken out, continuing on to page 8, there is wording that Joel Gilbertson had asked for, talking about substitution of one drug for another, on the top of page 8 we changed the word "and" to "or" part B, we removed some wording that looked at disclosing the cost of the drug, we took that part out, so now that section would require that there can be a substitution but if the substitution is for medical reasons that benefit the covered individual and the pharmacists benefits manager obtains the approval, in other words the doctor has to be in the loop, the money consideration was removed. Now we get to what has been added to the bill, at least we wanted to make sure that the covered entity at least offer the option of taking the fees, not taking any of rebates, taking some of the rebates, or taking all of the rebates. And then it says that there is the audit provision and the agreement between the PBM and covered entity must include a provision allowing the covered entity to audit the PBM. And the next section which talks about the examination of the insured and that is where our insurance department, says the commissioner shall examine the contract between the company and the PBM and related records to determine if rebates and other benefits that the company has received have been applied for the use of the companies rates and I added the wording that says " or have been distributed to covered individuals.

Representative Kasper: Does the covered individuals cover employers or people?

Chuck Johnson: People. And we left in the section that says "to facilitate the examination of the company and again that is the insurance departments examination of the company, the company must disclose annually to the commissioner the benefits of the rebates and other discounts received under contracts with the PBM and must describe the manner in which the rebate are applied toward the rate. The next section gives the commissioner rule making authority, we took out the confidentiality section because it is covered under trade secret wording later.

Dr. Patricia Hill: Our concern has to do with a brief note on page 3, at the top of the page it says "mail service pharmacy", if you make note of that and you turn to page 8, and at the bottom of that page where number 3 has been crossed off, its speaks to coinsurance, co-payments, deductible, and days of supplies in terms of discriminating practices by PBM's, you may or may not choose to leave it in or take it out at this point, I'm not going to tell which way to do that, I'm going to suggest to you that is does indeed have a very direct relationship to the disclosure and the transparency that we have been trying to get at during all of these hearings. We have talked about the incentives that are used to entice consumers to purchase medications through the mail even when they are offered more expensive and not necessarily less expensive though they might be promoted to be less expensive to either the consumer or the prime sponsor, we have more supportive information if you want it I will give it to you. If you leave number 3

and the reference to mail order, the only way that these particular actives in mail order can be transparent to employer and consumer as well, is through a piece of legislation like this. And I have attached a piece of Century Code that does guarantee North Dakotans freedom of choice for their pharmacists services, but if in fact they don't have a choice because of the incentives that are being used. And incentives lead to in some cases, the whole issue about rebates, and discounts, and the spreads, etc. and I'm not sure you can leave that out, but if you choose to leave it out at this point I make reference to it publicly at this hearing that hopefully when you let your colleagues in the Senate debate this issue we can bring it up with them and it will be on record as having been brought to your attention.

Rod St. Aubyn: If we don't remove those and you look at the Medicare rules, then all of a sudden the Medicare recall to allow for that, so when part D Medicare prescription drug benefits comes about then all of a sudden were for changing our senior citizens of North Dakota saying that they can't have the same options that the other states have. As I understand the audit situation is between, on page 9, the agreement between the PBM and the covered entity, "must include provisional allowing for covered entity to audit", what they are really referring to in this, is really the health insurer and the PBM in most cases, however if you do have someone who is contracting directly with the PBM, is whoever has that contract between the PBM and the entity whether that is the employer or if it is a health insurer. I just want to comment that Ms. Hill's allegation about South

Dakota, the BLUES PLAN, that is totally false, the BLUES PLAN is actually Iowa and South Dakota and they contract privately for a separate PBM, this does not exempt them in any fashion. All we are saying is if you are en entity that would elect to do it yourself rather then go through a PBM and I can't imagine right off the top of my head that our state is large enough to handle that, but if you did, it doesn't make sense, because there is no contract between two entities, it is yourself, and the insurance commissioner has full rights to audit our records the way it is.

Pat Ward, Medco: I think we have come along way our official position is, we still think a study would be a preferred alternative, the difference between my amendments which is based on something that Chuck had already worked up, if you look on page 2 of the amendments, the word "or", and Chuck has already taken care of that, I have a question about the sight and I checked your book as well, there is no Section 1902.202 in the code, it should be 1902.102, then on the third page, with respect to audit, I would like to see just a little change in that language there, "to an out side audit, that we have mutually agreed upon. All this would do, with respect to the contract in 05, in the pharmacy Benefit management agreement between the pharmacy benefit manager and the covered entity, it would allow for us to have an independent auditor to look at the books, rather then have it done by the covered entity. And with that small change I think my clients can live with this.

2005 HOUSE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. HB 1332

House Industry, Business and Labor Committee

❑ Conference Committee

Hearing Date 2-14-05

Tape Number	Side A	Side B	Meter #
3	x		8.3-40.1

Committee Clerk Signature Jodey Burke

Minutes:

Chairman Keiser: Reconvened on HB 1332.

Representative Kasper: We have come along way with this bill, we are now to the point where we would have the insurance department authority to audit and regulate PBM's there are some exceptions in the bill, for what the insurance department could or could not do. The amendments that are presented by Chuck Johnson with the insurance department had some input from both sides, there is some clean up that needs to be done.

Representative Keiser: I would just like to comment on the mail order service, I appreciate the frustration of the pharmacists of our state relative to mail service, but they do serve a purpose, if you read what they are itemizing in A, B, and C, are the functions of PBM's from my prospective I have to agree that mail service pharmacy is not a direct function of a PBM, so I would support striking it. I

would love to leave it in, but it really is a different operation.

Representative Amerman: If it isn't a direct function of a PBM, whose function is it?

Representative Keiser: It could be a separate corporation that sets itself up and provides mail service pharmacy. I see no reason why a pharmacy that is currently located in the state of North Dakota could not start a mail order pharmacy.

Hearing closed

2005 HOUSE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. HB 1332 final

House Industry, Business and Labor Committee

☐ Conference Committee

Hearing Date 2-15-05

Tape Number	Side A	Side B	Meter #
1	x		19.8-32.9

Committee Clerk Signature

Minutes:

Chairman Keiser: Reconvened on HB 1332.

Representative N. Johnson: I would like to put back in the mail service pharmacy part on page 3 and also on page 8 this is all off the engrossed.

Representative N. Johnson: I would **Move** this motion to amendment this in HB1332.

Representative Vigesaa: I would **SECOND** that motion.

Motion carried.

Representative Dosch: I move to further **ADOPT** amendments.

Representative Johnson: I **SECOND** the motion to **ADOPT** amendments.

Motion carried.

Representative Kasper: I would further **AMEND** HB 1332.

Representative Boe: SECOND the motion to further amend.

Motion carried

Representative N. Johnson: I **MOVE** a **DO PASS AS AMENDED**.

Representative Boe: I **SECOND** the **DO PASS** as **AMENDED** motion.

Motion carried. **VOTE: 12-YES 1-NO 1Absent.**

Representative Vigesaa will carry the bill on the floor.

FISCAL NOTE

Requested by Legislative Council
03/01/2005

Amendment to: HB 1332

1A. **State fiscal effect:** *Identify the state fiscal effect and the fiscal effect on agency appropriations compared to funding levels and appropriations anticipated under current law.*

	2003-2005 Biennium		2005-2007 Biennium		2007-2009 Biennium	
	General Fund	Other Funds	General Fund	Other Funds	General Fund	Other Funds
Revenues	$0	$0	$0	$0	$0	$0
Expenditures	$0	$0	$0	$0	$0	$0
Appropriations	$0	$0	$0	$0	$0	$0

1B. **County, city, and school district fiscal effect:** *Identify the fiscal effect on the appropriate political subdivision.*

2003-2005 Biennium			2005-2007 Biennium			2007-2009 Biennium		
Counties	Cities	School Districts	Counties	Cities	School Districts	Counties	Cities	School Districts
$0	$0	$0	$0	$0	$0	$0	$0	$0

2. **Narrative:** *Identify the aspects of the measure which cause fiscal impact and include any comments relevant to your analysis.*

Under Engrossed HB 1332, the Insurance Department will receive rebate information and review an insurance company's books and records to assure that pharmacy rebates are being applied toward reducing insurance premiums. The review will occur during the company's overall financial review. The Insurance Department does not anticipate any significant increase in costs or general fund expenditures to result from this engrossed bill.

3. **State fiscal effect detail:** *For information shown under state fiscal effect in 1A, please:*
   A. **Revenues:** *Explain the revenue amounts. Provide detail, when appropriate, for each revenue type and fund affected and any amounts included in the executive budget.*

N/A

   B. **Expenditures:** *Explain the expenditure amounts. Provide detail, when appropriate, for each agency, line item, and fund affected and the number of FTE positions affected.*

N/A

   C. **Appropriations:** *Explain the appropriation amounts. Provide detail, when appropriate, of the effect on the biennial appropriation for each agency and fund affected and any amounts included in the executive budget. Indicate the relationship between the amounts shown for expenditures and appropriations.*

N/A

Name:	Charles E. Johnson	**Agency:**	Insurance Department
Phone Number:	328-4984	**Date Prepared:**	03/04/2005

Date: 2-15-05

Roll Call Vote #: 1

2005 HOUSE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 1332

House **INDUSTRY, BUSINESS AND LABOR** Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number

Action Taken Adopt amendments Motion to remove struck language. page 8 (Adjustment

Motion Made By Rep. Johnson Seconded By Rep. Vigesaa

Representatives	Yes	No	Representatives	Yes	No
G. Keiser-Chairman			Rep. B. Amerman		
N. Johnson-Vice Chairman			Rep. T. Boe		
Rep. D. Clark			Rep. M. Ekstrom		
Rep. D. Dietrich	A	A	Rep. E. Thorpe		
Rep. M. Dosch					
Rep. G. Froseth					
Rep. J. Kasper					
Rep. D. Nottestad					
Rep. D. Ruby					
Rep. D. Vigesaa					

Total (Yes) 11 No 2

Absent

Floor Assignment

If the vote is on an amendment, briefly indicate intent:

Date: 2-15-05

Roll Call Vote #: 2

2005 HOUSE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 1332

House **INDUSTRY, BUSINESS AND LABOR** Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number

Action Taken further adopt "may" to "shall"

Motion Made By Rep Johnson Seconded By Rep Ekstrom

Representatives	Yes	No	Representatives	Yes	No
G. Keiser-Chairman			Rep. B. Amerman		
N. Johnson-Vice Chairman			Rep. T. Boe		
Rep. D. Clark			Rep. M. Ekstrom		
Rep. D. Dietrich	A	A	Rep. E. Thorpe		
Rep. M. Dosch					
Rep. G. Froseth					
Rep. J. Kasper					
Rep. D. Nottestad					
Rep. D. Ruby					
Rep. D. Vigesaa					

Total (Yes) 13 No 0

Absent (1) Dietrich

Floor Assignment

If the vote is on an amendment, briefly indicate intent:

Date: 2-15 05

Roll Call Vote #: 3

2005 HOUSE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 1332

House **INDUSTRY, BUSINESS AND LABOR** Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number

Action Taken Adopt Amends as adjusted all of change Engross

Motion Made By Rep. Dosch Seconded By Rep. Johnson

Representatives	Yes	No	Representatives	Yes	No
G. Keiser-Chairman	X		Rep. B. Amerman	X	
N. Johnson-Vice Chairman	X		Rep. T. Boe	X	
Rep. D. Clark	X		Rep. M. Ekstrom	X	
Rep. D. Dietrich	A		Rep. E. Thorpe		X
Rep. M. Dosch	X				
Rep. G. Froseth	X				
Rep. J. Kasper	X				
Rep. D. Nottestad	X				
Rep. D. Ruby	X				
Rep. D. Vigesaa	X				

Total (Yes) 12 No 1

Absent (1) Dietrich

Floor Assignment

If the vote is on an amendment, briefly indicate intent:

Date: 2-15-05

Roll Call Vote #: 4

2005 HOUSE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 1332

House **INDUSTRY, BUSINESS AND LABOR** Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number

Action Taken Further Amend out Striking "Subsidiary" page 3

Motion Made By Rep Kasper Seconded By Rep. Boe

Representatives	Yes	No	Representatives	Yes	No
G. Keiser-Chairman			Rep. B. Amerman		
N. Johnson-Vice Chairman			Rep. T. Boe		X
Rep. D. Clark			Rep. M. Ekstrom		
Rep. D. Dietrich			Rep. E. Thorpe		
Rep. M. Dosch					
Rep. G. Froseth					
Rep. J. Kasper					
Rep. D. Nottestad					
Rep. D. Ruby		X			
Rep. D. Vigesaa					

Total (Yes) 12 No 1

Absent (1) Dietrich

Floor Assignment

If the vote is on an amendment, briefly indicate intent:

Date: 2-15-05

Roll Call Vote #: 5

2005 HOUSE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 1332

House **INDUSTRY, BUSINESS AND LABOR** Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number

Action Taken Do Pass As Amended

Motion Made By Rep. Johns Seconded By Rep Boe

Representatives	Yes	No	Representatives	Yes	No
G. Keiser-Chairman	X		Rep. B. Amerman	X	
N. Johnson-Vice Chairman	X		Rep. T. Boe	X	
Rep. D. Clark	X		Rep. M. Ekstrom	X	
Rep. D. Dietrich	A		Rep. E. Thorpe		X
Rep. M. Dosch	X				
Rep. G. Froseth	X				
Rep. J. Kasper	X				
Rep. D. Nottestad	X				
Rep. D. Ruby	X				
Rep. D. Vigesaa	X				

Total (Yes) 12 No 1

Absent (1) Dietrich

Floor Assignment Rep. Vigesaa

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE

HB 1332: Industry, Business and Labor Committee (Rep. Keiser, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (12 YEAS, 1 NAY, 1 ABSENT AND NOT VOTING). HB 1332 was placed on the Sixth order on the calendar.

Page 1, line 2, remove "; and"

Page 1, line 3, remove "to provide for application"

Page 2, after line 2, insert:

"3. "De-identified information" means information from which the name, address, telephone number, and other variables have been removed in accordance with requirements of title 45, Code of Federal Regulations, part 164, section 512, subsections (a) or (b)."

Page 2, line 3, replace "3." with "4."

Page 2, line 5, replace "4." with "5."

Page 2, line 9, replace "5." with "6."

Page 2, line 17, after the semicolon insert "or"

Page 2, line 18, replace the semicolon with a period

Page 2, remove lines 19 through 21

Page 2, line 22, replace "6." with "7."

Page 2, line 27, after the period insert "The term does not include a health carrier licensed under title 26.1 if the health carrier is providing pharmacy benefits management to its insureds and does not include a public self-funded pool or a private single-employer self-funded plan that provides pharmacy benefits management directly to its beneficiaries.

8. "Rebate" includes the nature, type, and amount of all other revenue received by the pharmacy benefits manager from each pharmaceutical manufacturer or labeler for any other product or service provided, including any formulary management and drug-switch program, educational support, claims processing, and pharmacy network fees that are changed from retail pharmacies and data sales fees, with respect to programs that the covered entity offers or provides to the covered entity's enrollees.

9. "Utilization information" means de-identified information regarding the quantity of drug prescriptions dispensed to members of a health plan during a specified time period."

Page 2, remove lines 28 through 30

Page 3, remove lines 1 through 8

Page 3, remove lines 12 through 17

Page 3, line 18, replace "**26.1-27.1-04**" with "**26.1-27.1-03**"

Page 3, line 20, remove "or affiliation"

Page 3, remove line 30

Page 4, remove lines 1 through 31

Page 5, remove lines 1 through 3

Page 5, replace "**26.1-27.1-06**" with "**26.1-27.1-04**"

Page 5, line 7, replace "and" with "or"

Page 5, line 12, remove ", after disclosing to the covered individual and covered entity the"

Page 5, remove line 13

Page 5, line 14, remove "the pharmacy benefits manager as a result of the substitution"

Page 5, replace lines 25 through 31 with:

"4. This section does not permit the substitution of an equivalent drug product contrary to section 19-02.1-02.

26.1-27.1-05. Contents of pharmacy benefits management agreement - Requirements.

1. A pharmacy benefits manager shall offer to a covered entity options for the covered entity to contract for services that must include:

   a. A transaction fee without a sharing of rebates and other retrospective utilization discounts;

   b. A combination of a transaction fee and a sharing of rebates and other retrospective utilization discounts; or

   c. A transaction fee based on the covered entity receiving all the benefits of rebates and other retrospective utilization discounts.

2. The agreement between the pharmacy benefits manager and the covered entity must include a provision allowing the covered entity to audit the pharmacy benefits manager's books, accounts, and records, including de-identified utilization information, as necessary to confirm that the benefit of rebates and other retrospective utilization discounts are being shared as required by the contract.

26.1-27.1-06. Examination of insurer-covered entity.

1. During an examination of a company as provided for in chapter 26.1-03, 26.1-17, or 26.1-18.1, the commissioner shall examine any contract between the company and a pharmacy benefits manager and any related record to determine if the rebates and other retrospective utilization discount benefits that the company received from the pharmacy benefits manager have been applied toward reducing the company's rates or have been distributed to covered individuals.

2. To facilitate the examination of the company, the company shall disclose annually to the commissioner the benefits of rebates and other

retrospective utilization discounts received under any contract with a pharmacy benefits manager and shall describe the manner in which the rebates and other retrospective utilization discounts are applied toward reducing rates.

3. Any information disclosed to the commissioner under this section is considered a trade secret under chapter 47-25.1.

26.1-27.1-07. Rulemaking authority. The commissioner shall adopt rules as necessary before implementation of this chapter."

Page 6, remove lines 1 through 31

Page 7, remove lines 1 through 7

Renumber accordingly

2005 SENATE INDUSTRY, BUSINESS AND LABOR

HB 1332

2005 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. HB 1332

Senate Industry, Business and Labor Committee

☐ Conference Committee

Hearing Date 3-07-05

Tape Number	Side A	Side B	Meter #
1	xxx		100-end
1		xxx	0-end
2	xxx		0-3345

Committee Clerk Signature Lisa VanBerkom

Minutes: **Chairman Mutch opened the hearing on HB 1332. All Senators were present.**

HB 1332 relates to regulation of pharmacy benefits management.

Rep. Nancy Johnson introduced the bill. See written testimony with attached amendments.

Jim Poolman, North Dakota Insurance Commissioner, spoke in support of the bill. See written testimony.

Bob Treitline, pharmacy owner from Dickinson, spoke in support of the bill. See written testimony.

Senator Klein: In looking at your important facts, and listening to your testimony, it says you don't have a financial advantage, and certainly when you look at these things, we have to sort that out. It certainly sounds that there is an opportunity here for people to go beyond or through these PBM's than the local pharmacy which would then, wouldn't that change your bottom line?

Bob: It would increase our volume to a certain degree, but I think the bottom line to the prime sponsor would be better service because it's local. Plus the fact that we are under contract with the PBM's.

Senator Klein: Most everything I hear is "PBM's are bad".

Bob: I think what we are trying to point out is that, profit is not a dirty word, but they are taking that and not being fair with the profits they generate through the discounts and pass through the consumer, which is why the discounts were there in the first place. We attribute that to a horrific increase in the cost of drugs.

Senator Klein: What you are saying is that PBM's are getting the deal and you are not. And you want to have the transparency to know that they are getting a deal and.....

Bob: .....passing it on to the consumer.

Chairman Mutch: How do PBM's operate?

Bob: They most often work through an insurance company, so in North Dakota, Prime therapeutics is the prime one here, and they work through Blue Cross Blue Shield and Blue Cross Blue Shield also owns part of that company.

Senator Klein: So the PBM that Blue Cross works through is owned by Blue Cross?

Bob: A portion of it. Originally, PBM's were supposed to be claims processors. Now they have devised ways to put these formularies together. Our position for the bill would be so this information is disclosed that this is going on.

Senator Klein: Wouldn't Blue Cross want to work with someone who is helping to drive down the cost of the prescription? Wouldn't you say they are working to keep those prices down on a legitimate basis?

Bob: We are not seeing the money come back.

Chairman Mutch: If that's the case, why would someone want to deal with a mail-order?

Bob: They absolutely don't know. Most employers and consumers don't know.

Chairman Mutch: Apparently the manufacturers of the drug are using PBM's rather than probably you couldn't even buy directly from the factory?

Bob: That's exactly right. Pharmacy inflation over the last few years has been up to twelve percent.

Chairman Mutch: Would it be logical to assume that every drug store would subscribe to a PBM?

Bob: The PBM pays us and then charges the insurance company. They have no product or liability.

Senator Nething: I think you said something that PBM's should get a reasonable amount of money for doing this. What is reasonable?

Bob: I'm not sure if I have a number for reasonable, but it is surely not forty percent.

Senator Nething: There are other places where they get a forty percent mark up.

Bob: We are contributing that to a lot of the escalating cost of drug. We are having inflation. When I started, the average prescription price was five dollars and now it is fifty-seven in my store and in some places it is closer to sixty-two dollars.

Senator Nething: What's reasonable?

Bob: There is a PBM that is operating on less than seven percent. We don't even know what the rebates are to the PBM's. I would guess that the average is twenty-four percent, or more.

Senator Krebsbach: Has there been any discussion on the federal level?

Bob: I'm not sure that there has been. There have been several states that have taken the initiative to try to make this a saving position for them.

Patricia Hill, Executive Vice President for the North Dakota Pharmacists Association, spoke in support of the bill.

Senator Nething: How many employers are there that pay directly and how many use insurance to pay?

Hill: I think about eighty-two percent of the North Dakota market is covered with Blue Cross Blue Shield, and about half of those are covered by self-funded plans which fall under federal law.

Senator Nething: Is the bill in South Dakota identical to the bill here?

Hill: No, the original bill that was introduced in North Dakota was based on the verbiage that passed in South Dakota. It had been amended several times, some of the amended language is in this handout.

Senator Klein: You are suggesting that because of transparency they got the additional spenders who sought to bid that because they now can provide this transparency?

Hill: Because of transparency, it simply provided all of the information that is currently not available. So in other words, when you go in as an employer, and you pay for premiums that include drug benefits, there is no way you could know.

Senator Klein: I don't see the same rational here.

Hill: They received on bid, and that was Blue Cross. They were not allowed to unbundle each section of that bid. In other words, if they had been allowed to take other bids from other PBM's... so what would happen, if they were allowed to take bids from PBM's, they would go

into the bidding process, about all of the details of the rebates and discounts, that are negotiated by each PBM, and then decide, which one of those contracts best suits their interest. They do not currently have access to that information.

Senator Nething: If South Dakota has a different law than we are going to have if this passed, how do we say that we are going to get the same amount of benefits that they get?

Hill: The mechanism that allows for the savings to happen is the disclosure of information that is currently not available to anyone. That's what the transparency refers to. Transparency means that they disclose all of the information about any negotiations and discounts that are being received by the PBM from the drug company who then has their product. The disclosure is in essence, what the bill provides in terms of saving money.

Senator Fairfield: My understanding of your using the example of South Dakota, was to assure us that transparency would not detour PBM's from bidding on RFP. That is my understanding.

Hill: True, also, I wanted to demonstrate that in a state where a law like this has passed that there was savings because of the transparency.

Senator Fairfield: You also mention that in North Dakota it is different because we have the system bundled. We have one RFP, does this bill address that issue and unbundle, or will that remain the same?

Hill: When I said that, Mr. St.Aubyn interjected, saying it wasn't true, so I think I will let him answer that question.

Senator Espegard: I look at that disclosure that the PBM's has to disclose if he has any relationship with an insurance company. Am I right?

Hill: That was based on the notion that some insurance companies own PBM's.

Senator Espegard: Number three, beginning on line thirteen?

Hill: Yes.

Senator Espegard: That doesn't look like it has to do with mail-order business.

Hill: That is what I am going to explain. The PBM's cannot discriminate on the basis of CO-payments and days of supply.

Senator Fairfield: The only entities that actually know what is in the contract are the insurance companies that are contracting with the PBM's, they know what is happening. Now, are you saying that the insurance companies are contracting with PBM's in some cases, also have ownership interest, or profit interests in the PBM's. Can an insurance company own a PBM so that the contract that they have with them that are confidential, are profit centers?

Hill: This is a good question for Mr. St. Aubyn.

Senator Klein: Who knows what a pharmacist makes?

Hill: I would defer to a pharmacist.

Senator Klein: I wasn't sure how long we are taking pro testimony and if we are cutting it off because we have gone on and on.

Chairman Mutch: Is that of any concern of the bill?

Senator Nething: The whole industry.

Tony Welder, Pharmacist, spoke.

Tony: There have been instances where PBM's switch drugs from generic to name brand. Typically generic manufacturers do not rebate to the PBM's. There is some financial incentive and it has happened. A PBM will favor the dispensing of the high priced brand name drug when there is a generic equivalent available because of the rebate that is given to them.

Tony: It would be really hard to outline the profit on every single prescription because there are thousands of them. But I can tell you that national statistics show that the pharmacy typically generate gross profit basis from seventeen to twenty percent. The net profit base is down in the two to three percent range. To do them individually would be a horrendous task.

Senator Klein: Yeah.

Tony: The House side, the PBM's testified that they negotiate with pharmacies for contract.

Chairman Mutch allowed the opposition to speak at this time.

Rod St. Aubyn, Blue Cross Blue Shield, spoke in opposition to the bill. See written testimony.

Senator Klein: You had indicated that it could lower reimbursement for pharmacists? Why would they be in favor of something that is going to lower their....

Rod St. Aubyn: If all of the sudden, as a result of all of this, there is less rebates available, we have less money to pay for the dispensing fee, things like that, ultimately, to the pharmacists.

Senator Klein: What do you mean by "dispensing fee" ?

Rod St. Aubyn: In the contract with the pharmacist, they are reimbursed, a rate that has been established, but in addition, they are reimbursed a dispensing fee.

Senator Klein: Over and above the cost of a drug?

Rod St. Aubyn: Correct.

Senator Fairfield: What happens if they don't sign the contract?

Rod St. Aubyn: They can still... and we reimburse....the difference is, for our members if they go to a pharmacist that is a nonparticipating pharmacist, what will happen is member will pay the price of the drug in full. And then they submit the claim to us, and then the PBM reimburses the

member. There is usually a penalty to go to a nonparticipating member, because we want them to go the participating. That is a big advantage. The other advantage, is they get the money directly.

Senator Fairfield: So, if they don't go through a PBM (the pharmacist), there is a penalty for being a non-participant?

St. Aubyn: Not to the pharmacist, to the member. The consumer.

Senator Fairfield: Basically, you are pushing customers away from pharmacies that do not contract with PBM's? So aren't you telling pharmacists that either you sign the contract, or you don't have customers that go there.

St. Aubyn: You can look at it that way.

Senator Fairfield: If your intent is to save money for the consumer, wouldn't you also agree that PBM's should be regulated?

St. Aubyn: First of all, it is in our best interest that we do that. It's a contract between us and that PBM. So in terms of regulation, this is not going to do anything different than what we are doing right now.

Chairman Mutch: As with the PBM and Blue Cross, do you contract with one or many PBM's? I am assuming you are part owner of a PBM.

St. Aubyn: We have one contract with one PBM and that's BTI, which we are part owners. And the reason we don't have multiple PBM's is that it gets back to market share. I wish they would get rid of rebates, period.

Senator Klein: But in the case of your little contract with the PBM that you do business with, you have transparency, I would assume, since you are part owner. So does this really affect you?

St. Aubyn: It is transparent right now, and this bill... you have to understand that transparency is going to be between the health insurer and the PBM. It's not disclosed anywhere else, other than the insurance commissioner. So that's why I say, nothing's going to be gained by the bill.

Chairman Mutch: Pharmacists are not happy, that is what the problem is.

St. Aubyn: One pharmacist said he didn't have a problem with the PBM that BCBS owns.

Patrick Ward, attorney representing MedCo Heath Solutions (PBM), spoke in opposition to the bill. See written. See attached amendments proposed by Ward.

Peter Harty, Vice President, Government Affairs and Policy for MedCo Health Solution, Inc. See written testimony.

Senator Fairfield: Talking about the nonpartisan organizations, but you also have listed the Heritage Foundation, do you also consider them a nonpartisan, non bias source for economic analysis?

Peter: I consider that to be a credible source. We can argue about whether they are bias or not, but that is one of many sources.

Senator Fairfield: Of these reports, are they just accepted as fact,or was there controversy surrounding those reports?

Peter: No matter what action any government body takes, people are going to look at it and they are going to pursue their agenda and look at it in the light that best suits their objectives. I urge you to read the reports yourself and you can draw whatever conclusions you might want from that.

Senator Fairfield: What portion of the bill, expressly restricts the profits of a PBM must be reasonable?

Peter: I never said that there is anything in here that restricts our profits, what I was talking to was the testimony presented earlier.

Senator Fairfield: Didn't you say in your testimony that there is no restriction on mail-order pharmacies here, other than they have to be treated equally. Do you agree with that assessment? Because where is that in here that says it can only be through a local pharmacist?

Peter: The affect of that is to remove any incentives that can be made for employees to go to mail-order pharmacies. The pharmacy's intent is to remove any incentives that can be made for members or employees to go to mail service pharmacies because that incentive cannot be provided, there is no reason for people to go to that mail service pharmacy, which is where you get the three percent cost increase. It's about keeping business in their stores in such a way that you can't incent people to use mail-service.

Senator Fairfield: And yet, you can incent people to stick with pharmacies that have contracts with PBM's. So the incentive is good on one side, and not on the other.

Peter: In the health care world and the idea of networks, it is our way to control cost. The FTC looked at state's that have any willing provider laws, their analysis was any provider laws impacted increasing by two percent. Because you don't have that competition.

Senator Klein: Does the AARP have their own PBM to provide their members at the lower price?

Peter: AARP does offer access to discounts with a mail service component.

Senator Klein: All of these lawsuits that MedCo is involved in, that you haven't been found to be guilty of anything at this point?

Peter: In one instance, we did settle with them out of court.

Senator Heitkamp: So the one instance involved twenty states?

Peter: Yes.

Senator Fairfield: Do you operate in Canada? Or do other PBM's?

Peter: We do not. Canada is different.

Julie Fedorchak, America's Heath Insurance Plans, stated her opposition to the bill.

Robert Harms, CareMark, Inc,. spoke in opposition, see written testimony.

Senator Klein: After the January 2003, JO report, congress didn't see a real need to create some uniformity on how we treat these PBM's, or is there some action pending?

Robert: My understanding is that they called for the GAO to conduct a study.

Senator Klein: So there was no alarm at that point?

Robert: No.

Senator Nething: Did you testify in the House?

Robert: No. I just learned about PBM's ten days ago.

Senator Fairfield: In your testimony, you say that this will limit mail service and savings, so your contention is that it is okay for PBM's to discriminate on the basis of days of supply, and in fact preferential treatment is acceptable in these cases, and without preferential treatment and discrimination, then that is somehow limiting consumer choice.

Robert: People should have the choice of mail order.

The hearing was closed. No action was taken at this time.

2005 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. HB 1332

Senate Industry Business & Labor Committee

☐ Conference Committee

Hearing Date March 21, 2005

Tape Number	Side A	Side B	Meter #
1	X		1-END
1		X	1-END
2	X		1-END
Committee Clerk Signature			
2		X	1-4245

Minutes: **Chairman Mutch opened the meeting to discuss HB 1332, relating to the regulation of pharmaceutical benefits managers. All Senators were present.**

Patty Hill, Executive Vice-President of the ND Pharmacists, appeared before the committee in support of the bill. See written testimony.

Senator Klein- Who saved the $ 2 million in SD? Is there a federal model for states to follow?

Patty- The state employees group, which is similar to the ND Public Employees group. There is a large group of lobbyists at the federal level for this type of legislation.

Senator Nething- Under SD law, do they exclude mail order service? This bill excludes mail order service?

Patty- There are amendments to have mail order service deleted from this bill. In South Dakota, their law does not allow mandated mail order service. PBM's depend on mail service as a part of their business operations.

Senator Heitkamp- You used to get 31% in the 1980's, and now you are getting 10%? (referring to chart #1)

David Oleg, a pharmacist from Fargo, ND appeared before the committee. See section 3 in white binder "overview of PBM's."

Senator Nething- You say that PBM's haven't earned it? However, they negotiated the cost. Its a question of what's reasonable in their mind and what's reasonable in your mind?

David- There are PBM's that average 2-3% administrative costs for the rebate program. We can't get it bill done like this at the federal level, this is occuring in 29 other states.

Senator Espegaard- When you refer to markups, that's another negotiation that PBM's have had with the drug company, that pharmacists do not share in?

David- Correct. He gave an example to the committee of higher rebates that occur on a daily basis.

Senator Nething- So, rebates go to PBM's, they don't go to pharmacists?

David- No, we don't get rebates from any manufacturers.

Senator Klein- What would change under this bill?

David- It would save the patient some money with the rebate programs.

Senator Nething- During the initial hearing for this bill, we were informed that the plans were negotiated between the PBM and the insurance company. The PBM in this case said they worked with health care purchasers.

David- Those health care purchasers are human resource directors and insurance specialists for groups.

Chairman Mutch- Do you have a price list that you use when you negotiate with PBM's?

David- No. Branded products are sold at average wholesale price. Generic products are placed on a different list. The generic drugs not on the list are under a different system.

Senator Fairfield- It seems that the case with PBM's is negotiating loosely with a contract. PBM's have a different relationship with insurance companies.

David- A lot of it has to do with the pharmacy's location and the amount of volume gets figured in to the cost.

Senator Fairfield- The issue here is that PBM's have become an unregulated profit center and they are able to influence the direction of pharmaceuticals.

Senator Klein- Prescription costs are constantly going up, and several people are trying to find ways to lower the costs. The question is where do we end this transparency?

David- The escalation of prescription drug costs have been driven by the PBM's because they are handling the largest amount of prescription drug claims in the country. The mail orders are put into place to turn in more profits for PBM's.

Senator Nething- I understand the transparency, but I don't see how that will lower the price with this bill.

David- There are many PBM's out there, its a very competitive industry. There are over 60 PBM's in the state. We need to find out how much of the rebates PBM's are retaining.

Senator Fairfield- So, transparency will help us to get a handle on how PBM's relate to the cost of pharmaceuticals?

David- It opens the door to more information on the issue.

Senator Nething- So, the only thing you want in this bill is transparency?

David- No. There needs to be a level playing field in place. As it currently stands, contracts with PBM's are not negotiable.

Chairman Mutch- Are PBM's fixing prices amongst themselves?

David- Its a very competitive industry.

Senator Klein- Do PBM's affect 100% of the prescriptions that you write?

David- 89% of the prescriptions.

Senator Klein- Does this bill put money back in the pockets of pharmacists?

David- No. Our contracts won't change. We are fixing a problem with PBM's, the industry will remain competitive.

Senator Krebsbach- In my estimation the problem lies with the manufacturers. Is the discount the same with a manufacturer to PBM's? The insurance department will examine contracts to determine if rebates and discounts will be applied.

Patty Hill- The disclosure of information would allow to send it to the Insurance Commissioner, so they have options.

David gave examples of problems he has experienced with rebates and mail order plans in his pharmacy.

Senator Klein- Isn't that the consumer's right to figure that out? So, sometimes if a person goes to a pharmacist, it can save them money, rather than the mail order?

David- It depends on how things are set up with the copay programs.

Senator Fairfield- So, the 3-10 cent increase for claims processing, do they just raise it without negotiation? Do they have the flexibility to raise prices like that?

David -Yes.

Senator Espegaard- The cost of the pharmacy fee is $15, the copay is $15, the PBM doesn't pay anything to the pharmacy, but they invoiced the plan because of additional discounts?

David- Some medications have a maximum allowable cost that would need to be figured in. The cost would be 42 cents per tablet plus the dispensing fee.

Chairman Mutch- So, the dispensing fee is paid to the PBM from the pharmacist?

David- Yes.

Senator Espegaard- How does this save the consumer money? Co-pays are set by the drug plan, correct?

David- The PBM's can structure them anyway they would like.

Senator Espegaard- It isn't that the drugs are costing more or less, its that the MAC prices give the PBM more money because they have a different list?

David- Yes.

Chairman Mutch- Perhaps small independent pharmacists should form their own buy-in group.

David- There are several buy-in groups, but pharmaceutical manufacturers do not bid buy-in groups. As pharmacists we only get discounts on generic drugs, but not on a brand name drugs. The seniors in this country are paying too much for prescription drugs because of those rebates.

Arlin Fisher, a concerned consumer appeared before the committee. See written testimony.

Senator Fairfield- What I'm gathering from your testimony is because PBM's direct people away from their local pharmacy to mail order, that has concerns on people's health?

Arlin- The quality of care has definitely decreased with the mail order drugs. The way PBM's do business puts people at risk.

Rod St. Aubyn, representing Blue Cross Blue Shield appeared in opposition to the bill. See written testimony.

Senator Fairfield- This bill may limit PBM's ability to guide customers to a lower cost pharmacy. Is that the role of PBM's?

Rod- That was the testimony of the FTC. They want to save money for the consumer and the employer's health care plan. The role of PBM's have expanded, they do more than just processing.

Senator Nething- I received a letter from a doctor with Dakota Clinic in Fargo, concerning the time it takes to contact a PBM versus the time it takes to contact a retail pharmacist.

Rod- The Insurance Department would have the ability to establish some standards that PBM's would have to abide by.

Senator Nething- Where are the cost savings coming from when Blue Cross using a PBM?

Rod- We negotiate and establish the specifics of our PBM's, part of the agreement is allowing PBM's to maintain 8%.

Senator Nething- Are PBM rebates passed on to those who pay the premium, whether it be individuals or businesses?

Rod- That is what is taking place. We are a nonprofit organization, and those individuals would be getting the benefits.

Senator Nething read a letter to the committee from a pharmacist in Bismarck who had some concerns about the issue

Senator Nething- What would this bill do to mail order pharmacies?

Rod- It would affect prohibitive practices with those pharmacies.

Senator Nething- What is the PBM's gross profit margin?

Rod- We allow our PBM's to retain 8%, that figure varies with other businesses. This bill would apply to only 1/3 of the citizens in ND.

Senator Espegaard- Who regulates Days of Supply on a maintenance drug?

Rod- All of those are planned designs, where it depends on the pharmaceutical benefits.

Senator Fairfield- So, PBM's have incentives for going with the mail order?

Rod- If you make everything equal, then we have to apply a dispensing fee and raise the cost. The contracts are very complex.

Senator Espegaard- The co-pay sometimes is actually 100% of the cost, and the PBM doesn't get anything. How does that work when the PBM bills the MAC?

Rod- Not sure.

Senator Nething- You claim that less than 1/3 of the people in the state will be affecting by the bill?

Rod- Actually less than 20% of the prescriptions in the state would be affected by mail order services.

Chairman Mutch- Does your PBM cover more than one state? How does that work with dividing up the rebates?

Rod- We could establish our own network if we wanted to. We don't have the ability to negotiate with several other states.

Senator Fairfield- Why is Blue Cross so interested in having this bill defeated?

Rod- We are struggling to maintain employer groups when it comes to health insurance.

Senator Fairfield- Since you are part owners of these PBM's you must get some of the benefits in the rebates you are getting.

Rod- The profitability of the PBM's would go back to our members. It is all accounted for, the Insurance Department audits us.

Bob Harms, from Caremark, a PBM, appeared in opposition to the bill. Caremark agrees with the comments offered by Blue Cross/Blue Shield. Competition is the guiding principle that we should all follow in this case. The issue with PBM's and prescription drugs is similar to the health care crisis a few years ago. The rising cost of drugs is due to a number of factors, its a complex problem that requires a complex solution. If you pass this bill you get transparency and reduced drug prices, something that is not exactly true. There was a DAO report that did an objective analysis of the situation. It will lower competition, and end up reducing choices in the mail order arena, and increase prescription drug prices. He agrees that the mail order pharmacy services are available, but would not be likely to occur because of the prohibitive intentions of the bill. There are several companies that save 40% on prescription drug costs by going through the mail order process. This bill has unintended consequences, if we don't know all the complexities, the committee should defeat this bill.

Senator Nething- In your testimony from the first hearing, you made reference to California assembly bill # 1960, that it was similar to HB 1332. Could you expand on how the two are the same?

Bob- The basic premise of both of the bills is if you regulate the PBM industry, lower drug prices will occur.

Senator Nething- You claim that PBM services affect 460,000 people and save $112 million annually. I believe there was testimony earlier that countered those numbers.

Bob- Those figures came directly out of Price-Waterhouse. I believe the figure should be around $50 million instead of $112 million.

Linda Wurtz, representing the AARP appeared in opposition to the bill. See written testimony.

Senator Nething- You did not comment on the mail order component, it was mentioned in previous testimony that the mail order component has to be in agreement. I would believe that the AARP would come under the mail order definition.

Linda- I don't represent anyone who has a mail order, I'm here to advocate for our members.

Pat Ward, representing Medco appeared in opposition to the bill. See written testimony.

Senator Nething- In your testimony, you indicated that freezing out competition in the pharmacy business, would that affect limiting mail order pharmacies from their competitive advantages over local pharmacies. Please explain.

Pat- I understand the position of pharmacists, there are lots of concerns facing them. The individual consumer's have a different view on the situation. This bill takes out one of the advantages with co-pays with mail orders.

Senator Nething- The other states are more interested in the legislation of mail order pharmacies. Do your amendments work with the amendments offered by Mr. St. Aubyn?

Pat- Yes. The House committee decided at the last minute to place the mail order section back in the bill. If this bill were to pass the amount of the prescribed would have to be the same under mail order services, which would take away the competitive advantage.

Vickie Knighton appeared before the committee- We deal with a lot of Fortune 500 companies, where most hire economists and benefit specialists to work with them. They advise companies on their medical benefits, there are several resources available with performance measures. There are different options available to save money, but the final decision is always left up to the purchaser.

Senator Nething- So, there is a negotiation process that occurs?

Vickie- Absolutely. When the company puts together a proposal, we receive a copy of it. They will take everyone's responses together and look into ways to save the plan money.

Senator Heitkamp- If someone is going to come to the table and say "this is the price," how can a small town pharmacy compete with that?

Vickie- There are two different functions, the PBM is providing claims processing and disease management programs. In Illinois, chain stores like Wal-greens actually bid on the PBM contract. The retail network is different in services, the contracting was to do the dispensing of prescriptions.

Senator Heitkamp- How can small town pharmacies compete with Walgreens when it comes to bidding?

Vickie- Local retail pharmacies are under a lot of pressure when it comes to mail services from chain stores and importing drugs from Canada, and pressure from Medicare and Medicaid. My contract is with the health plan and it is my job to save them money. These situations have been escalating for quite some time.

Senator Fairfield- Are there two MAC lists out there?

Vickie- I have not heard about that before, but I can check into it.

Senator Krebsbach- Initially the PBM's start out as benefit managers and then transferred into price negotiations with manufacturers. When did this change take place?

Vickie- Around 15-18 years ago. The PBM's saw a need with large employers and health plans.

Senator Espegard- We were led to believe this morning, that there could be a situation where the PBM's pays nothing, but can still invoice the plan, because of a different MAC list.

Vickie- There are some drugs that are more expensive by mail order than at retail. I was not aware of these different MAC lists that are out there.

Patty Hill appeared before the committee with additional testimony. See attached.

Chairman Mutch closed the hearing on HB 1332. No action was taken.

On 3-23-05, the committee met to take action on the bill. Tape 1, side A, meter number: 3000.

Senator Klein introduced and moved to adopt amendments 50433.0303.

Senator Nething seconded. Roll Call Vote: 6 yes. 1 no. 0 absent.

Senator Klein moved a DO PASS AS AMENDED. Senator Nething seconded.

Roll Call Vote 7yes. 0 no. 0 absent.

Carrier: Senator Nething

50433.0303
Title.

Prepared by the Legislative Council staff for
Senator Klein
March 18, 2005

PROPOSED AMENDMENTS TO ENGROSSED HOUSE BILL NO. 1332

Page 1, line 2, after "management" insert "; and to provide for a legislative council study"

Page 2, after line 12, insert:

"6. "Payment received by the pharmacy benefits manager" means the aggregate amount of the following types of payments:

a. A rebate collected by the pharmacy benefits manager which is allocated to a covered entity;

b. An administrative fee collected from the manufacturer in consideration of an administrative service provided by the pharmacy benefits manager to the manufacturer;

c. A pharmacy network fee; and

d. Any other fee or amount collected by the pharmacy benefits manager from a manufacturer or labeler for a drug switch program, educational support, or data sales related to a covered individual."

Page 2, line 13, replace "6." with "7."

Page 2, remove line 18

Page 2, line 19, replace "b." with "a."

Page 2, line 21, replace "c." with "b."

Page 2, line 22, replace "d." with "c."

Page 2, line 23, replace "7." with "8."

Page 2, line 26, remove "and includes mail service pharmacy"

Page 2, line 30, replace "and does not include a" with a period

Page 3, replace lines 1 through 9 with:

"9. "Rebate" means a retrospective reimbursement of a monetary amount by a manufacturer under a manufacturer's discount program with a pharmacy benefits manager for drugs dispensed to a covered individual."

Page 3, line 10, replace "9." with "10."

Page 3, remove lines 29 and 30

Page 4, line 7, remove "2."

Page 4, remove lines 1 through 6

Page 4, line 10, replace "solely because the pharmacist or" with "if the pharmacist or pharmacy accepts the terms, conditions, and reimbursement rates of the pharmacy benefits manager's contract."

Page 4, remove lines 11 through 16

Page 4, line 17, remove "4."

Page 4, line 22, replace "that" with "which"

Page 4, line 23, replace "rebates and other retrospective" with "a payment received by the pharmacy benefits manager;"

Page 4, remove line 24

Page 4, line 25, replace "rebates and other" with "a payment received by the pharmacy benefits manager; or"

Page 4, remove line 26

Page 4, replace line 28 with "a payment received by the pharmacy benefits manager."

Page 5, line 1, replace "rebates and other" with "a payment received by the pharmacy benefits manager is"

Page 5, line 2, remove "retrospective utilization discounts are"

Page 5, line 4, replace "company" with "covered entity"

Page 5, line 5, replace "company" with "covered entity"

Page 5, replace line 7 with "payment received by the pharmacy benefits manager which the covered entity"

Page 5, line 8, replace "have" with "has"

Page 5, line 9, replace "company's" with "covered entity's" and replace "have" with "has"

Page 5, line 10, remove "of the company" and replace the second "company" with "covered entity"

Page 5, line 11, replace "rebates and other retrospective utilization" with "the payment received by the pharmacy benefits manager"

Page 5, line 12, remove "discounts"

Page 5, line 13, replace "rebates and other retrospective utilization" with "payment received by the pharmacy benefits manager is"

Page 5, line 14, remove "discounts are" and after "rates" insert "or is distributed to cover individuals"

Page 5, after line 18, insert:

"**SECTION 3. PHARMACY BENEFITS MANAGEMENT INDUSTRY - LEGISLATIVE COUNCIL STUDY.** The legislative council shall consider studying, during the 2005-06 interim, the pharmacy benefits management industry, including the extent of competition in the marketplace for health insurance and prescription drugs; whether protecting the confidentiality of trade secret or proprietary information has a positive or negative impact on prescription drug prices; the ownership interest or affiliation between insurance companies and pharmacy benefits management companies and whether such relationships are good for the consumer; the impact of disclosure of information regarding relationships between pharmacy benefits management companies and their customers; the use of various cost-containment methods by pharmacy benefits managers, including the extent to which pharmacy benefits managers promote the use of generic drugs; the actual impact of the use of pharmacy benefits management techniques on community pharmacies; the price consumers actually pay for prescription drugs in North Dakota; and consideration of the legality of imposing statutory restrictions on pharmacy benefits managers. The legislative council shall report its findings and recommendations, together with any legislation required to implement the recommendations, to the sixtieth legislative assembly."

Renumber accordingly

Date: 3-23-05
Roll Call Vote #: 1

2005 SENATE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 1332

Senate **Industry, Business, and Labor** Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number 50433.0303

Action Taken Adopt Amendments as revised

Motion Made By Klein Seconded By Nething

Senators	Yes	No	Senators	Yes	No
Chairman Mutch	X		**Senator Fairfield**		X
Senator Klein	X		**Senator Heitkamp**	X	
Senator Krebsbach	X				
Senator Espegard	X				
Senator Nething	X				

Total (Yes) 6 No 1

Absent 0

Floor Assignment

If the vote is on an amendment, briefly indicate intent:

Date: 3-23-05
Roll Call Vote #: 2

2005 SENATE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 1332

Senate **Industry, Business, and Labor** Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number

Action Taken DPAM

Motion Made By Klein Seconded By Nething

Senators	Yes	No	Senators	Yes	No
Chairman Mutch	X		**Senator Fairfield**	X	
Senator Klein	X		**Senator Heitkamp**	X	
Senator Krebsbach	X				
Senator Espegard	X				
Senator Nething	X				

Total (Yes) 7 No 0

Absent 0

Floor Assignment Nething

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE

HB 1332, as engrossed: Industry, Business and Labor Committee (Sen. Mutch, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (7 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). Engrossed HB 1332 was placed on the Sixth order on the calendar.

Page 1, line 2, after "management" insert "; and to provide for a legislative council study"

Page 2, after line 12, insert:

"6. "Payment received by the pharmacy benefits manager" means the aggregate amount of the following types of payments:

a. A rebate collected by the pharmacy benefits manager which is allocated to a covered entity;

b. An administrative fee collected from the manufacturer in consideration of an administrative service provided by the pharmacy benefits manager to the manufacturer;

c. A pharmacy network fee; and

d. Any other fee or amount collected by the pharmacy benefits manager from a manufacturer or labeler for a drug switch program, educational support, or data sales related to a covered individual."

Page 2, line 13, replace "6." with "7."

Page 2, remove line 18

Page 2, line 19, replace "b." with "a."

Page 2, line 21, replace "c." with "b."

Page 2, line 22, replace "d." with "c."

Page 2, line 23, replace "7." with "8."

Page 2, line 26, remove "and includes mail service pharmacy"

Page 2, line 30, replace "and does not include a" with a period

Page 3, replace lines 1 through 9 with:

"9. "Rebate" means a retrospective reimbursement of a monetary amount by a manufacturer under a manufacturer's discount program with a pharmacy benefits manager for drugs dispensed to a covered individual."

Page 3, line 10, replace "9." with "10."

Page 3, remove lines 29 and 30

Page 4, remove lines 1 through 6

Page 4, line 7, remove "2."

Page 4, line 10, replace "solely because the pharmacist or" with "if the pharmacist or pharmacy accepts the terms, conditions, and reimbursement rates of the pharmacy benefits manager's contract."

Page 4, remove lines 11 through 16

Page 4, line 17, remove "4."

Page 4, line 22, replace "that" with "which"

Page 4, line 23, replace "rebates and other retrospective" with "a payment received by the pharmacy benefits manager;"

Page 4, remove line 24

Page 4, line 25, replace "rebates and other" with "a payment received by the pharmacy benefits manager; or"

Page 4, remove line 26

Page 4, replace line 28 with "a payment received by the pharmacy benefits manager."

Page 5, line 1, replace "rebates and other" with "a payment received by the pharmacy benefits manager is"

Page 5, line 2, remove "retrospective utilization discounts are"

Page 5, line 4, replace "company" with "covered entity"

Page 5, line 5, replace "company" with "covered entity"

Page 5, replace line 7 with "payment received by the pharmacy benefits manager which the covered entity"

Page 5, line 8, replace "have" with "has"

Page 5, line 9, replace "company's" with "covered entity's" and replace "have" with "has"

Page 5, line 10, remove "of the company" and replace the second "company" with "covered entity"

Page 5, line 11, replace "rebates and other retrospective utilization" with "the payment received by the pharmacy benefits manager"

Page 5, line 12, remove "discounts"

Page 5, line 13, replace "rebates and other retrospective utilization" with "payment received by the pharmacy benefits manager is"

Page 5, line 14, remove "discounts are" and after "rates" insert "or is distributed to cover individuals"

Page 5, after line 18, insert:

"**SECTION 3. PHARMACY BENEFITS MANAGEMENT INDUSTRY - LEGISLATIVE COUNCIL STUDY.** The legislative council shall study, during the 2005-06 interim, the pharmacy benefits management industry, including the extent of

competition in the marketplace for health insurance and prescription drugs; whether protecting the confidentiality of trade secret or proprietary information has a positive or negative impact on prescription drug prices; the ownership interest or affiliation between insurance companies and pharmacy benefits management companies and whether such relationships are good for the consumer; the impact of disclosure of information regarding relationships between pharmacy benefits management companies and their customers; the use of various cost-containment methods by pharmacy benefits managers, including the extent to which pharmacy benefits managers promote the use of generic drugs; the actual impact of the use of pharmacy benefits management techniques on community pharmacies; the price consumers actually pay for prescription drugs in North Dakota; and consideration of the legality of imposing statutory restrictions on pharmacy benefits managers. The legislative council shall report its findings and recommendations, together with any legislation required to implement the recommendations, to the sixtieth legislative assembly."

Renumber accordingly

2005 HOUSE INDUSTRY, BUSINESS AND LABOR

CONFERENCE COMMITTEE

HB 1332

2005 HOUSE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. HB 1332

House Industry, Business and Labor Committee

☒ Conference Committee

Hearing Date 4-6-05

Tape Number	Side A	Side B	Meter #
1	x		8.4-38.5

Committee Clerk Signature Joan Burke

Minutes:

Chairman Kasper: Opened the conference committee on HB 1332.

Chairman Kasper, Representative Vigesaa, Representative Ekstrom, Chairman Nething, Senator Mutch, Senator Heitkamp were present.

Chairman Kasper: Can the Senate explain the amendments that you have adopted?

Chairman Nething: On the first page, the only amendment was made was to add on the end of line 2, "and provide for a Legislative Council study" and we will explain that reasoning as we get to that section. Going over to page 2 after line 12, we kept all of the language up until that point and then we inserted another definition to describe what a payment received by the pharmacy benefits manager means. There we indicated of trying to come up with a better definition and it includes a rebate collected by the PBM which is allocated to covered entity, an administrative fee, which is collected from the manufacturer in consideration of an administrative service provided by the PBM, the service provided by the PBM to the manufacturer, the third type of

payment is a pharmacy network fee, and the fourth type of payment would be any other fee or amount collected by he PBM from a manufacturer or a labeler or a drug switch program educational support data sales related covered individual, so we thought would make it inclusive as to what we meant when we talked about the PBM's payment. We deleted line 18, which was the mail service pharmacy, we did not want the bill to cover mail service pharmacy, and we will talk about that as we get into more detail. On page 2 number 26, we removed mail service pharmacy there from the definition of the PBM. From page 3 we also deleted what the rebate definition was and replaced it with the following definition "rebate means a retrospective reimbursement of a monetary amount by a manufacturer, under a manufacturers discount program with a pharmacy benefits manager for drugs dispensed to a covered individual". And we thought that definition with the changes that we had made earlier as to what the payment received was, would make it more clear. On page 3 we removed lines 29 and 30 "under prohibited practices" and this get into, "the may not require a substitution of one prescription drug for another unless", and then we took out the rest of that section on page 4, by removing the lines 1-6, so that whole first paragraph under number 1, relating to substitution of one prescription for another, and the lowered price generic and so on was taken out. On line 8 page 4 it now reads " the pharmacy benefits manager may not exclude an otherwise qualified pharmacist or a pharmacy, from participation in a particular network, if the pharmacist or pharmacy accepts the terms, conditions and reimbursement rates of the PBM". Once that pharmacist accepts that contract, then they may not exclude him from participating in another network. On page 5, line 18, we inserted the study, basically what our amendments do, we retain all of the transparency that was critical to the pharmacists, they made that a strong point to us, that transparency is what

we needed, we retained that, we added the study because we had some what of a difficult time in our committee sorting through things, to have to legislative study part of it. the other big thing that was taken out of course was the mail order pharmacy, and part of that decision came to us from a letter we received (SEE ATTACHED TESTIMONY). This was the only information that we had from a neutral party, everyone else had a personal interest. The pharmacy folks contested the validity of it because they felt it was relying to much on information from another state, I think our committee felt that as we looked at it really did not make to much difference to us because the logic of the letter seem to carry a strong implication that if we didn't make some amendment changes as we did, we were going to find ourselves with our consumers not receiving any benefit but in some instances as they concluded, cost increases would likely undermine the ability of some consumers to obtain pharmaceuticals and health insurance they need at a price they can afford.

Representative Vigesaa: On the difference between the rebate descriptions, in our original rebate description we had a reference to the formulary management program, and I don't see anything in your description of payment or a rebate.

Chairman Nething: I think the rebate as we defined it, is a retrospective reimbursement of a monetary amount, so under a manufacturers discount program, I think that is more inclusive of what you are speaking of without getting into the detail of identification of such.

Chairman Kasper: Did the discussion come up about the differences between a discount and a rebate? The way that I look at this is there are 3 forms that the money comes from, it is the discount that you negotiate to put the drug in the formulary, and then there is the volume discount which I call the rebate, after the fact. Did that come up in your hearings at all?

Chairman Nething: It didn't, I don't remember, but I think in the amendments, I was under the impression that it was covered under any other fee or amount collected by the PBM from the manufacturer labeler, and that would be on page 2, line 21.

Chairman Kasper: I wonder if your qualifier is leaving something out? Let's say that I am negotiating with you, and I want to stipulate your drug on my formulary, I want to buy your drug at a discount because I'm going to stipulate yours and nobody else's. So instead of paying 100%, you say OK we will give you an 80% price, that is your discount. that is the first area that the dollars come in on almost any type of negotiation on PBM's is that discount price, but there is another dollar amount that comes to the PBM and that is the volume, which to me is the rebate, so you get the discount price on top of that, if you have a years contract, now because my volume was this much in addition to that I get a rebate on top of the discount so there are two sources of revenue. The rebate comes after the fact, based upon the volume.

Senator Heitkamp: If it isn't retrospective how do you know what the rebates should be?

Chairman Nething: I think it was our intention to include it. We wanted to be inclusive as we could as to what dollars flow to the PBM from the manufacturer, if we need to do something to clarify that we would certainly take a look at that.

Representative Ekstrom: You have eliminated mail service pharmacy entirely, I'm having trouble with that, why have we eliminated that?

Chairman Nething: there are a couple of reasons, number one you cant take it out of your part d, of the Medicare that is coming because it is already established federally, and the second reason, out of the big users in North Dakota have informed us that , and I'm talking about public retirement systems they want that ability to use in their contract that they negotiate with the PBM

to have mail order services to help keep the costs down, and when you don't that is reflected in cost, the third reason is that when you limit mail order service e you are getting in a very critical area with the federal law.

Representative Ekstrom: I have done a little research on this and I can't say that I am an expert, but it seems that the Medicare law, indicates that current contracted pharmacy network may be supplemented by a non regional pharmacy, indicating that it is optional of the Medicare for the mail order. I think that we have found that federal does allow for it.

Chairman Nething: We were provided information that is covered in that memo from the FTC.

Representative Ekstrom: In original testimony we were hearing that the PBM's that the mail order is in fact one of their segments of their markets that is growing very rapidly and a great source of revenue, we really need that disclosure.

Representative Kasper: What would be the harm of the Insurance commissioner looking over the next 2 years on the mail order side as well?

Chairman Nething: I don't think he has any jurisdiction.

Chairman Kasper: Meeting adjourned.

2005 HOUSE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. HB 1332

House Industry, Business and Labor Committee

☑ Conference Committee

Hearing Date 4-7-05

Tape Number	Side A	Side B	Meter #
1	x		0-25.7

Committee Clerk Signature Jodey Rinke

Minutes:

Chairman Kasper: Opened the conference committee on HB 1332.

Chairman Kasper, Representative Vigesaa, Representative Ekstrom, Chairman Nething, Senator Mutch, Senator Heitkamp were present.

Chairman Kasper: I want to start my just passing out the e-mail I received from Sparb Collins, on this bill, and question on some PERS plan on some of the amendments, just to clarify this e mail, the concern that they had is the section that the Senate amended out about the CO payments, I asked him further, which he did not address in this e-mail, if they had any concern if mail order was added to 1. a study, 2. the oversight by the Insurance commissioner. And he said that wouldn't effect the PERS plan.

Chairman Nething: One of the things that I was going to give was the PERS letter, we have that now, and I have a couple of pieces of information and I also have amendments prepared that cover the 3 things that you folks raised yesterday. This is from the Attorney Generals Office

and it talks about restrictions on CO payments, CO insurance and mail order drugs. Which were concerns that they pointed out to us.

Chairman Kasper: This is from Attorney General Stenejhem? and he did not put it on his letter head?

Chairman Nething: Right. Then I also have a long with that, even though it was only one page, they did a summary of what you just read. And then I also asked them if they could provide me with some evidence of problem with the mail order provision, and I have a case that talks about this, they feel that people opposed to the mail order position.

Chairman Kasper: I don't think its been the House's position to limit mail order, that was never their intent, correct me if I am wrong, the concern was to find out what is going on with mail order, as far as rebates, discounts and to see if the rebates and discounts were being passed on to the participant or the entity or the Insurance company, so never in our thoughts have we tried to limit mail order.

Chairman Nething: In our discussion in the Senate the question came up about that it was not unconstitutional to have mail order included in this bill, to limit the mail order. And that is why we took it out.

Chairman Kasper: It was not constitutional?

Chairman Nething: That it was not constitutional.

Representative Ekstrom: If I understand you correctly, your saying you can put it back in?

Chairman Nething: No, I'm saying you can't put it in.

Representative Kasper: If we look at the second sentence, " requiring business operations to be performed in the home state, that could be more efficiently performed elsewhere," that to me

looks like the brunt of what they are saying that you can't limit, we have no intention of doing that, our intention is to study the mail order side of things, not to limit it.

Chairman Nething: I guess we should probably go to the engrossment with the Senate amendments, this is where they would plug into. IF you go to page 2 line 22, after program, where we say...." or labeler for a drug switch program," then we would insert "formulary management program" so any other fee that was collected by the PBM from a manufacturer or a formulary management program would be added language, and I think that goes to what Representative Vigesaa was talking about. Then on line 22, you would remove the second "or", on line 23, after "individual" we would add, "or any other administrative function" we think that is pretty inclusive, then line 6 and 7 would be taken out. Page 5, line 5, replace cover with covered, that is only a typo correction. Then on page 5, line 21, after pharmacies, add "the impact of mail service pharmacies on consumers and community pharmacies" I think the question was raised that it wasn't included in the study, that is what that amendment would do.

Representative Ekstrom: The other concern that I have is the transparency, with regard to the mail service pharmacy, in other words, we are of an understanding that the PBM's, that this is the fastest growing market share of their business and I want to know how much of it is going on with the PBMs, that is why I really want it back in the bill where we talk about transparency.

Senator Nething: You show me where you want to put it, but let me finish my amendments first. There is no question that mail order issue is going to be there. On page 2, line 13, where it says six, this is where we go to the payment received by the PBMs, it means that the aggregate and if you go to "D", any other fee collected by the pharmacy benefits manager from a

manufacturer etc.... that is how it would read and then it would read "or administrative function" there.

Representative Ekstrom: On page 2, what was removed at line 29, regarding mail service pharmacy? This is where mail service pharmacy was taken out, and I don't understand why that was removed.

Chairman Kasper: I think I heard Senator Nething say yesterday and today, it was a concern with a Medicare problem, which I don't think is a problem. Is that correct Senator?

Chairman Nething: We have a Medicare problem if the bill doesn't eliminate the mail order pharmacy.

Chairman Kasper: That was the interpretation of the Senate?

Chairman Nething: That was the interpretation of the Attorney General.

Chairman Kasper: If that is what your sighting, I don't agree with that interpretation.

Chairman Nething: I'm talking about the regulations say as explained in this one hand out.

Chairman Kasper: And that is precisely what Representative Ekstrom was talking about yesterday and from the discussion that the house members have had, we don't think that is a legitimate concern and that is why we need the Attorney General to look at some other information that we have and dig into that a little bit further.

Mr. Mullen : I just want to clarify one point, what the material that Senator Nething distributed, I did prepare that material they were reviewed by the Deputy Attorney General, I do want to clarify one point, that supreme court case, our office did not make any determination that this provision is unconstitutional, Senator Nething asked me if there was any case law that were

related to this issue but we were not asked, we did not provided any opinion on the constitutionality of that, there are other issues regarding Medicare.

Chairman Kasper: This is just siting a paragraph out of a ruling of a case, which probably is a bigger case then just this one paragraph. This is why Representative Ekstrom should dig a little further. And Get something on official stationary that might have a little more depth, then what this overview is like.

Representative Ekstrom: Page 4 of the Senate Bill, line 12, dealing with a transaction fee, the words that were removed from our bill was " rebates or other retrospective utilization discounts" and I would like to keep that wording in there, and my reasoning goes to a letter that was written by Blue Cross Blue Shield employers which states on March 2005, the first paragraph says, " BCBS of ND receives retrospective discount payments, they also refer to them as rebates, somehow if the industry is referring to them as that, I think it would be clearer to the regulated community and to future legislatures what it is we meant. That language was taken out and I would like to add it back in, if that is the way the industry refers to things, I think for the sake of clarity that we keep that in there. **(SEE ATTACHED TESTIMONY)**

Representative Vigesaa: Another change from our bill is on page 4, the first section under prohibited practices, for discussion it is talking about PBM may not require pharmacies, or pharmacy to participate in one contract or to participate in another, now the language that we had in there said that solely "because the pharmacist or pharmacy declined to participate in another network or plan that is managed by the PBM" and that was taken out. I am just wondering does line one of that section cover the part that was taken out?

Chairman Nething: I think the idea is that, in other words, you can't say that you can't participate in this lucrative contract unless you take this one that is not so lucrative. That is what we are trying to say there.

Representative Ekstrom: I am also concerned , there are multiple Medicare Cards out there right not that consumers can choose from, and if in fact the PBMs are saying, "this is the one you will choose" with this particular pharmacy, I don't want to limit the consumer. Each of those Medicare cards depending on what kind of medication your taking, they each have a different kind of benefit to you, I take different things then my husband was taking and that is how we found out that they are all different, so that can happen within the same family

Chairman Nething: The PBM can only say what is in the agreement that they have with the covered provider, that is the contract that they in turn offer them.

Chairman Kasper: I can give you an example that has happened with my mother in Beulah, she had triple by pass surgery, about 2 years ago, and when she got out of the hospital she had hundreds of pills and bottles and it was costing her $600.00 to begin with per month, she couldn't afford it, so she got together with the pharmacist in Beulah, the pharmacist in Hazen and the Social Worker, and they looked at all of these available discounts sometimes directly from the pharmaceutical companies, sometimes on the discounts available, her drug costs now are at $80.00 per month, because of the multiple discounts that she was able to find, we want to be able to protect the people of North Dakota so they have that same opportunity.

Chairman Nething: Our goal is to try to keep the drugs available at the lowest possible cost, and mail order may be one of those, so we are not interfering with the mail order. The transparency comes of those who have to register with those entities. **Meeting adjourned.**

2005 HOUSE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. HB 1332

House Industry, Business and Labor Committee

☒ Conference Committee

Hearing Date 4-12-05

Tape Number	Side A	Side B	Meter #
1	x		0-12.7

Committee Clerk Signature Jodey Rinke

Minutes:

Chairman Kasper: Opened the conference committee meeting on HB 1332.

Chairman Kasper, Representative Vigesaa, Representative Ekstrom, Chairman Nething, Senator Mutch, Senator Heitkamp were present.

Chairman Kasper: presented a draft from yesterdays meeting., and maybe we can get to some final decisions today. On page one we all agree, and on page 2, the Senate amendments are highlighted in yellow and the House amendments are highlighted in blue. On item 6, I think we are all in agreement on that language, but if you go to the bottom on page two line 30 there was some discussion on moving the mail service pharmacy up to under "D" above. We will come back to that I just want to make that note there. On page 3, a point of discussion yet is "what definition of rebate we should be using", the blue is the house version, the yellow is the Senate, so we had them both put in and we need to decide on that. If we go to page 4, one of the problems from yesterday was the EOB explanation of benefits and that might be duplicated base

upon what the company is already doing. So we had the House give that up, and it has been removed to simplify matters and we will go without it. On page 5 there are some minor technical corrections at the top, we strike the words, "out or plan". On line 17 we had a concern on the language of auditing and we put the words "have audited" in there which solved some of the PBM problems that have been brought to our attention by Pat Ward. And then under the examination of the covered insured beginning on lines 22, we have the Senate language added in there which doesn't seem to be a problem anymore.

Representative Ekstrom: On page 5, line 19, on my copy the "benefit of rebates" should be highlight in blue.

Representative Kasper: That is correct, then on page 6, we have a study, and the yellow is the Senate version, and the blue is what the House has added back in, and we have overlooked in the study, line 18," the impacted of mail pharmacies on consumers and community pharmacies" so we have added that back in which was not a problem for anybody I believe.

Senator Heitkamp: So all we really have to do is settle on a language of what a rebate is?

Chairman Kasper: That is one area and there is a couple of other areas when visiting with some of the concerned parties. On the last form I had put in yellow the definition of rebates, and the reason being is we think we covered that on page 2 in item "D" we think we have adequate requirement there.

Representative Ekstrom: On page 2, line 30, was it Mike Mullen that had suggested that we put that here?

Chairman Kasper: I don't recall, but I think in the discussion we were wanting the mail service pharmacy to be part of the payment, so it is better up there then down here under the Pharmacy

Benefits Management area. And in my final handout I have moved that up. Based upon what we see here are there any other concerns besides a couple points I'll raise in my final handout that any committee member might have? Let's move to the new handout, if you go to page 2 at the bottom, you can see that we removed mail service pharmacy out of the "A" and moved it up under "D". If we move to page 3 number 9 you can see the rebate is now the Senate rebate definition, and if we move up to line 8 on page 3, beginning on line 6, there is some concern that we either keep that in or take it out. On page 4, 5, 6, are the same. Back on page 2, let us discuss lines 23, 24 where we include the words as it relates to pharmacy benefits management.

Representative Ekstrom: I would agree that it could be dropped, because number 6 says that that's what it is relating too.

Senator Nething: I would move that the Senate recede from the Senate amendments and adopt the amendments as presented.

Senator Mutch: I would **SECOND** the motion.

Motion carried. **VOTE: 6-YES 0-NO 0-ABSENT.**

Chairman Kasper will carry the bill to the floor.

Senator Nething
4-7-05

Proposed amendments to Engrossed House Bill No. 1332
First Engrossment with Senate Amendments

Page 2, line 22, after "program," insert "formulary management program,"

Page 2, line 22, remove the second "or"

Page 2, line 23, after "individual" insert ", or any other administrative function"

Page 4, line 5, remove "This"

Page 4, delete lines 6 and 7

Page 5, line 5, replace "cover" with "covered"

Page 5, line 21, after "pharmacies;" insert "the impact of mail service pharmacies on consumers and community pharmacies;"

Page 2, beginning on line 13.

6. "Payment received by the pharmacy benefits manager" means the aggregate amount of the following types of payments:
   a. A rebate collected by the pharmacy benefits manager which is allocated to a covered entity;
   b. An administrative fee collected from the manufacturer in consideration of an administrative service provided by the pharmacy benefits manager to the manufacturer;
   c. A pharmacy network fee; and
   d. Any other fee or amount collected by the pharmacy benefits manager from a manufacturer or labeler for a drug switch program, formulary management program, educational support, ~~or~~ data sales related to a covered individual, or any other administrative function.

Page 4, beginning on line 1

26.1-27.1-04. Prohibited practices. A pharmacy benefits manager may not require a pharmacist or pharmacy to participate in one contract in order to participate in another contract. The pharmacy benefits manager may not exclude an otherwise qualified pharmacist or pharmacy from participation in a particular network if the pharmacist or pharmacy accepts the terms, conditions, and reimbursement rates of the pharmacy benefits manager's contract. This section does not permit the substitution of an equivalent drug product contrary to section 19-02.1-02.

Page 5, beginning on line 5

2. To facilitate the examination, the covered entity shall disclose annually to the commissioner the benefits of the payment received by the pharmacy benefits manager received under any contract with a pharmacy benefits manager and shall describe the manner in which the payment received by the pharmacy benefits manager is applied toward reducing rates or is distributed to ~~cover~~ covered individuals.

Page 5, beginning on line 10

SECTION 3. PHARMACY BENEFITS MANAGEMENT INDUSTRY – LEGISLATIVE COUNCIL STUDY. The legislative council shall study, during the 2005-06 interim, the pharmacy benefits management industry, including the extent of competition in the marketplace for health insurance and prescription drugs; whether protecting the confidentiality of trade secret or proprietary information has a positive or negative impact on prescription drug prices; the ownership interest or affiliation between insurance companies and pharmacy benefits management companies and whether such relationships are good for the consumer; the impact of disclosure of information regarding relationships between pharmacy benefits management companies and their customers; the use of various cost-containment methods by pharmacy benefits managers, including the extent to which pharmacy benefits managers promote the use of generic drugs; the actual impact of the use of pharmacy benefits management techniques on community pharmacies; the impact of mail service pharmacies on consumers and community pharmacies; the price consumers actually pay for prescription drugs in North Dakota; and consideration of the legality of imposing statutory restrictions on pharmacy benefits managers. The legislative council shall report its findings and recommendations, together with any legislation required to implement the recommendations, to the sixtieth legislative assembly.

Original Senate Amendment's and Senator Nething's amendments

PROPOSED AMENDMENTS TO ENGROSSED HOUSE BILL NO. 1332

Page 1, line 2, after "management" insert "; and to provide for a legislative council study"

Page 2, after line 12, insert:

"6. "Payment received by the pharmacy benefits manager" means the aggregate amount of the following types of payments:

a. A rebate collected by the pharmacy benefits manager which is allocated to a covered entity;

b. An administrative fee collected from the manufacturer in consideration of an administrative service provided by the pharmacy benefits manager to the manufacturer;

c. A pharmacy network fee; and

d. Any other fee or amount collected by the pharmacy benefits manager from a manufacturer or labeler for a drug switch program, formulary management program, educational support, data sales related to a covered individual, or any other administrative function."

Page 2, line 13, replace "6." with "7."

Page 2, remove line 18

Page 2, line 19, replace "b." with "a."

Page 2, line 21, replace "c." with "b."

Page 2, line 22, replace "d." with "c."

Page 2, line 23, replace "7." with "8."

Page 2, line 26, remove "and includes mail service pharmacy"

Page 2, line 30, replace "and does not include a" with a period

Page 3, replace lines 1 through 9 with:

"9. "Rebate" means a retrospective reimbursement of a monetary amount by a manufacturer under a manufacturer's discount program with a pharmacy benefits manager for drugs dispensed to a covered individual."

Page 3, line 10, replace "9." with "10."

Page 3, remove lines 29 and 30

Page 4, remove lines 1 through 6

Page 4, line 7, remove "2."

Page 4, line 10, replace "solely because the pharmacist or" with "if the pharmacist or pharmacy accepts the terms, conditions, and reimbursement rates of the pharmacy benefits manager's contract."

Page 4, remove lines 11 through 18

Page 4, line 22, replace "that" with "which"

Page 4, line 23, replace "rebates and other retrospective" with "a payment received by the pharmacy benefits manager;"

Page 4, remove line 24

Page 4, line 25, replace "rebates and other" with "a payment received by the pharmacy benefits manager; or"

Page 4, remove line 26

Page 4, replace line 28 with "a payment received by the pharmacy benefits manager."

Page 5, line 1, replace "rebates and other" with "a payment received by the pharmacy benefits manager is"

Page 5, line 2, remove "retrospective utilization discounts are"

Page 5, line 4, replace "company" with "covered entity"

Page 5, line 5, replace "company" with "covered entity"

Page 5, replace line 7 with "payment received by the pharmacy benefits manager which the covered entity"

Page 5, line 8, replace "have" with "has"

Page 5, line 9, replace "company's" with "covered entity's" and replace "have" with "has"

Page 5, line 10, remove "of the company" and replace the second "company" with "covered entity"

Page 5, line 11, replace "rebates and other retrospective utilization" with "the payment received by the pharmacy benefits manager"

Page 5, line 12, remove "discounts"

Page 5, line 13, replace "rebates and other retrospective utilization" with "payment received by the pharmacy benefits manager is"

Page 5, line 14, remove "discounts are" and after "rates" insert "or is distributed to covered individuals"

Page 5, after line 18, insert:

"**SECTION 3. PHARMACY BENEFITS MANAGEMENT INDUSTRY - LEGISLATIVE COUNCIL STUDY.** The legislative council shall study, during the

2005-06 interim, the pharmacy benefits management industry, including the extent of competition in the marketplace for health insurance and prescription drugs; whether protecting the confidentiality of trade secret or proprietary information has a positive or negative impact on prescription drug prices; the ownership interest or affiliation between insurance companies and pharmacy benefits management companies and whether such relationships are good for the consumer; the impact of disclosure of information regarding relationships between pharmacy benefits management companies and their customers; the use of various cost-containment methods by pharmacy benefits managers, including the extent to which pharmacy benefits managers promote the use of generic drugs; the actual impact of the use of pharmacy benefits management techniques on community pharmacies; the impact of mail service pharmacies on consumers and community pharmacies; the price consumers actually pay for prescription drugs in North Dakota; and consideration of the legality of imposing statutory restrictions on pharmacy benefits managers. The legislative council shall report its findings and recommendations, together with any legislation required to implement the recommendations, to the sixtieth legislative assembly."

Renumber accordingly

REPORT OF CONFERENCE COMMITTEE
(ACCEDE/RECEDE)

Bill Number 1332 (, as (re)engrossed): Date: 4-12-05

Your Conference Committee IBL

For the Senate:	YES / NO	**For the House:**	YES / NO
Chairman Nething P	Y	Chairman Kasper P	Y
Senator Mutch P	Y	Rep. Vigesaa P	Y
Senator Heitkamp P	Y	Rep. Ekstrom P	Y

recommends that the (SENATE/HOUSE) (ACCEDE to/RECEDE from)

the (Senate/House) amendments on (SJ/HJ) page(s) _____ -- _____

____, and place on the Seventh order.

__X__, adopt (further) amendments as follows, and place 1332 on the Seventh order:

____, having been unable to agree, recommends that the committee be discharged and a new committee be appointed.

((Re)Engrossed) was placed on the Seventh order of business on the calendar.

DATE: 4-12-05
CARRIER:

LC NO. of amendment

LC NO. of engrossment

Emergency clause added or deleted
Statement of purpose of amendment

MOTION MADE BY: Nething

SECONDED BY: Mutch

VOTE COUNT 6 **YES** — **NO** — **ABSENT**

Revised 4/1/05

REPORT OF CONFERENCE COMMITTEE

HB 1332, as engrossed: Your conference committee (Sens. Nething, Mutch, Heitkamp and Reps. Kasper, Vigesaa, Ekstrom) recommends that the **SENATE RECEDE** from the Senate amendments on HJ pages 1420-1422, adopt amendments as follows, and place HB 1332 on the Seventh order:

That the Senate recede from its amendments as printed on pages 1056-1058 of the Senate Journal and pages 1420-1422 of the House Journal and that Engrossed House Bill No. 1332 be amended as follows:

Page 1, line 2, after "management" insert "; and to provide for a legislative council study"

Page 2, after line 12, insert:

"6. "Payment received by the pharmacy benefits manager" means the aggregate amount of the following types of payments:

a. A rebate collected by the pharmacy benefits manager which is allocated to a covered entity;

b. An administrative fee collected from the manufacturer in consideration of an administrative service provided by the pharmacy benefits manager to the manufacturer;

c. A pharmacy network fee; and

d. Any other fee or amount collected by the pharmacy benefits manager from a manufacturer or labeler for a drug switch program, formulary management program, mail service pharmacy, educational support, data sales related to a covered individual, or any other administrative function."

Page 2, line 13, replace "6." with "7."

Page 2, remove line 18

Page 2, line 19, replace "b." with "a."

Page 2, line 21, replace "c." with "b."

Page 2, line 22, replace "d." with "c."

Page 2, line 23, replace "7." with "8."

Page 2, line 26, remove "and includes mail service pharmacy"

Page 2, line 30, replace "and does not include a" with a period

Page 3, replace lines 1 through 9 with:

"9. "Rebate" means a retrospective reimbursement of a monetary amount by a manufacturer under a manufacturer's discount program with a pharmacy benefits manager for drugs dispensed to a covered individual."

Page 3, line 10, replace "9." with "10."

Page 3, line 29, replace "may not request a" with "shall comply with chapter 19-02.1 regarding the"

Page 3, line 30, replace "unless:" with a period

Page 4, remove lines 1 through 6

Page 4, line 10, replace "solely because the pharmacist or" with "if the pharmacist or pharmacy accepts the terms, conditions, and reimbursement rates of the pharmacy benefits manager's contract."

Page 4, remove lines 11 through 18

Page 4, line 23, replace "rebates and other retrospective" with "a payment received by the pharmacy benefits manager;"

Page 4, remove line 24

Page 4, line 25, replace "rebates and other" with "a payment received by the pharmacy benefits manager; or"

Page 4, remove line 26

Page 4, replace line 28 with "a payment received by the pharmacy benefits manager."

Page 4, line 30, replace "audit" with "have audited"

Page 5, line 1, replace "rebates and other" with "a payment received by the pharmacy benefits manager is"

Page 5, line 2, remove "retrospective utilization discounts are"

Page 5, line 4, replace "company" with "covered entity"

Page 5, line 5, replace "company" with "covered entity"

Page 5, replace line 7 with "payment received by the pharmacy benefits manager which the covered entity"

Page 5, line 8, replace "have" with "has"

Page 5, line 9, replace "company's" with "covered entity's" and replace "have" with "has"

Page 5, line 10, remove "of the company" and replace the second "company" with "covered entity"

Page 5, line 11, replace "rebates and other retrospective utilization" with "the payment received by the pharmacy benefits manager"

Page 5, line 12, remove "discounts"

Page 5, line 13, replace "rebates and other retrospective utilization" with "payment received by the pharmacy benefits manager is"

Page 5, line 14, remove "discounts are" and after "rates" insert "or is distributed to covered individuals"

Page 5, after line 18, insert:

"**SECTION 3. PHARMACY BENEFITS MANAGEMENT INDUSTRY - LEGISLATIVE COUNCIL STUDY.** The legislative council shall study, during the 2005-06 interim, the pharmacy benefits management industry, including the extent of competition in the marketplace for health insurance and prescription drugs; whether protecting the confidentiality of trade secret or proprietary information has a positive or negative impact on prescription drug prices; the ownership interest or affiliation between insurance companies and pharmacy benefits management companies and whether such relationships are good for the consumer; the impact of disclosure of information regarding relationships between pharmacy benefits management companies and their customers; the use of various cost-containment methods by pharmacy benefits managers, including the extent to which pharmacy benefits managers promote the use of generic drugs; the actual impact of the use of pharmacy benefits management techniques on community pharmacies; the impact of mail service pharmacies on consumers and community pharmacies; the impact of generic and brand name drugs in formulary development, drug switches and mail order operations, as well as spread pricing, data sales and manufacturers rebates and discounts; the price consumers actually pay for prescription drugs in North Dakota; and consideration of the legality of imposing statutory restrictions on pharmacy benefits managers. The legislative council shall report its findings and recommendations, together with any legislation required to implement the recommendations, to the sixtieth legislative assembly."

Renumber accordingly

Engrossed HB 1332 was placed on the Seventh order of business on the calendar.

2005 TESTIMONY

HB 1332

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IN-FORUM News

Monday, January 24, 2005

The Forum

Bill aims to regulate 'middleman' firms

By Patrick Springer, The Forum
Published Sunday, January 23, 2005

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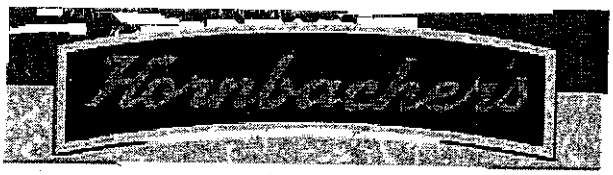

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North Dakota legislators will decide if "middleman" firms that process prescription claims should be regulated and forced to disclose any rebates they receive from drug makers.

The bill, backed by pharmacists, is part of a growing movement among states trying to regulate so-called pharmacy benefit managers, or PBMs, an important layer of administration invisible to most consumers.

The proposal also has the support of North Dakota Insurance Commissioner Jim Poolman, whose department would regulate the firms that handle the vast majority of prescription claims.

"I call this the employers' right-to-know bill," Poolman said. Through the health insurance employers provide for their workers, they pay a large part of the state's prescription drug costs.

"How much of those dollars are being eaten up by middlemen?" Poolman asked. "I think this will provide some transparency to

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them."

The bill would force pharmacy benefit managers to disclose any rebates they receive from drug manufacturers, as well as revenues they receive. It also would restrict the substitution of brand-name drugs with generics without the doctor's approval.

Major pharmacy benefit managers have come under increasing scrutiny. Several lawsuits have accused them of inflating prescription drug prices by "cutting inside deals" with drug makers and pocketing some rebates without passing the savings along to payers.

Blue Cross Blue Shield of North Dakota, which uses a pharmacy benefits manager it partly owns, opposes the legislation. Prime Therapeutics, based in the Twin Cities, is owned by Blue Cross Blue Shield plans in the region, and processes the Blues' prescription claims in North Dakota.

Rod St. Aubyn, a lobbyist for the North Dakota Blues, said laws similar to the one proposed in North Dakota have come under injunction in Maine and the District of Columbia because of constitutional questions.

"When you find out the true facts of this, I think legislators are seeing this is really intrusive," he said about forcing the disclosure of financial details not required of other industries.

"We're in a competitive environment," he said, adding his firm is a nonprofit dedicated to saving money for members, not gouging them.

"We are opposed to this legislation because we're doing what the bill is mandating," said Larry Gauper, a vice president at Blue Cross Blue Shield of North Dakota. "This new law would add costly red tape and administrative headaches."

A similar measure in California recently was vetoed by Gov. Arnold Schwarzenegger, St. Aubyn said. The veto came after a critical review by the Federal Trade Commission, which said a requirement to disclose prices actually could backfire by allowing "tacit collusion" in setting drug prices.

But Patricia Hill, executive vice president of the North Dakota Pharmacists Association, said the FTC analysis has been criticized for relying on a federal report based on unconfirmed information supplied by pharmacy benefit managers.

Also, the California market is much different than North Dakota, which is dominated by the North Dakota Blues that have more than 80 percent of the health insurance market.

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Hill said PBMs also have the power to deny patients using less-expensive generic equivalents, a problem that recently was documented in Minnesota.

The North Dakota proposal avoids problems that earlier states encountered, she said.

Tom Christensen, director of pharmacy management for Blue Cross Blue Shield of North Dakota, said processing costs for prescription drug claims handled electronically are "slightly below" the national average of 30 cents to 40 cents.

Pharmacists and Blue Cross Blue Shield also are clashing over a move by the health insurer to significantly reduce the dispensing fees pharmacists are paid for filling prescriptions and advising patients. Christensen said dispensing fees in North Dakota are more than twice the national average.

"Pharmacists hate PBMs," he said. Yet he contends the "middleman" firms have saved consumers billions of dollars over the years.

Readers can reach Forum reporter Patrick Springer at (701) 241-5522

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1-25-05

Testimony for HB 1332

HB 1332 Pharmacy Benefits Managers

Chairman Keiser and fellow members of the House IBL Committee.
For the record, my name is Nancy Johnson, Representative from District 37, Dickinson.

Before you is HB 1332 relating to Pharmacy Benefits Managers, or PBMs. A PBM is a third party administrator for a prescription drug program. They were created to handle the claims process for employer-sponsored healthcare plans that include a drug benefit. Today they have expanded their functions to include developing and maintaining the formulary, negotiating discounts and rebates with drug manufacturers, determining reimbursement rates and contracting with pharmacies. In addition some PBMs own a mail order pharmacy business.

We are all aware of and concerned about the cost of healthcare, particularly prescription drugs. This bill would bring some transparency to the costs involved and the regulation of PBMs through the Insurance Commissioner.

You may be wondering just what the problem is. To my testimony I have attached an article printed in the "*NoDak Pharmacy*" magazine and another article by an Associated Press writer from Nashville, TN. I've highlighted some of the recent court actions involving PMBs.

Are the PBMs operating in ND suspect? I don't know. I don't know because none of the information needed to make that decision is available to the employer who contracts with a PMB. The employer doesn't know how much of a rebate the PBM receives. The employer doesn't know how much of that will be shared to reduce healthcare costs. The employee receiving a drug doesn't know whether or not the PBM has switched the drug to a different one because the PBM could get a better rebate on the replacement drug.

This bill requires disclosure of all financial information directly related to the drug benefit in healthcare plans which are sponsored by employers - so they will know the exact amount that is being passed through to them as savings. This bill would not allow drug switching unless it was therapeutically equivalent or disclosed to the individual.

In this bill we've tried to maintain the confidentiality of the information a PBM would need to share with the employer who contracts with it.

I know you will have many questions. There are people here from the industry to further explain the need for the bill and how it will work.

Thank you for your time. I encourage your support of HB 1332.

PHARMACY *News Briefs*

ND Legislature to consider PBM bill

Nancy Johnson, (R-District 37), is the prime sponsor of legislation to mandate disclosure of information by pharmacy benefit managers (PBMs) operating in North Dakota. This ***"Employer's Right to Know"*** bill is cosponsored by Rep. George Keiser (R-District 47), Rep. Clara Sue Price, (R- District 40), Rep. Bill Devlin (R- District 23), Senator Judy Lee, (R-District 13), and Senator Tom Fischer, (R-District 46).

North Dakota joins 15 other states where similar legislation was recently introduced. Concerns over escalating healthcare costs have motivated states to introduce laws that regulate PBMs and mandate transparency. Currently, PBMs are not regulated at the state or federal level, and they refuse to disclose any information related to rebates or discounts that they negotiate with the drug manufacturers. The ***"Employer's Right to Know"*** bill mandates disclosure of all financial information directly related to the drug benefit in healthcare plans, which are sponsored by employers – so they know the exact amount that is (or is not) being passed through as savings to them.

National scrutiny of PBMs prompts lawsuits and investigations

Increased scrutiny has led to lawsuits against PBMs in more than 20 states alleging fraud, kickbacks, and drug switching schemes that have sent healthcare costs skyrocketing. A brief summary of litigation includes:

2004

December – The Justice Department in US District Court in Philadelphia filed suit alleging the PBM – Medco offered kickbacks of more than $200 million to a major health insurer in exchange for its business.

Last year the US Justice Department filed suit against Medco in another case of fraud involving kickbacks of $87 million. The Justice Department accused Medco of "a systematic pattern of conduct to defraud the federal government and its employees or retirees who received mail order prescriptions under a contract with Blue Cross and Blue Shield. As a result Medco lost this 5-year US government contract.

November - Texas drug benefit program for state employees and retirees is demanding information to explain 245% increases over the past four years in the contract with PBM – Medco. During the same time reimbursement to pharmacies decreased, and a majority of the pharmacy business has transferred to Medco's mail order pharmacy

August - New York State AG filed suit against the PBM - Express Scripts, alleging they defrauded the state by inflating the cost of prescription drugs. The fraud resulted from a failure to include rebates in determining the price for some drugs in the state's benefit plan. Nineteen more states are expected to bring similar actions.

Summer – The number two (Advance PCS) and number four (Caremark) largest pharmacy benefit managers in the US merged and now control 20 percent of the market...leaving 22 percent to the largest PBM Medco, and 12 percent to Express Scripts (number three).

This merger motivated a lawsuit by the Pharmacy Freedom Fund and the National Community Pharmacists Association alleging violations of anti-trust laws. In addition to controlling prices through their market dominance, the PBMs are accused of setting artificially low payments to retail pharmacies and preventing fair competition with the mail order pharmacies owned by the PBM.

April – Medco settled one lawsuit (out of court) involving 20 states. The suit accused the PBM of violating consumer protection and mail fraud. Drug switching added to costs for patients and health plans. Medco paid $29 million.

Limited space does not allow for a complete listing of all pending lawsuits against PBMs, which date back several years. Most lawsuits and legislation target full disclosure to reveal all financial information directly related to the cost of a drug benefit to plan sponsors, to enable them to determine what portion of these funds can be passed through to lower healthcare costs for plan sponsors and consumers.

Caremark Stock Drops on Word of 19-State Probe

By Amber McDowell Associated Press Writer
Published: Jul 2, 2004

NASHVILLE, Tenn. (AP) - Caremark Rx Inc., the nation's second-largest pharmaceutical benefits management company, said Friday that 19 states are probing its business practices.

As a result, the company's stock sank $1.82, or more than 5.5 percent, to $30.38 in early morning trading on the New York Stock Exchange.

Nashville-based Caremark said it received an information request, known as a civil investigative demand, on Thursday from Washington state's attorney general. The administrative subpoena concerns consumer protection statutes and business practices of Caremark and its recently acquired AdvancePCS unit, the company said.

State officials in Washington told Caremark that 18 other states would follow with their own investigative demands, the company said.

Company spokesman Gerard Carney said the administrative subpoenas "appear to request information from us relating to issues that are similar to those addressed in other recent industry settlements."

In April, Medco - the nation's largest prescription benefit manager - announced a $29 million settlement with attorneys general in 20 states over charges it pressured doctors to switch patients' medicines to ones bringing the company more revenue.

Under the settlement, Medco agreed to change business practices and, when changing patients' prescriptions, to inform them and their health plans about any rebates involved and about details such as how a switch would affect their costs.

Caremark believes its business practices "comply in all material respects with applicable laws and regulations. The company intends to fully cooperate with the requests for information," it said in a statement.

The Caremark investigation comes as the company continues to deal with a separate controversy involving two Florida pharmacists who worked in its mail-order unit.

Michael and Peppi Fowler filed a lawsuit in 2003 alleging that the company routinely resold drugs that other patients returned without testing the medication to see if it had been tampered with.

Last month, Caremark, in an unusual twist, said it backed a motion filed by the Florida attorney general to intervene in the case.

—

Caremark: www.caremark.com

AP-ES-07-02-04 1215EDT

Introduction -

HB 1332 – Pharmacy Benefits Managers

Senate Industry, Business and Labor Committee
Senator Duane Mutch, Chair
March 7, 2005

Testimony of Rep. Nancy Johnson, District #37, Dickinson

Before you today is engrossed HB 1332 relating to Pharmacy Benefits Managers, or PBMs. A PBM is a third party administrator for a prescription drug program. They were created to handle the claims process for employer-sponsored healthcare plans that included a drug benefit. Today they have expanded their functions to include developing and maintaining the formulary, negotiating discounts and rebates with drug manufacturers, determining reimbursement rates and contracting with pharmacies. In addition, some PBMs own mail order pharmacy businesses.

We are all aware of and concerned about the rising cost of healthcare, particularly prescription drugs. This bill would bring some transparency to the costs involved and the regulation of PBMs through the Insurance Commissioner.

You may be wondering just what the problem is. To my testimony I've attached an article printed in the "*NoDak Pharmacy*" magazine and another article by an Associated Press writer from Nashville, TN. I've highlighted some of the recent court actions involving PBMs.

Are the PBMs operating in ND suspect? I don't know. I don't know because none of the information needed to make that decision is available to the employer who contracts with a PBM. An employer doesn't know how much of a rebate the PBM receives. An employer doesn't know how much of that rebate will be shared to reduce healthcare costs. An employee receiving a drug doesn't know whether or not the PBM has switched the drug to a different one because the PBM could get a better rebate on the replacement drug.

Before agreeing to sponsor this legislation I talked with members of the ND Pharmacists Association for over 4 hours and read a lot of information about PBMs. I wanted to understand the pharmacist's concerns and how the system operates. This is a very complex issue.

In the House hearing it was mentioned that there weren't very many employers there to complain about ill treatment by PBMs. After learning about the issue, it doesn't surprise me. I've since visited with employers and asked them what they know about how PBMs operate. Most don't even know what a PBM is much less how their operations might affect drug costs. They know that the cost of their insurance premiums are rising but not how the drug benefit is involved. They don't know just how much of a rebate the PBM may receive on a drug or what their share really is. Pharmacists who are concerned about the rising costs of prescription drugs and who know their costs are the ones who understand the issue and bring it forward to you.

The bill you have before you today is different from the one first introduced. Your House IB&L members had an initial 3 hour hearing. It then went into a sub-committee that met at least 5 times to first understand what a PBM is, how it operates, and then to work out the concerns and differences.

In the original bill the PBM was to directly share information on rebates and discounts with the employer. The PBMs were concern about proprietary information so it was amended to having the disclosure and oversight through the Insurance Commissioner who will keep the proprietary information confidential.

Another concern was the confidentiality required through HIPPA. This bill maintains compliance.

I know you probably have questions. There are people here from the industry to further explain the need for this bill and how it will work. We worked hard in the House IB&L committee and sub-committee to understand and address the concerns and I know you will too.

Thank you for your time. I encourage your support of engrossed HB 1332.

Amendment to HB 1332

Submitted by Rep. Nancy Johnson

On page 2, line 28 delete "The"
Delete lines 29 and 30.

On page 3, delete lines 1 and 2.

HOUSE BILL NO. 1332

Presented by: Charles E. Johnson
General Counsel
North Dakota Insurance Department

Before: House Industry, Business and Labor Committee
Representative George Keiser, Chairman

Date: January 25, 2005

TESTIMONY

Chairman Keiser and members of the committee:

On behalf of Commissioner Jim Poolman, I appear before you today in support of House Bill No. 1332.

It is estimated that retail prescription drug costs are increasing at a trend of 17 to 18 percent per year. It is estimated that prescription drug costs make up over 10% of all health care costs, and this figure may be rising.

Pharmacy benefit management companies (PBMs) help control drug costs. We understand that PBMs receive rebates and discounts on the prices of prescription drugs on behalf of their clients – health insurers, employers, HMOs and government entities.

Commissioner Poolman supports this bill as an "Employer's Right to Know" bill. An employer with a self-funded plan, who contracts with a PBM to manage the prescription drug program for the plan, should have a right to know if the PBM is passing the benefits of its discounts and rebates on to its clients. This bill could also be called an "Insurer's Right to Know" bill, as an insurer also should have a right to know if the PBM is treating the company fairly.

This bill requires that a PBM disclose to its clients the rebates and discounts that the PBM receives from the drug manufacturers. The bill does not prohibit or regulate the rebates, but rather only requires disclosure. The bill protects the information by deeming it confidential.

This bill will provide PBM clients with information that will be helpful in evaluating the PBM's performance. In the end, Commissioner Poolman hopes that greater transparency will result in greater savings in the pharmaceutical system to be passed along to the health plans, and in turn to the consumers. Commissioner Poolman believes this disclosure is an important tool in helping to manage rising health insurance costs in this state.

Commissioner Poolman respectfully requests a "do pass" recommendation from this committee on House Bill No. 1332.

Memo

To: Commissioner Poolman
From: Chuck Johnson and Carole Kessel
Date: February 7, 2005

RE: Authority in Title 26.1 Relating to Requesting Information From a Pharmacy Benefits Manufacturer (PBM)

1. Authority-26.1-03-19.2(1)

The Insurance Commissioner has authority to examine the books and records of an insurance company generally under 26.1-03.

Specifically, 26.1-03-19.2(1) provides in part:

> 1. The commissioner or any of the commissioner's examiners may conduct an examination under this chapter of any company whenever the commissioner in the commissioner's sole discretion deems appropriate. . .

This section, however, applies only to domestic and foreign insurance companies. See 26.1-03-19.1.

This section does not apply to a non-insurance company, such as a PBM. Thus, section 26.1-03-19.1(1) would not allow the Commissioner to request information from a PBM.

2. Authority-26.1-03-19.2 (2)

Section 26.1-03-19.2 (2) extends the Commissioner's authority to request information from non-insurance companies, such as a PBM, and reads:

> 2. For purposes of completing an examination of any company under this chapter, the commissioner may examine or investigate any person, or the business of any person, insofar as the examination or investigation is, in the sole discretion of the commissioner, necessary or material to the examination of the company. (Emphasis added.)

Please note that the investigation of a non-insurance company must relate to information that is, "necessary or material to the examination of the company."

Since this section pertains to financial examinations, it is implied that the investigation of a non-insurance company must be necessary or material to the financial examination of an insurance company.

I understand that in the past our examiners have requested and have reviewed contracts between an insurance company and a PBM.

For example, I understand that our examiners have reviewed a contract between Blue Cross Blue Shield of North Dakota (BCBSND) and Prime Therapeutics, a PBM, but the examiners have not reviewed any contracts between a PBM and a drug manufacturer.

Our examiners, however, would not have the authority to generally request rebate or drug discount information from a PBM. They would only have the authority to request information that relates to the PBM's business with the insurance company being examined and then only in so far as the information is 'necessary or material to the financial examination'.

The above section may provide the authority under which the Commissioner could request drug discount and rebate information from a PBM such as Prime Therapeutics, but the PBM may not honor the request, in which case the Commissioner would have to convince a court that the information is necessary or material to the financial examination of the insurance company being examined.

3. Confidentiality of Work Papers-26.1-03-19.4(6) (a),

It should be noted that even if a PBM or a drug manufacturer honored the commissioner's request and provided information relating to discounts and rebates, the information would be considered to be examination work papers and would be privileged and confidential. Section 26.1-03-19.4(6) (a) reads:

> All working papers, recorded information, documents, and copies thereof produced by, obtained by, or disclosed to the commissioner or any other person in the course of an financial examination made under this chapter must be given confidential treatment and are not subject to subpoena and may not be made public by the commissioner or an other person, except to the extent provided in subsection 5.

4. Conclusion

In short, even though the Commissioner may have some limited authority to ask for information concerning a PBM's contracts with an insurance company being

examined, the Commissioner's authority is limited and the information produced, if any, must be kept confidential.

As a practical matter, our present authority does not appear to be a substitute for the disclosure requirements in HB 1332.

2-1405

Memo Re PBM Amendments

HB 1332

The PBM amendments:

- Require that the PBM give an employer or insurance company (covered entity) the option to elect to either:
  - pay a flat fee for service and allow the PBM to keep all the rebates,
  - share in the rebates with the PBM for a lesser fee, or
  - take all the rebates for a minimum fee.
- Require that the PBM disclose to a covered entity (employer or insurance company) the past three years of rebate history before contracting so that the covered entity can make an informed decision regarding the sharing of rebates, etc.
- The amendments allow the covered entity to audit the PBM as necessary to confirm that rebates are being shared as agreed.
- Provide that the insurance department must examine the contracts between the PBM and an insurance company so as to identify the rebates received by the insurer pursuant to a contract with a PBM.
- Requires that the insurance department verify that the rebates are being fairly applied to reducing the insurer's rates.
- Require that the insurer disclose annually the rebates received for each contract.
- Remove most all of the original text of the bill, except some definitions, and except the wording regarding disclosure of conflicts of interest and regarding the substituting drugs.
- Gives the commissioner rulemaking authority and gives trade secret protection to the information disclosed to the commissioner.

I hope this helps. Let me know if you need more. Chuck J. 328-4984

PROPOSED AMENDMENTS TO HOUSE BILL NO. 1332

Page 1, line 2, remove "; and"

Page 1, line 3, remove "to provide for application"

Page 2, after line 2, insert:

"3. "De-identified information" means information from which the name, address, telephone number, and other variables have been removed in accordance with requirements of title 45, Code of Federal Regulations, part 164, section 512, subsections (a) or (b)."

Page 2, line 3, replace "3" with "4"

Page 2, line 5, replace "4" with "5"

Page 2, line 9, replace "5" with "6"

Page 2, remove line 14

Page 2, line 15, replace "b" with "a"

Page 2, line 17, replace "c" with "b" and after the semicolon insert "or"

Page 2, line 18, replace "d" with "c" and replace the semicolon with a period

Page 2, remove lines 19 through 21

Page 2, line 22, replace "6" with "7"

Page 2, line 27, after the period insert "This term does not include a health carrier licensed pursuant to title 26.1 when the health carrier or its subsidiary is providing pharmacy benefits management to its own insureds; or a public self-funded pool or a private single employer self-funded plan that provides such benefits or services directly to its beneficiaries."

Page 2, remove lines 28 through 30

Page 3, remove lines 1 through 8

Page 3, after line 8, insert:

"8. "Rebate" includes the nature, type, and amount of all other revenue received by the pharmacy benefits manager, directly or indirectly, from each pharmaceutical manufacturer or labeler for any other products or services provided, including

formulary management and drug-switch programs, educational support, claims processing, and pharmacy network fees that are charged from retail pharmacies and data sales fees, with respect to programs that the covered entity offers or provides to the covered entity's enrollees.

9. "Utilization information" means de-identified information regarding the quantity of drug prescriptions dispensed to members of a health plan during a specified time period."

Page 3, remove lines 12 through 17

Page 3, line 18, replace "26.1-27.1-04" with "26.1-27.1-03"

Page 3, line 20, remove "or affiliation"

Page 3, remove line 30

Page 4, remove lines 1 through 31

Page 5, remove lines 1 through 3

Page 5, line 4, replace "26.1-27.1-06" with "26.1-27.1-04"

Page 5, line 7, replace "and" with "or"

Page 5, line 12, remove ", after disclosing to the covered individual and covered entity the"

Page 5, remove line 13

Page 5, line 14, remove "the pharmacy benefits manager as a result of the substitution"

Page 5, after line 14, insert:

"c. Nothing in this section permits the substitution of an equivalent drug product contrary to section 19-02.2-02."

Page 5, remove lines 21 through 27

Page 5, after line 27, insert:

"**26.1-27.1-05. Contents of pharmacy benefits management agreement – Requirements.** A pharmacy benefits manager must offer to a covered entity options for the covered entity to contract for services that must include:

1. A transaction fee without a sharing of rebates and other retrospective utilization discounts; or

2. A combination of a transaction fee and a sharing of rebates and other retrospective utilization discounts; or

3. A transaction fee based on the covered entity receiving all the benefits of rebates and other retrospective utilization discounts.

The agreement between the pharmacy benefits manager and the covered entity must include a provision allowing the covered entity to audit the pharmacy benefit manager's books, accounts and records, including de-identified utilization information, as necessary to confirm that the benefit of rebates and other retrospective utilization discounts are being shared as required by the contract.

26.1-27.1-06. Examination of insurer-covered entity. During an examination of a company as provided for in chapter 26.1-03, 26.1-17, or 26.1-18.1, the commissioner shall examine the contracts between the company and a pharmacy benefits manager and related records to determine if the rebates and other retrospective utilization discount benefits that the company received from the pharmacy benefits manager have been applied toward reducing the company's rates or have been distributed to covered individuals.

To facilitate the examination of the company, the company must disclose annually to the commissioner the benefits of rebates and other retrospective utilization discounts received under contracts with a pharmacy benefits manager and must describe the manner in which the rebates and other retrospective utilization discounts are applied toward reducing rates.

The information disclosed to the commissioner is considered a trade secret under chapter 47-25.1.

26.1-27.1-07. Rulemaking authority. The commissioner may adopt rules as necessary to implement this chapter."

Page 5, remove lines 28 through 31

Page 6, remove lines 1 through 31

Page 7, remove lines 1 through 7

Renumber accordingly

ENGROSSED HOUSE BILL NO. 1332

Presented by: **Jim Poolman**
Commissioner
North Dakota Insurance Department

Before: **Senate Industry, Business and Labor Committee**
Senator Duane Mutch, Chairman

Date: **March 7, 2005**

TESTIMONY

Chairman Mutch and members of the committee:

I appear before you today in support of Engrossed House Bill No. 1332.

It is estimated that retail prescription drug costs are increasing at a trend of 17 to 18 percent per year. It is estimated that prescription drug costs make up over 10% of all health care costs, and this figure may be rising.

Pharmacy benefit management companies (PBMs) help control drug costs. We understand that PBMs receive rebates and discounts on the prices of prescription drugs on behalf of their clients – health insurers, employers, HMOs and government entities.

I support this bill as an "Employer's Right to Know" bill. An employer with a self-funded plan, who contracts with a PBM to manage the prescription drug program for the plan, should have a right to know if the PBM is passing the benefits of its discounts and rebates on to its clients. This bill could also be called an "Insurer's Right to Know" bill, as an insurer also should have a right to know if the PBM is treating the company fairly.

Engrossed House Bill No. 1332 allows the Commissioner to examine a contract between an insurance company and a PBM. It also allows the Commissioner to inspect

the insurance company's records to determine if the rebates and other considerations that the insurance company has received from a PBM have been applied toward reducing the company's rates or have been distributed to covered individuals. To facilitate that exam, it requires that the insurance company disclose annually to the Commissioner the rebates and other considerations received from a PBM and how those rebates have been applied toward reducing rates.

In the end, I hope that greater transparency in the dealings between an insurance company and a PBM will result in greater savings in the pharmaceutical system to be passed along to the health plans, and in turn to the consumers.

I respectfully request a "do pass" recommendation from this committee on Engrossed House Bill No. 1332.

The
Take Back Medicare
Campaign

News from the States

Insurance commissioner objects to drug manager's marketing

07/07/04 | Source: Associated Press | By: Dale Wetzel

BISMARCK, N.D. - A company partly owned by Blue Cross Blue Shield of North Dakota has tried to strong-arm pharmacies into accepting its Medicare discount drug card, Insurance Commissioner Jim Poolman says.

Poolman, in a letter to the Fargo insurer's president, demanded a halt to what he said were illegal marketing practices that might violate North Dakota's antitrust laws.

One pharmacist said he accepted the card from the Minnesota-based company, Prime Therapeutics LLC, a pharmacy benefit manager, because he believed his business would be at risk if he declined.

"They were forcing me to accept it, or lose all my Blue Cross Blue Shield contracts," said Tom Moe, owner of Northbrook Drug in Bismarck. "I didn't think they could do it, but I wasn't taking the chance."

Larry Gauper, a Blue Cross Blue Shield of North Dakota spokesman, said any pharmacy's refusal to accept the discount card would not affect its other business relationships with the insurer.

Teresa Storm, a spokeswoman for Prime Therapeutics, called the matter a "misunderstanding." She and Gauper said a formal response to Poolman's letter was being prepared.

"We do everything to ensure we're doing things in the right way," Storm said Tuesday. "I think it's just a matter of clarifying some things."

Blue Cross Blue Shield of North Dakota is the state's dominant health care insurer, with more than 70 percent of the state's market. It is among a group of Blue Cross Blue Shield companies in eight states that own Prime Therapeutics, which is based in St. Paul, Minn.

The company is one of dozens that are offering Medicare discount drug cards to seniors as part of the run-up to a new federal prescription drug benefit for Medicare recipients in the next two years. Low-income seniors may be eligible for a $600 credit on their discount cards.

Many North Dakota pharmacies are honoring a discount card endorsed by the state pharmacy association, called Community Care Rx. It offers cheaper prescriptions without shortchanging pharmacists, or trying to steer their customers to mail-order drug sellers, said David Robinson, owner of Rx Plus, a Williston pharmacy.

ISSUES & CAMPA
Social Security
Education
Energy Indepenc
» Take Back Mec
Health Care
Corporate Accou
Jobs and Growth
Economic Stimul
SIGN UP FOR UP
your email
SEARCH
REAL PEOPLE IN
CAMPAIGN FOR AME
MoveOr
Democracy in
Allia
Ret
Ame
Afford
Health
For
See a compreher
groups fighting tc
Medicare »

"The prices that some of these plans want us to sell the prescriptions for, they are below our operating costs," Robinson said.

Moe and Wishek Drug owner Carla Aipperspach said they initially agreed to honor the Prime Therapeutics discount card, which is called PrimeScript.

However, after examining more details of the agreement, both decided they did not want to handle the card. Pharmacists may cancel agreements to take discount cards.

"As a pharmacy, we take the full brunt of the discount," Aipperspach said. "Some of these cards don't allow us to make enough to stay in business."

Aipperspach said she had not heard from Prime Therapeutics since she notified the company of her decision to cancel. Moe said he reconsidered after a company representative told him he could lose all of his Blue Cross Blue Shield of North Dakota contracts, which he said would effectively prevent him from servicing anyone covered by a Blue Cross Blue Shield health policy.

"I'm taking their card if they come in with it. I'm on the list," he said.

Poolman said Prime Therapeutics' sales practices reflect poorly on Blue Cross Blue Shield.

"They are calling North Dakota pharmacists, saying, 'Take our card, or else you'll be cut off by Blue Cross Blue Shield.' We don't think that's appropriate, and it may be illegal," Poolman said.

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HB 1332

PHARMACY BENFIT MANAGER (PBM) OVERSIGHT/TRANSPARENCY

House I.B.L. Committee Hearing 1/25/05

David Olig, R.PH.

1. This bill protects North Dakota health care purchasers/employers.
2. Transparency and oversight are necessary to protect the investment of health care purchasers in North Dakota.
3. PBMs' original, and in my feeling, appropriate role, is to process pharmacy claims for health care purchasers.
4. Currently, the purchasing of pharmaceuticals through a PBM is or can be a very confusing and convoluted process. This confusion can lead to deception, which tends to lead to increased costs.
5. PBMs claim that they reduce health care costs by decreasing pharmaceutical spending. However, they are directly responsible for a significant portion of the increase in pharmaceutical costs.
6. Currently, there is a "pay to play" scenario involved with the PBMs and the pharmaceutical manufacturers. If you want your medications on the PBM's preferred product list, you must offer a rebate/discount/kickback. Formulary decisions can be based on rebates, not therapeutics. Although the volume purchases, driven by the health care purchaser, are the reason for the rebate/discount, a significant portion of the rebate/discount is retained by the PBM in the name of "administration costs". These retained rebates total millions of dollars. Furthermore, these retained rebates are not given to the health care purchaser who earned them, but are instead kept by the PBM.
7. All of these rebates lead to higher costs. The manufacturers must pass along the costs of the discounts in higher Average Wholesale Prices (AWP) or actual acquisition costs. These rebates are <u>not</u> free. The manufactures must recoup these costs in higher prices.
8. I do not believe any PBM has ever actually shown a decrease in pharmaceutical spending. The price of the products increases at a faster rate than the discount. Mathematics demonstrates this.
9. Health care purchasers have the right to know exactly what rebates/discounts they earn. Moreover, they should expect to retain the extreme majority of them. These numbers are auditable and should be made available. Currently, many PBMs retain this information as "proprietary" and <u>do not</u> share actual numbers with their purchasers. **THIS LAW REQUIRES THAT PBMs DO AND SHOULD SHARE THIS INFORMATION WITH THEIR PURCHASERS.**
10. There is a very confusing scenario concerning PBMs, as well as their mail order pharmacies, and AWP and Maximum Allowable Cost (MAC). MAC involves the price paid for multisource (generic) drugs. The price differential, spread, between the amount the health care purchasers pay, the amount paid to the health care purchasers' local providers (pharmacies), and the purchasers' contracted amount is large.
11. Researchers at Creighton University College of Pharmacy conducted a very large study of 400,000 prescriptions and found that PBMs, as well as their mailorder pharmacies, paid their contracted pharmacies one price, while charging their purchasing groups a different price. The "spread" in these charges was attributed to the repackaging of drugs, the using of different NDC numbers (how drugs are identified), alternative (higher) AWP, and different MAC prices. Ultimately: **PAY YOUR PROVIDERS ONE PRICE, CHARGE THE PLAN ANOTHER, AND KEEP THE DIFFERENCE.**

12. Various state attorney generals have invoked numerous lawsuits and fines against PBMs. Total fines exceed $150 million for employing the aforementioned tactics. This amount was in fraudulent overcharges to health plans, or illegal kickbacks to other players. These lawsuits and fines are on public record.
13. Transparency and oversight would help to eliminate such acts. With mandated exposure to the "light of day", it is my hope that some of these acts would cease.
14. There are those that say "it is not a problem in North Dakota." Our major insurer says that they do not participate in or condone these practices. I believe that is very fortunate for North Dakota health care purchasers. However, that is not to say that they could not or would not participate. Rather, they have not participated yet. If the rest of the industry participates, why wouldn't North Dakota? This bill only holds them to the standard of excellence that they are already exhibiting, as well I think it should.
15. There is already evidence of other PBMs doing exactly what I have stated in North Dakota.
16. All PBMs should be held to the highest standard and scrutiny. They currently handle a very large portion of the health care dollar and are under absolutely no oversight or mandated transparency. I feel very deeply that this bill is necessary to protect the pharmaceutical health care dollar investment of the health care purchasers in the state of North Dakota. .

IBL Subcommittee Hearing on HB 1332
Rep. James Kasper, Chair
February 2, 2005

Testimony in support of HB 1332

Chairman Kasper and members of the subcommittee, my name is Dave Olig and I am a pharmacist, a small business owner, an employer, a health plan sponsor, and a consumer. I want to thank you for this opportunity to share a few more insights – and we have been asked to address several key issues so let's get started.

You have my testimony and some handouts that will guide us through this presentation. This information was requested to help understand what contributes to the cost of prescription medications. At the first hearing you heard about common business practices by PBMs that are estimated to substantially increase the cost of drugs to plan sponsors and consumers. HB 1332 specifically requires that ALL these activities would be disclosed to plan sponsors so they could determine if, in fact, they are or are not receiving a fair share of the various revenue streams created by PBMs.

Beginning on page one there are some common terms used throughout my comments.

- AWP – average wholesale price. This is a number assigned by the drug manufacturer or repackager and/or national companies (Medispan or First Data Bank) which was initially used as a means of estimating the cost of drugs sold by wholesalers to pharmacies. The AWP is what PBMs "discount" when offering contracts to pharmacies, generally in the range of -14% to –20%. When a pharmacy purchases drug inventory from a wholesaler, the difference between AWP and what the pharmacy buys for is from -17% to -20%, leaving a margin of profit (without the dispensing fee which averages $2) of from 3% to 6%

- Brand name drug. A drug that is available from a manufacturer for which there may or may not be a generic equivalent. If no generic is available, it is termed a "single source drug." If a generic is also available, it is termed a "multi-source drug."

- Generic drug. A drug that is a therapeutic equivalent for a brand name drug that is already on the market. These drugs are required by the FDA to meet the same stringent efficacy and safety requirements as brand name products.

- MAC. Maximum allowed cost. This number is the amount that a PBM pays a pharmacy or charges a plan sponsor per tablet, capsule, milliliter, gram, or unit of drug product dispensed. This number is decided totally by the PBM and can be changed without any notice. MAC pricing is used for generic prescriptions and can often lag behind cost increases by weeks, causing the pharmacy to dispense these medications below their actual cost. The PBMs benefit by paying the pharmacy less than what is really due based on cost increases of a drug. There can be more than one MAC list and we'll speak to this scenario in moment.

- NDC. National drug code. This is the number assigned by the manufacturer or repackager which identifies a specific product, manufacturer label code, and bottle size. Example: the NDC for Prozac 20 mg capsules in 100 count bottles is: 00777-3105-02. The 00777 identifies the manufacturer, the 3105 identifies the drug as Prozac 20 mg capsules, and the 02 identifies the bottle size as 100.

- Spread pricing. This is a pricing method often used by PBMs where by the pharmacy is paid one price for providing the prescription, but the plan sponsor is being billed a higher price. This difference, or "spread" is kept by the PBM. The spread is entirely separate from any rebates the PBM takes in.

PBMs go to various drug manufacturers and "bid for rebates" to see where the greatest number of dollars can be generated. The example on page three shows three different manufacturers who produce blood pressure medications. These are in the same class, and are for the most part therapeutically interchangeable. Note that the costs to the pharmacy are close.

When these medications are dispensed through the PBM the manufacturer of Monopril is willing to give a 7 percent rebate (.0805) for each tablet dispensed - the manufacturer of Accupril is offering a 9 percent rebate (.1026) for each tablet dispensed, and the maker of Lotensin offers a 10% rebate (.1026) per tablet dispensed. In this example the PBM has a financial incentive to accept the rebate (kickback) from the manufacturer of Accupril since this is where the greatest revenues for the PBM will be generated.

The PBM in making recommendations to the plan sponsor about which drug(s) should be on the formulary to be a covered drug is now looking at income streams (and hopefully drug efficacy) instead of simply looking for desired outcomes from this class of drugs in treating hypertension. The PBM then decides if one, two or three drugs will be considered for the formulary.

The examples given here are conservative rebates - we've heard of rebates as high as 40%...in one case that was on Lipitor. The plan sponsor thought it was good because the rebate was 40% and they received half. My question was why not all of it? He didn't know. The push for formulary versus non formulary is heavily influenced by kickbacks the PBM can get from the manufacturers.

Pages 4 and 5 show the relationship and the process between the plan sponsor, the patient, the pharmacy and the PBM. The Patient gets a prescription for #30 Accupril 10 mg. Cost for 30 tablets is $34.50 and the AWP is $43.26

- The PBM has a contract with the pharmacy for AWP – 15% + $2
- The pharmacy is reimbursed as follows: ($43.26 – 15%) + $2.00 = $38.77
- Pharmacy's gross profit to fill this prescription is $4.27

- The PBM has a contract with the plan sponsor for AWP – 13% + $2, so the plan sponsor is billed ($43.26 – 13%) + $2 = $39.64
- The plan sponsor pays $39.64 (less any co-pay which the patient pays) and the PBM keeps the difference of 87 cents (pharmacy was paid $38.77)
- This spread price of 87 cents – kept by the PBM – does not factor in any rebates collected for this prescription. In this example of Accupril with a rebate of $0.1026 per tablet, the PBM also collected an additional $3.08 rebate from the manufacturer. Did any part of the rebate make it back to the plan sponsor?

PBMs have found various ways of doing spread pricing which is meant to confuse plans sponsors into thinking they are getting a good deal, when in fact, huge profits are being taken in by PBMs that push up the cost of prescriptions drugs for those plan sponsors. In the previous example we saw how the PBM pays the pharmacy using a more aggressive AWP discount on brand name drugs than what is used to bill the plan sponsor.

Reaffirmation of the spread concept has been shown in a current lawsuit between AARP and Caremark PCS. After the transfer of a contract for a discount card (100% copay), from PCS to Express Scripts, AARP is suing PCS for $18.00/prescription. Remember, no money was changing hands. This $18.00/Rx was thought to be generated from the sale of drug sales data to pharmaceutical manufacturers and rebates. All of which increases the price of drugs to everyone else.

Generic drugs are also used extensively to create spread pricing and increase costs to plan sponsors. There are several ways this can be done.....if you'll look on page 7:

1. Paying the pharmacy a MAC price but billing the plan sponsor from a discounted AWP
2. Pushing plan sponsors to mail order, then using a different MAC list with different prices for mail order than what is used for your local community pharmacy
3. Pushing plan sponsors to mail order, then using the SAMe MAC list, but increasing the MAC reimbursement to the mail order pharmacy owned by the PBM

Let's take each of these individually so you get a better understanding of these business practices. In the example on page 8, the generic drug Quinapril has a cost of $0.785 per tablet and AWP is $1.222 per tablet, with a MAC price paid to the pharmacy of $0.89 per tablet. Here we are using a prescription for 30 tablets...the pharmacy is paid the MAC per tablet of 89 cents plus a $2 dispensing fee. The plan sponsor is billed AWP – 13% + $2 for the same prescription. Here's what that looks like:

($0.89 x 30) + $2 = $28.70 reimbursed to the pharmacy
($1.222 x 30 – 13%) + $2 = $33.89 billed to plan sponsor
$33.89 - $28.70 = $5.19 is the spread price kept by the PBM

In the second example on page 9, the PBM works very hard to get the plan sponsors to endorse mail order for their employees, but instead of using the same MAC list that the community pharmacy is assigned to use, the PBM uses a shorter list and the MAC prices are inflated. Typical MAC lists to pharmacies are about 1100 items long. For mail order it

can be as low as 200 items. The PBM determines which lists are used, and purposefully chooses a shorter list so most drugs will not be covered and will then charge the sponsor at the contract rate (AWP -% + fee), which is a much higher reimbursement to the PBM.

If you will look at the chart on the last page of the article published by the Creighton University investigators, you will see an excellent example of this in practice. Note: This is not a cherry picked list. These Rx's are from the same time period, employer plan and identical prescriptions.

In the third example on page 10, the PBM uses the same number of items on their MAC list, but for their own mail order pharmacy the MAC prices are higher than what is paid to the community pharmacy. AND the plan sponsor is ONLY told that MAC pricing is used for generics. In both examples - #2 and #3 - the difference between what is paid to the pharmacy versus what is billed to the plan sponsor is kept by the PBM. In all examples, the "spread" is in addition to the rebates that can also be kept by the PBM.

On page 11, is the issue of "repackaging" is presented. Many consumers are completely unaware of this activity, where a PBM obtains a license to receive bulk shipments of medications that arrive with a specific NDC number but are "repackaged" into smaller quantities and assigned NEW NDC numbers to reflect a smaller size and a new, higher price. The example is a simple demonstration of how this works:

The PBM mail order pharmacy receives a bulk shipment of 1000 tablets for 10 cents each = $100 (Arrive with NDC # for 1000). The bulk shipment is repackaged into 10 packages of 100 each @ 20 cents each = $200. A new NDC number is assigned for the smaller size, which corresponds to a higher price. PBMs can then sell these medications through their own mail order to plan sponsors for the higher price and keep the difference.

The Medispan database is a compilation of all National Drug Codes (NDC numbers) and prices - shows over 100 NDCs for Celebrex with AWPs ranging from $3 to $8. *Source: Ed Heckman, PAAS.*

Pages 12, 13 and 14 give you examples of how the 87 cent spread, a minimal rebate, and the transaction fee paid by all pharmacies would result in considerable profit to PBMs. Page 12 is a large North Dakota employer with coverage for more than 50,000 people generating a conservative estimate of more than $600,000 in profits.

- ☐ Spread = 87 cents Rebate = $3.08 (30 tablets for one script)

- ☐ 25,000 employees and 27,000 dependents – 500,000 prescriptions/year

100,000 fills x 87 cents	= $ 87,000	(only 20% of all fills w/min.spread)
500,000 x $1 rebate	= $ 500,000	(conservative $1 rebate/all fills)
500,000 x 10 cents	= $ 50,000	(transaction fee for all fills)
Profit to PBM	$637,000	Revenue after receiving total reimbursement for actual cost of the product (which is part of

formula paid by the plan sponsor
and the employee's co-pay)

Page 13 shows a small business with 500 employees, and page 14 shows a very conservative estimate of profits to the three largest PBMs in the country – filling prescriptions for more than 200 million people and creating revenues near $2 BILLION.

You may hear from the opponents that the contracts for pharmacies are "negotiated" which implies that the pharmacy is part of some consultation or bargaining process to determine what they receive from the PBM... and ultimately that impacts cost to the consumer. The fact is, these contracts are mandated, with little or no discussion. For example, on pages 15 and 16 are examples of text taken directly from several different contracts. We provide this information to give you the "flavor" of these documents and to reveal the true nature of limitations a pharmacy must deal with.

- "Your pharmacy's ability to continue filling prescriptions...will end if you fail to sign and return the (attached) network agreement by February 28, 2005.

  Reimbursement: AWP – 15% + $1.50 for brand name drugs
  AWP – 30% + $1.50, or MAC + $1.50 for generics

- 4.4 Pricing, Terms and Conditions: WPM shall compensate Pharmacy according to terms of Article 5 hereof. WPM is ultimately responsible for determining prices, terms and conditions of the Agreement, and for paying compensation pursuant to its terms. The responsibility for determining prices, terms and conditions has not and shall not be delegated.

  Article 5.4 Compensation: Pharmacy shall accept the compensation set forth in pricing schedules attached hereto and incorporated by reference and/or rates set forth in addenda...

  Reimbursement: AWP – 16% + $1.85 for brand name drugs
  MAC + $1.85 for generic

- Standard terms and conditions: Participant's covenants and undertakings include 2.3 Scope of services – Participant (pharmacy) shall be required to college from each eligible plan member any co-pay or ancillary charge which Rx (PBM) requires as a cost containment measure, and may require (pharmacy) to (i) offer 24 hour – 7 days per week emergency services,...(v) provide such additional and ancillary services as Rx (the PBM) may, from time to time, uniformly and reasonably impose upon all participants...

  Reimbursement: AWP – 15% + $1.75 for brand and
  AWP -38% + $2 for generic
  (or MAC + $2, whichever is lower).

On page 17, you can see the consequences to the pharmacy based on the reimbursements in one of the contracts included in your handouts, using two well known prescription medications at prices of a ND wholesaler on January 31, 2005.

AWP – 16% + $2 for brand name drugs and MAC + $2 for generics (30 day supply)
AWP – 19% + $1 for brand name and MAC + $1 for generics (90 day supply)

Zithromax 250 mg
AWP = $49.84
Net Cost = $41.51
AWP – 16% + $2
49.84 – 7.97 + $2 = $43.87
Profit of $2.36 to pharmacy

Prevacid 30 mg (90 days)
AWP = $428.76
Net Cost = $357.16
AWP – 16% + $1
428.76 – 81.46 + $1 = $348.30
Loss to the pharmacy of $8.86

Keep in mind, "Net cost" does not include pharmacy's general operation costs such as pill bottles, shipping/freight, labels, time of pharmacist to check for drug interactions – alternative drugs, and then counsel the patient on most effective use.

We have been told previously that ExpressScripts has a1-2% net profit which is being refuted in the Wall Street Journal as well as other places. One way these numbers have been deflated has bee to included patient copays (not a business expense to PBMs) and COGS which again is not a cost to a PBM. When you factor out these items, the net profit levels are indeed well over 20% as is being reported nationwide. Voo Doo economics??

Dr. Hill is going to wrap this up for you, but I must emphasize that all this information is provided to demonstrate the "need" for HB 1332. HB 1332 does not provide financial gain to pharmacies in North Dakota, it specifically gives employers a chance to find out exactly what is going on with the escalating healthcare costs they face every year. It gives these plan sponsors information they currently do not have and allows them to make choices about plans and providers based on ALL the various components that contribute to their costs.

I request your support for HB 1332, and will wait to answer questions until we have covered the next few pages and completed our testimony. Thank you.

April 14, 2005

The testimony beginning with "Common Terms," contained pages identical to some of the sheets in the testimony that begins "Payment for PBM Services." That is why there are pages missing in the "Payment for PBM Services " set of records. They were duplicates.

Common terms

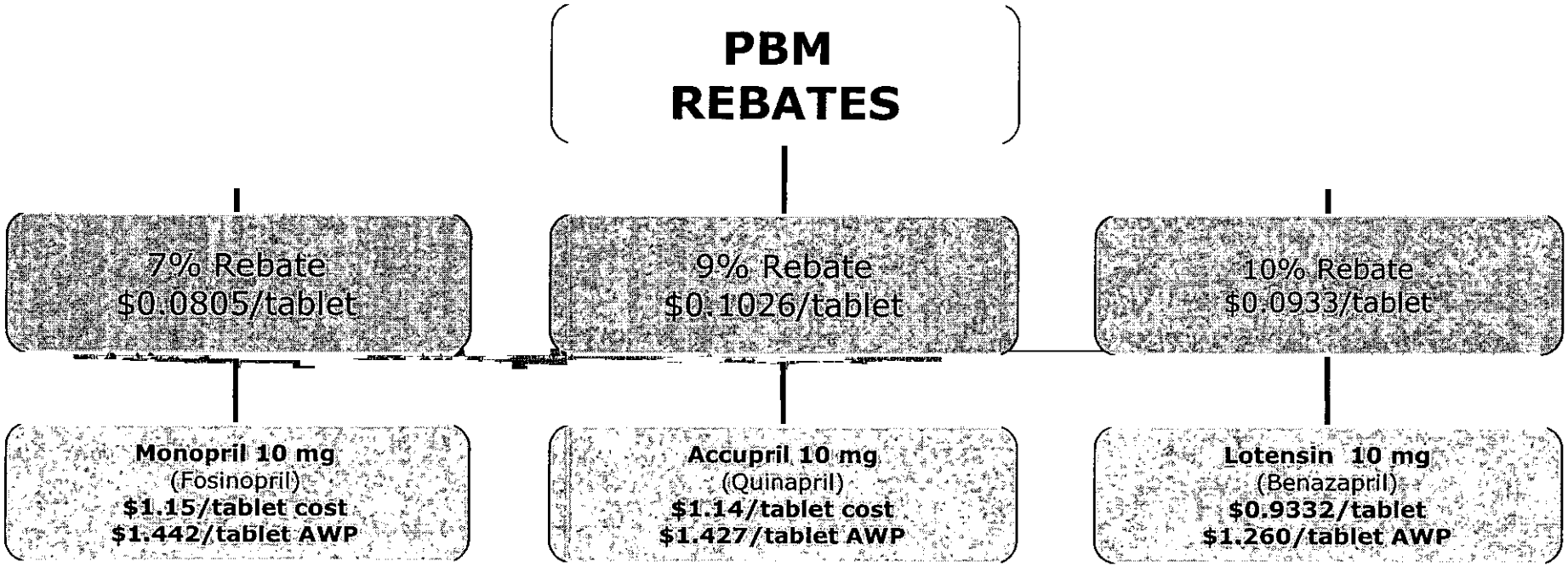
- AWP – average wholesale price. This is a number assigned by the drug manufacturer and/or national companies (Medispan or First Data Bank) which was initially used as a means of estimating the cost of drugs sold by wholesalers to pharmacies. The AWP is what PBMs "discount" when offering contracts to pharmacies, generally in the range of -14% to -16%. When a pharmacy purchases drug inventory from a wholesaler, the difference between AWP and what the pharmacy buys for is from -17% to -20%, leaving a margin of profit (without the dispensing fee which averages $2) of from 3% to 6%

- Brand name drug. A drug that is available from a manufacturer for which there may or may not be a generic equivalent. If no generic is available, it is termed a "single source drug." If a generic is also available, it is termed a "multi-source drug."

- Generic drug. A drug that is a therapeutic equivalent for a brand name drug that is already on the market. These drugs are required by the FDA to meet the same stringent efficacy and safety requirements as brand name products.

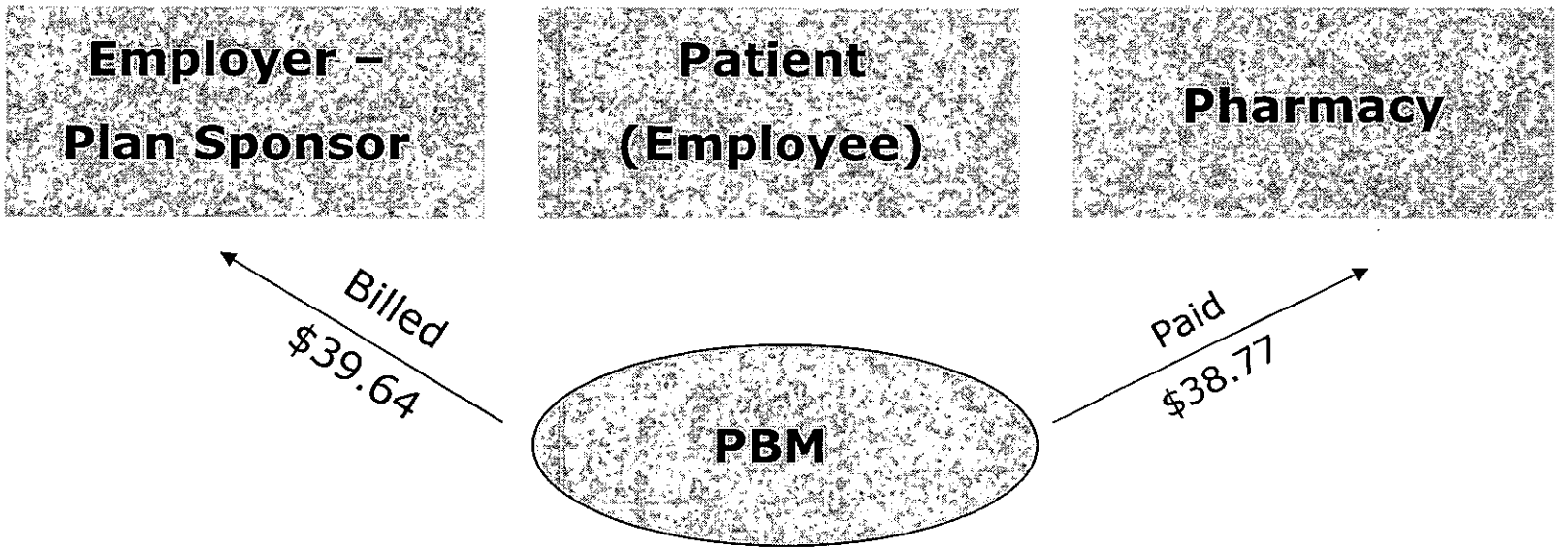
- MAC. Maximum allowed cost. This number is the amount that a PBM pays a pharmacy per tablet, capsule, milliliter, gram, or unit of drug product dispensed. This number is decided totally by the PBM and changes without any notice. MAC pricing is used for generic prescriptions and often follows behind cost increases by 2 to 3 weeks, causing the pharmacy to lose money on prescriptions. The PBMs benefit by paying the pharmacy less than what is really due based on cost increases of a drug.

- NDC. National drug code. This is the number assigned by the manufacturer which identifies a specific product, manufacturer label code, and bottle size. Example: the NDC for Prozac 20 mg capsules in 100 count bottles is: 00777-3105-02. The 00777 identifies the manufacturer, the 3105 identifies the drug as Prozac 20 mg capsules, and the 02 identifies the bottle size as 100.
- Spread pricing. This is a pricing method often used by PBMs where by the pharmacy is paid one price for providing the prescription, but the plan sponsor is being billed a higher price. This difference, or "spread" is kept by the PBM. The spread is entirely separate from any rebates the PBM takes in.



1. PBMs go to various manufacturers and "bid for rates"
2. Above the manufacturer of Monopril offers a 7% rebate ($0.0805) per tablet, Accupril manufacturer offers 8% ($0.1026), and the maker of Lotensin offers 10% ($0.0933)
3. PBM selects covered drugs on plan formulary based on revenue, instead of solely for efficacy.
4. These are conservative rebates, some are as high as 40%
5. Formularies vs. Non-formularies is driven by kickbacks received by the PBMs

Spread Pricing Example



PBM keeps $0.87 "spread" plus

a portion or all of the rebate from the manufacturer, plus the pharmacy pays the PBM a transaction fee for each claim

Spreads continued

- Contract pays pharmacy AWP – 15% + $2
- ($43.26 – 15%) + $2.00 = $38.77
- Pharmacy's gross profit to fill this prescription is $4.27

- The PBM has a contract with the plan sponsor for AWP – 13% + $2, so plan sponsor is billed ($43.26 – 13%) + $2 = $39.64
- The plan sponsor pays $39.64 (less any co-pay which the patient paid) and the PBM keeps the difference of 87 cents (pharmacy only paid $38.77)

- This spread price of 87 cents – kept by the PBM – does not factor in any rebates collected for this prescription. In this example of Accupril with a rebate of $0.1026 per tablet, the PBM also collected a $3.08 rebate from the manufacturer. Did any part of the rebate make it back to the plan sponsor?

More Spread Pricing

- PBMs have found devious ways of doing spread pricing which is meant to confuse plans sponsors into thinking they are getting a good deal, when in fact, huge profits are being taken in by PBMs that push up the cost of prescriptions drugs for those plan sponsors.

Spread Pricing continued

- 1. Pay the pharmacy a MAC price and bill the plan sponsor from a discounted AWP

- 2. Push plan sponsors to mail order and then use a different MAC list with different pricing for mail order than what is used for the community pharmacy

- 3. Push plan sponsors to mail order, using the same MAC list, but increasing the MAC reimbursement for the PBM's own mail order facilities.

Source: Shining the Light on Non-transparent PBM Cash Flows, by Robert Garis, PhD.,Creighton University published in the American Pharmacist, November 2004

1. Pay pharmacy MAC and bill plan sponsor from discounted AWP

- The generic drug Quinapril costs $0.785 per tablet and AWP is $1.222 per tablet, with a MAC price paid to the pharmacy of $0.89 per tablet

- For 30 tablets the pharmacy is paid the MAC per tablet of 89 cents plus a $2 dispensing fee. The plan sponsor is billed AWP – 13% + $2 for the same prescription. Here's what that looks like:

  ($0.89 x 30) + $2 = $28.70 reimbursed to the pharmacy
  ($1.222 x 30 – 13%) + $2 = $33.89 billed to plan sponsor
  $33.89 - $28.70 = $5.19 is the spread price kept by the PBM

2. Push plan sponsors to mail order and then use a different MAC list with different pricing for mail order than what is used for the community pharmacy

- ☐ Community pharmacy allowed to use MAC list of about 1100 prescription drugs
- ☐ PBM uses shorter MAC list of 200 for mail order, with inflated prices
- ☐ The PBM determines the lists used, and purposefully chooses a shorter list so most drugs will not be covered and will then charge the sponsor at the contract rate (AWP -% + fee), which is a much higher reimbursement to the PBM

3. Push plan sponsors to mail order, using the same MAC list, but increasing the MAC reimbursement for the PBM's own mail order facilities.

- ☐ PBM's mail order pharmacy uses the same MAC list as the community pharmacy but the PBM reimburses itself more than they allow for the local pharmacy

- ☐ In both #2 and #3 the difference between what is paid to the pharmacy versus what is billed to the plan sponsor is kept by the PBM

- ☐ In all examples, the "spread" is in addition to the rebates that are also kept by the PBM

Repackaging at PBM mail order facilities – impact on price/cost

- License to "repackage" drugs from bulk to smaller sizes
- Reassign the NDC numbers to reflect "new size being dispensed"

Bulk receipt of 1000 tablets for 10 cents each = $100 NDC # for 1000

Repackage into 10 packages of 100 each @ 20 cents each = $200 **

Assign new NDC# for smaller size which increases price

- PBMs can sell through their own mail order to plan sponsors for the higher price and keep the difference

***Note: this is a simplified example to demonstrate another revenue stream not typically revealed to plan sponsors and consumers*

- Medispan database is a compilation of all National Drug Codes (NDC numbers) and prices - shows over 100 NDCs for Celebrex with AWPs ranging from $3 to $8

Source: Ed Heckman, PAAS

Example of a large ND employer

- Spread = 87 cents — Rebate = $3.08 (30 tablets for one script)
- 25,000 employees and 27,000 dependents – 500,000 prescriptions/year

100,000 fills x 87 cents	= $ 87,000	(only 20% of all fills w/min.spread)
500,000 x $1 rebate	= $ 500,000	(conservative $1 rebate/all fills)
500,000 x 10 cents	= $ 50,000	(transaction fee for all fills)
Profit to PBM	$637,000	Revenue after receiving total reimbursement for actual cost of the product (which is part of formula paid by the plan sponsor and the employee's co-pay)

Note: these examples are for demonstration only and do not represent actual financial data from a specific company

Example of small ND business

- Spread = 87 cents — Rebate = $3.08 (30 tablets for one script)
- 500 employees and their dependents – 50,000 prescriptions/year

50,000 fills x 87 cents	= $ 43,500	(only 20% of all fills w/min.spread)
50,000 x $1 rebate	= $ 50,000	(conservative $1 rebate/all fills)
50,000 x 10 cents	= $ 5,000	(transaction fee for all fills)
Profit to PBM	$ 98,000	Revenue after receiving total reimbursement for actual cost of the product (which is part of formula paid by the plan sponsor and the employee's co-pay)

Note: these examples are for demonstration only and do not represent actual financial data from a specific company

3 largest PBMs in USA

- 200 million lives @ 5 scripts/year = 1 billion prescriptions filled (conservative estimate)

- 1 billion x 87 cents = $ 870,000,000 (87 cent spread)
  1 billion x $1 rebate = $ 1,000,000,000 ($1 rebate/fill)
  1 billion x 10 cents = $ 1,000,000 (10 cents transaction fee)

Profits to PBMs **$ 1,871,000,000**

Revenue after receiving total reimbursement for actual cost of the product (which is part of formula paid by the plan sponsor and the employee's co-pay)

Note: these examples are for demonstration only and do not represent actual financial data from a specific company

Contracts terms are not negotiated

- "Your pharmacy's ability to continue filling prescriptions...will end if you fail to sign and return the (attached) network agreement by February 28, 2005.
  Reimbursement: AWP – 15% + $1.50 for brand
  AWP – 30% + $1.50, or MAC + $1.50 for generics

- 4.4 Pricing, Terms and Conditions: WPM shall compensate Pharmacy according to terms of Article 5 hereof. WPM is ultimately responsible for determining prices, terms and conditions of the Agreement, and for paying compensation pursuant to its terms. The responsibility for determining prices, terms and conditions has not and shall not be delegated.

  Article 5.4 Compensation: Pharmacy shall accept the compensation set forth in pricing schedules attached hereto and incorporated by reference and/or rates set forth in addenda...

  Reimbursement: AWP – 16% + $1.85 for brand
  MAC + $1.85 for generic

Contracts terms are not negotiated

- Standard terms and conditions: Participant's covenants and undertakings include

  2.3 Scope of services – Participant (pharmacy) shall be required to college from each eligible plan member any co-pay or ancillary charge which Rx (PBM) requires as a cost containment measure, and may require (pharmacy) to (i) offer 24 hour – 7 days per week emergency services,...(v) provide such additional and ancillary services as Rx (the PBM) may, from time to time, uniformly and reasonably impose upon all participants...

  Reimbursement: AWP – 15% + $1.75 for brand and AWP -38% + $2 for generic (or MAC + $2, whichever is lower)

Note: contracts are up to 40 pages in length... see example in exhibits

Example of contract reimbursement impact on pharmacies

- AWP – 16% + $2 for brand name drugs and MAC + $2 for generics (30 day supply)
- AWP – 19% + $1 for brand name and MAC + $1 for generics (90 day supply)

- Zithromax 250 mg
  AWP = $49.84
  Net Cost = $41.51
  AWP – 16% + $2
  49.84 – 7.97 + $2 = $43.87
  Profit of $2.36 to pharmacy

- Prevacid 30 mg (90 days)
  AWP = $428.76
  Net Cost = $357.16
  AWP – 16% + $1
  428.76 – 81.46 + $1 = $348.30
  Loss to pharmacy of $8.86

"Net" does not include pharmacy's general operation costs such as pill bottles, shipping/freight, labels, time of pharmacist to check for drug interactions – alternative drugs, and then counsel the patient on most effective use.

Injunctions: "Takings Clause"

- **Jeff Bloomberg @ 605-773-3148**
  - Attorney wrote the South Dakota bill
  - Reviewed the judge's decision in Maine, and specifically crafted the South Dakota PBM legislation to address the concerns identified by the judge regarding confidentiality and trade secrets

- **PBMs threatened to leave SD and disrupt all pharmacy benefit coverage**
  - State employees sent out RFPs and bids included the new PBM regulations
  - 9 transparent PBMs participated and totally agreed to abide by the new disclosure law, 3 were interviewed, and the new contract for the state is less expensive than all previous contracts

Support for HB 1332

- ND Retailers Association

  testified at first hearing: 325 businesses of varying sizes all across the state

- Letters of support received since last week's hearing

- ND Insurance Department full support

- Drug Companies – neutral, perhaps to end the cycle?

Implications for State Medicaid

- ☐ Office of the Inspector General 2001 report to US Dept of Health & Human Services – "Medicaid Recovery of Pharmacy Payments from Liable Third Parties"

Highlights:

- Any/all entities involved in payment of claims included in report (includes PBMs)
- Estimates 70% of all claims are handled by PBMs – means Medicaid must often recover payment of claims from PBMs
- 58% of states recover less than 40% of the money they pursue
- PBMs are cited as creating the most obstacles for payment recovery
- PBMs not processing Medicaid claims, not willing to identify insurance companies, nor employers they contract with
- Claims denied for missing data are resubmitted with new information. One PBM does not point out ALL the data elements that are missing. Following each additional resubmission this PBM simply identified yet another data error forcing the state to continually find data and resubmit. One PBM denies claims not submitted in a certain sequence, and some reimburse at lower rates as a penalty for submitting out of sequence or in the wrong format. This process is extremely expensive for state Medicaid programs.

More problems with PBMs than all other 3rd party types combined…

- Comparison of 'Problem" 3rd Parties

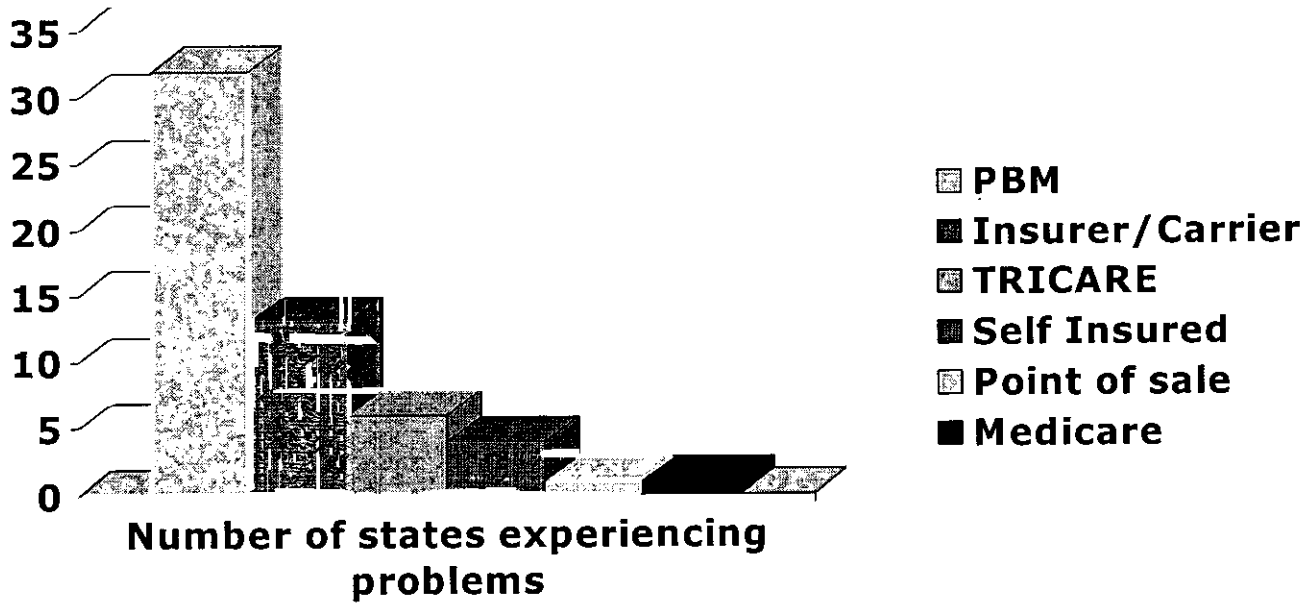


Table on page 10 of report. Source: State Medicaid data provided to OIG.

Percent of Medicaid dollars at risk

- Estimates in Appendix A and B of the report:
  - Between 40 % and 99% of funding from claims pursued by Medicaid from 3rd Parties are not recovered (at risk)
  - ND data limited to total pharmacy expenditures= $33.9 million
  - Based on average of other states, ND could have up to 65% of claims at risk (not recovered from 3rd party payers)

- Wyoming = $24.3M total, $400,000 pursued, $271,436 at risk
- Minnesota= $215M total, $4.9M pursued, $2.6M at risk

US Dept Health & Human Services Report *Prescription drug coverage, spending, utilization and prices,* 2000

- Drug coverage declining as costs rise (40% to 28% from 1993 – 1999)
- Process to determine actual cost of drugs is too complex for most consumers or plan sponsors to understand
- **A key limitation in the analysis of drug prices is the inability to incorporate the effect of rebates provided by manufacturers to insurers and PBMs.**
- **Data on manufacturer rebates, if available, would reduce the total amount paid... data on rebate arrangements, however, are confidential and unavailable to this study.**
- **Estimates of rebates range from 2% to 35%...these are not reflected in retail store prices, but are instead paid directly to insurers and PBMs that manage drug benefits after they have reimbursed the pharmacy.**

Source: US Dept of Health & Human Services: http://aspe.hhs.gov/heatlh/reports/drugstudy

"Paying the price"
US Public Interest Research Group, October 2004

- PBMs – the pharmaceutical middle men - use deceptive trade practices
- PBMs control 80% of the prescription drug market
- Despite any positive impacts on healthcare spending, PBM business practices are surrounded in secrecy… now uncovered through investigations and lawsuits to reveal negotiated deals with drug manufacturers that increase PBMs revenues without passing cost savings to plan sponsors

- 20 state lawsuit against Medco, 19 state lawsuit against Caremark & NY state lawsuit against Express Scripts

RECOMMENDATION: Increase transparency and accountability of PBMs

Questions

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Payment for PBM Services

- PBM service / claims processing
  - Very valuable service
  - PBM deserves a reasonable return
  - Key issue
    - Hidden cash flows to the PBM to make up for artificially low PBM administration fees.
  - Purchasers generally **DO NOT** know the actual price of their PBM service
    - PBM cash flows go "under the radar" of purchasers

Cash flow in the PBM industry

- Some PBMs charge a fair administration fee for their service
  - Generally good value
- Other PBMs charge a very low administration fee
  - Augment the low fee with "markups" on individual prescriptions
    - Spread pricing
    - PBM-owned mail order pharmacy—Excessive markups

PBMs – original claims processors, now...

- Create preferred drug lists, called formularies - covered by the plan
- Negotiate with drug manufacturers who offer kickbacks to ensure that their products are on the list of preferred drugs – guaranteed purchase and an increasing market share
- Have switched drugs on the list to secure increased rebate (& keep it)
- Offer contracts to plan sponsors based on these formularies
- Contract with pharmacies to fill prescriptions for the plans
- Many own mail order pharmacies and compete with the pharmacies – offering financial incentives not available to the pharmacies

PBMs

- Set the pharmacy reimbursement rate in contracts
- Set the price to be charged for the medications
- Set the fee charged to the pharmacy for each claim
- Set the amount of rebates, discounts and other revenues
- Set amount from revenues to be retained
- Set MAC lists allowed at local pharmacies
- Set MAC lists used at their mail order pharmacies (often provide greater profits than allowed at pharmacies)
- Set the amount they reimburse their own mail order (often higher than amount to pharmacies)
- Set amount of "spread" they keep
- Set the amount they keep from rebates and discounts

No accountability

- ☐ No inventory
- ☐ No financial risk
- ☐ No ethical obligations
- ☐ No regulation or oversight

Claims processors with unlimited authority over the industry but no accountability to patients, and no responsibility to lower costs & increase assess to more consumers

Follow the money.....

- Rebates
- Spreads
- MAC reimbursement vs AWP
- Drug substitution
- Co-pays & Days of Supply
- Repackaging
- Contracts

Disclosure doesn't change the game

- A drug manufacturer participates in rebates to move market share of their products... it's the only way to "stay in the game"
- Unfounded Theory that disclosure will cause less negotiation, less kickbacks, & higher prices
- Knowing rebate amounts does not change the game...the drug company must still offer rebates to keep their products on the formulary and move market share on their products

How does the "spread" work?

- The drug pricing "standard" which forms the basis of the discounted prices
  - Is not necessarily standard
    - There is variation in the "standard" price
  - Is many times a grossly elevated price
    - Particularly with generic drugs
  - Is known as Average Wholesale Price (AWP)
    - We call AWP "ain't what's paid"!

Spread Pricing not for consumers

- *Tim Dickman, CEO of Prime Therapeutics, the PBM owned by BCBS wrote (March 12, 2003, St Paul, MN PRNewswire):*

" ...PBMs need major renovation...the traditional model clearly falls short of adequately serving the needs and interests of PBM clients."

" Today's unrelenting focus on discounts, and other revenue streams must be aligned with client interests"

"...revenue streams from manufacturers (i.e., rebates, sale of data, mail order, drug switching, research grants, clinical programs) have become pervasive in recent years, they are counter-intuitive to sound business practices."

" how do we clean up our house? Government regulation of the PBM industry that curtails or prohibits rebates... a real possibility if we fail to take corrective action and very soon."

Spread Pricing continued – 3 examples

- 1. Pay the pharmacy a MAC price and bill the plan sponsor from a discounted AWP

- 2. Push plan sponsors to mail order and then use a different MAC list with different pricing for mail order than what is used for the community pharmacy

- 3. Push plan sponsors to mail order, using the same MAC list, but increasing the MAC reimbursement for the PBM's own mail order facilities.

Source: Shining the Light on Non-transparent PBM Cash Flows, by Robert Garis, PhD.,Creighton University published in the American Pharmacist, November 2004

Spread example in ND

Pharmacy Claim Forms (within 100 miles of Bismarck)

DATE	NDC NUMBER & NAME	SUPPLY (DAYS)	COST + FEE PHARM PAID (Dispensing fee)	COPAY	PBM PAID	INVOICE TO PLAN	CLAIM FEE
1-04	59772002503 Estradiol .5mg	30	12.50 + 2.50 ✓	$15	.00	7.44	.25
1-04	00378214605 Sprionolactone 25 mg	30	13.08 + 2.50	$15	.58	8.10	.25
1-04	0037820101 Lisinopril-HCTZ	30	12.50 + 2.50	$15	.00	5.18	.25
1-04	59930156001 Albuteral 90 mcg	30	23.75+ 2.50	$15	11.25	27.77	.25
1-04	00047008430 Gemfibrozil 600 mg	30	18.04 + 2.50	$15	5.54	13.21	.25
2-04	00378050301 Bisoproplol/HCTZ	14	12.50 + 2.50	$15	.00	8.06	.25

DATE	NDC NUMBER & NAME	SUPPLY (DAYS)	COST + FEE PHARM PAID	COPAY	PBM PAID	INVOICE TO PLAN	CLAIM FEE
2-04	00172439018 Albuterol	10	15.83 + 2.50	$15	3.33	14.30	.25
3-04	00378116591 Buspirone HCL 15 mg	30	25.49 + 2.50	$15	12.99	34.20	.25
3-04	00185440051 Tizanidine HCL 4mg	12	43.33 + 2.50	$15	30.83	59.87	.25
3-04	00172443560 Metformin HCL	30	66.31 + 2.50	$5	63.81	70.79	.25
3-04	00406036105 Hydrocodone	22	11.53 + 2.50	$10	4.03	14.63	.25

Drug substitution

- Select product based on price and profit, not necessarily on medical efficacy (often additional discount not forwarded)
- Change without notice
- Without professional consultation – leading to interactions, allergic reactions, ineffective medications, hospitalizations, etc.

Substitution examples

- Bismarck patient receives mandated mail order inhalers for asthma. Delivered in 30 below temps, left on doorstep...arrive home after work and medication not usable. Doesn't matter, medication ordered was substituted and inhalers delivered by the PBM cause allergic reaction so patient never used them.

- Fargo patient receives injectable prescription that must be kept refrigerated during shipment. Left on doorstep in July, destroyed by the time she arrives home from work. Must go to local pharmacy for temporary refill until next shipment is ordered and delivered.

Generic Drug Pricing

- Generic drugs have two prices
  1. The AWP price
     - This is grossly higher than the drug's actual acquisition cost in the supply chain.

  2. The "maximum allowable cost" (MAC) price
     - Relatively close to the actual acquisition cost

An example will demonstrate the fluctuation in AWP for generic drugs

AWP Fluctuation of Generic Prozac 20 mg

Manufacturer	AWP Price / 100 tablets Source: Price Alert 10/15/04
Andrix	**$ 266.80**
Barr	**$ 266.81**
Ivax	**$ 265.30**
Par	**$ 266.81**
Prozac Lilly (Originator)	**$ 417.09**
Maximum allowable cost (MAC)	**$ 25.00**

Differential Contracting

Billing terms AWP - 50% to plan sponsor:

AWP = $266.00 - 50% discount = $133.00 / 100 tab

Payment terms to pharmacy:

MAC price = $ 25.00 / 100 tab

Spread to PBM $108.00

($133.00 billed - $25.00 paid)

Generic Substitution examples

- Plendil 5 mg for high blood pressure

  Patient allowed to choose brand or generic –

Generic		Brand		
Patient copay	$69.24	Patient copay	$43.96	(Patient incentive 25.28)
Plan cost	$44.24	Plan cost	$86.88	
	$113.48		$130.84	

- Gludophage XR 750 for diabetes

  Patient mandated by PBM formulary to take the brand name version, generic claim for equivalent denied.

  Cost the patient 22 cents per tablet MORE for brand name

Mail order pharmacy

- Plan sponsors have been convinced that PBM-affiliated mail order is a "bargain"
- Channel their members **away from** community pharmacy and **toward** mail order

Let's see how mail order really works!

Co Pays and Days of Supply

- ☐ Offer incentives that drive consumers to the mail order owned by the PBM

- ☐ Do not allow patients to choose a local pharmacies and get the same incentives

No patient freedom of choice for pharmacy services, as guaranteed in state statute (Cent.Code 26.1-36-12.2)

Medicare reference:

(10) Level playing field between mail order and network pharmacies. A Part D sponsor must permit its Part D plan enrollees to receive benefits which may include a 90-day supply of covered Part D drugs, at any of its network pharmacies that are retail pharmacies. (Federal Register/Vol.70, No.18/Friday, January 28, 2005, pg 4537.)

Employer #1 - Mail and Retail (Community) Pharmacy Prices Compared

Trucking company with 3000 covered lives in the plan

Drug Name & Strength	Drug Qty.	Mail $	Community$	Saving in Community
Atenolol 50 mg	90	$38	$8	$30
Cyclobenzaprine 10 mg	90	$43	$8	$35
Fluoxetine 20 mg	90	$120	$54	$66
Gemfibrozil 600 mg	180	$112	$39	$73
Naproxen 500 mg	180	$117	$33	$84
Temazepam 30 mg	30	$13	$5	$8
Trazodone 50 mg	90	$19	$6	$13
Verapamil 240 mg	90	$73	$32	$41
Minocycline 100 mg	60	$102	$47	$55

Source: R. Garis, RP, MBA, PhD, Creighton University School of Pharmacy & Win-Rx,LLC Pharmacy benefit consulting

Employer 2* Mail and Retail (Community) Pharmacy Prices Compared

Transportation company with 15,000 covered lives in the plan

Drug Name & Strength	Drug Qty	Mail$	Community $	Saving in Community
Alprazolam 0.25mg	90	$31	$10	$21
Atenolol 100 mg	90	$56	$10	$46
Avandia 8 mg	90	$370	$318	$52
Captopril 50 mg	90	$52	$16	$36
Cyclobenzaprine 10 mg	90	$46	$17	$29
Doxycycline 100 mg	90	$63	$40	$23
Evista 60 mg	90	$177	$159	$18
Fluoxetine 20 mg Cap	90	$120	$56	$64
Fluoxetine 20 mg Tab	90	$126	$86	$40

Source: R. Garis, RP, MBA, PhD, Creighton University School of Pharmacy & Win-Rx,LLC Pharmacy benefit consulting

Employer 3* Mail and Retail (Community) Pharmacy Prices Compared

University with 2500 covered lives in the plan

Drug Name & Strength	Drug Qty.	Mail $	Community $	Saving in Community
Atenolol 25mg	30	$3	$2	$1
Doxazosin 4mg	45	$22	$15	$7
Fluoxetine 20mg	60	$35	$23	$12
Hyoscyamine 0.375mg	30	$17	$8	$9
Klor-Con 10mEq	60	$11	$8	$3
Methylphenidate 10mg	60	$25	$19	$6
Tamoxifen 20mg	30	$61	$35	$26
Timolol 0.5%	10ml	$17	$7	$10
Triam/HCTZ 37.5mg/25mg	60	$19	$13	$6

Source: R. Garis, RP, MBA, PhD, Creighton University School of Pharmacy & Win-Rx,LLC Pharmacy benefit consulting

Mail order shell game, not automatic savings

MEDICATION	SUPPLY	Local Pharmacy PLAN PAID	Local Pharmacy MEMBER PAID	Mail Order PLAN PAID	Mail Order MEMBER PAID
Alprazolam .5	270	00	21.19	00	19.06
Doxazosin 2mg	90	00	18.27	8.34	30.00
Ibuprofen 800 mg	270	00	19.35	7.03	30.00
Local copays (3 @ $15)			45.00		
Mail order copays (2 @ $15)					30.00
Total costs		00	103.81	15.46	109.06
			103.81		**124.52**
Drug costs only			**58.81**		**94.52 ($35.71 profit)**

Actual example from Prime Therapeutics

HB 1332 requires less than Medco agreed to...

- 20 state lawsuit - unfair trade practices against Medco settled in April 2004. $29 million penalty plus requires Medco to:

  - **stop switching drugs** for profit and to avoid competition with generics
  - **disclose to prescribers and patients** the minimum or actual cost savings for health plans & the difference in copayments made by patients;
  - **disclose to prescribers and patients** financial incentives for drug switchs
  - **disclose to prescribers** material differences ni side effects between prescribed drugs and proposed drugs;
  - **reimburse patients for out-of-pocket costs** for drug switch-related healthcare costs – & notify patients & prescribers that such reimbursement is available;
  - **obtain express, verifiable authorization from the prescriber** for all drug switches
  - **inform patients that they may decline the drug switch** and receive the initially prescribed drug;
  - **monitor effects of drug switches** on the health of patients;
  - **adopt** the American Pharmacists Association **code of ethics** and principles of practice for pharmacy care for employees at their mail order facilities and call centers

HB 1332
PHARMACY BENFIT MANAGER (PBM) OVERSIGHT/TRANSPARENCY
House I.B.L. Committee Hearing 1/25/05
Steve Irsfeld, RPh

What is a Pharmacy Benefit Manager (PBM)? PBMs are companies that contract with insurance companies and employers to "manage" prescription drug benefits offered through health plans.

PBMs have evolved from their original role of claims processors into the unauthorized practice of medicine and pharmacy with inappropriate consequences, including the following:

- PBMs **dictate** what medication the patient may have based on special payments the PBM receives, not on the basis of the patients' health status. This is done with the use of formularies.
- PBMs coerce patients into using mail order. Studies show that patients, especially seniors, prefer their local independent pharmacy to mail order. PBMs restrict the local pharmacy to offer a 30-day prescription and then offer a 90-day mail order prescription with special incentives. i.e.: 30 days supply locally for $20.00 or 90-day supply via mail for $30.00.
- PBMs are gouging payers, resulting in further escalation in the cost of prescription drug coverage through devious practices known as "spread pricing."

PBMs are creating chaos in community pharmacies. PBMs do not allow pharmacists to perform their professional functions because they are forced to act as plan intermediaries, which takes time away from patient care.

PBMs operations are unregulated, while pharmacists, pharmacies, and insurers are highly regulated by states. PBMs refuse to disclose information about their business practices. They add language to their contracts that prohibits release of that information to their clients. They thrive on the complexity of the overall industry to cloud the way they make their profits. A business is entitled to a fair return on investment and to be paid for the services they provide. The PBMs are supposed to save money for clients, not use every trick at their disposal to take the money and run.

The following is a quote from **Medco Health Solutions, Inc. 2003 annual report**:

"In client request for additional transparency of rebates – consultants agree that Medco has *the most transparent contracts in 2004 in all regards."*

Lisa Gill, VP and Senior Research Analyst, JP Morgan

HB 1332 will help protect the consumers and providers of health care insurance from the current lack of checks and balances that the PBMs operate under. HB 1332 has the potential to save money statewide, for businesses and consumers.

HB 1332
PHARMACY BENFIT MANAGER (PBM) OVERSIGHT/TRANSPARENCY
Senate I.B.L. Committee Hearing 3/21/05
Steve Irsfeld, RPh

Once a drug is approved, the drug company, of course, hopes to market it and sell it to pharmacies at a profit. A formulary drug is more appealing to a consumer with insurance because it is lower cost to them than a non-formulary drug, whether they understand why or not. Drug companies will do better business with a particular drug if it is formulary.

What happens if the drug company doesn't get a drug on the formulary list of PBM X? They sell less product. In order to meet their quota for this drug, they now need more urgently to be on the formulary list of PBM Y? How do they assure this? They treat PBM Y to a greater, more attractive "rebate" for the drug to make it more enticing for PBM Y to include their drug on their "formulary" list.

What does this do to the consumer? Your initial reaction might be "sounds good if you need that particular drug from PBM Y"? But how does the drug company make up for offering this rebate and still make the same profit? Who pays? Sue pays. Jack pays. You pays. Me pays. We all pays.

Why? Because the rebate program becomes an operating expense for the drug companies, thus lowering their margin. To regain that lost margin – they're not just going to give up out of the goodness of their heart. They increase their prices. And the process goes around again and again. And what's sad is that the biggest losers in this whole deal are the customers who can't afford insurance. We all suffer, because we all pay for the PBM's benefit, but chances are we're all in it – if we have insurance. The uninsured pay and get no benefit. And who are they going to tell. They don't even know what's happening to them. They just know they can't afford their medicine. But I know and that's why I'm here. You may wonder why I would come here if it wouldn't benefit me and not be home taking care of my patients at Irsfeld Pharmacy. By being here I am taking care of my patients at Irsfeld Pharmacy.

I don't know exactly how much impact this bill will have on price but it at least begins to separate, sort, and bring into the light some of the pieces in the puzzle of what drives our health care costs. Ultimately more of the public can begin to understand how this system works and employers will understand the benefits they are buying for their employees. You will hear testimony from the PBMs regarding how sophisticated corporations are at purchasing healthcare. This may be true of corporations like GM, Microsoft and General Electric but when I visited with several of our large Dickinson employers, Steffes Corporation, Fisher Industries and Community Action, that is not the case. As you can read from their letters they would like to see transparency to better gage their healthcare costs. With transparency PBMs will not be able to hide behind the bureaucracy they create.

I recently visited with a pharmaceutical representative as to why her drug was not on formulary with BCBSND (therefore, patients on this drug received less coverage). She said that her company does not participate in the rebate and discount programs that other drug

companies offer. They choose to not offer the insurance company a deal. Therefore, her drug does not make their prime coverage list. The AWP of her drug Lexapro 20mg is $253.39/100. The AWPs of similar drugs in this category of antidepressants are: Zoloft 100mg $301.70/100 & Effexor XR 150mg $371.06/100. Why are these similar drugs of other companies higher priced? Simple, they have to cover the rebate they need to pay to the PBM. You pay to play. The manufacturers are caught between a rock and a hard place or should I say between a rock and a PBM? Perhaps they are not opposed to HB 1332 because they would prefer to have this vicious cycle stop too.

Now the insurance companies have said that this rebate program keeps their costs down, keeping insurance coverage more affordable. Not if the drug companies just keep increasing overall prices to offset the rebates to PBMs. Again, the uninsured are the biggest victims. And I, myself, am not convinced that the savings is passed along to the insured and not just another way for the insurance company to make a profit.

The PBMs say also (they did in the first hearing) that this bill will drive business out of our state. After all look what happened in SD. Several large PBMs will no longer be writing new business there. But what they don't tell you is that when the state employees group, upon searching for a new PBM- because, yes, their PBM was one of those who chose to move out rather than disclose, received 13 requests from new PBMs that would be willing to comply with transparency.

In fact the Medco Health Solutions, Inc. 2003 annual report boasts.

"In client request for additional transparency of rebates – consultants agree that Medco has *the most transparent contracts in 2004 in all regards."*
Lisa Gill, VP and Senior Research Analyst, JP Morgan

And a New York Times article of February 3, 2005 quotes Tim Wentworth – Senior executive with Medco – saying, *" When you have nothing to hide, transparency is no problem."*

I'm surprised we're here since the PBMs testifying in opposition to HB 1332 requiring transparency are also publicly stating full support for transparency. Or is that all just marketing for your stockholders.

What's honest, fair, and right – for the people.

TESTIMONY OF PATRICK WARD IN OPPOSITION TO HB 1332

HOUSE INDUSTRY, BUSINESS AND LABOR COMMITTEE
JANUARY 25, 2005

Mr. Chairman and Members of the House IBL Committee. My name is Patrick Ward. I am a partner in the Bismarck law firm of Zuger Kirmis & Smith. I represent Medco Health Solutions, Inc., a pharmacy benefits management company, in opposition to HB 1332.

Other people have already explained to you what a pharmacy benefits management company does. I am here to explain to you reasons why we think this bill should be defeated. I am providing you written testimony of Mr. Peter Harty, Vice President of Government Affairs and Policy for Medco Health Solutions, Inc., who could not make it here because he is ill today.

Medco is a leading provider of comprehensive, high quality, affordable prescription drug care in the United States. They work with patients, pharmacists, physicians, and health plan sponsors to improve the quality of pharmaceutical care provided to patients while helping to control the growth in drug costs.

Medco's clients include very sophisticated health care purchasers including Fortune 500 corporations; local state and federal employee and retiree groups; Blue Cross Blue Shield plans; unions; and insurance carriers and managed care

plans. These very sophisticated customers, use in-house attorneys and pharmacists, and often are assisted by benefits consulting firms. Each plan makes its own decisions regarding cost-sharing in the form of deductibles and co-payments, use of mail service or retail pharmacies, formularies or lists of drugs which can be covered under the plan, and conditions under which certain drugs can be substituted for others. Selection of a company like Medco is usually the result of a competitive bidding process. These contracts address issues such as fiduciary responsibilities, disclosure of financial information, allocation of manufacturer rebates, auditing, and other terms negotiated by the parties.

There is no such thing as a form contract in this area. Every deal is different based on the needs of each group. There is absolutely no need for this state or any other state to mandate a one-size-fits-all approach. We can think of no other private sector of business which has a statutory obligation to disclose proprietary financial information to its customers. Although similar legislation to this has been introduced in many states, only four other states have passed the legislation. In two of those jurisdictions, Maine and the District of Columbia, there are federal court injunctions in place against application of statute. In one of those jurisdictions, California, Governor Schwarzenegger has vetoed the legislation. So far, only South Dakota has recently passed this legislation. The companies and trade associations have not yet decided whether to bring a court challenge against the South Dakota statute.

The Federal Trade Commission has noted that competition among PBMs for business is "vigorous." We believe this competition provides savings for customers in the cost of drugs. Many employer and other groups are being pushed to the breaking point by rising costs and numbers, and may decline to offer this benefit in the future if the cost saving tools of the marketplace are unavailable to them. The Federal Trade Commission has noted that consumers with PBM administered drug plans saved substantially on their drug costs as compared to cash paying customers. Medco has the knowledge and experience to negotiate the best possible deals with the drug companies and others in the distribution network and to administer the pharmacy benefit in a cost effective manner.

I am attaching data compiled by Price Waterhouse Coopers which will show the economic impact on North Dakota related plans if this legislation were to pass.

We strongly urge you to recommend a Do Not Pass on HB 1332.

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NORTH DAKOTA

The Value of Pharmacy Benefit Management & Cost of Proposed PBM Legislation[1]

KEY FINDINGS

PBM Cost Savings in North Dakota

- In 2005, the number of North Dakota residents with prescription drug coverage administered through PBMs is estimated to be 456,000.
- In 2005, drug spending managed by PBM arrangements in North Dakota is estimated to be $330 million.
- In 2005, PBMs are estimated to save North Dakota consumers and employers $112 million on the cost of their prescription drugs.
- From 2005-2014, PBMs are estimated to save North Dakota consumers and employers $2.7 billion on the cost of their prescription drugs.

Cost of PBM Legislation in North Dakota

Legislative Proposal	Change in Managed Drug Spending			Increase in Uninsured Population, 2005
	2005 (in millions)	2005-14 (in billions)	Percent Change	
Option 1: Limit Therapeutic Interchange	$15 million	$352 million	5.2%	329
Option 2: Limit Drug Management Techniques	$13 million	$335 million	4.9%	302
Assuming Therapeutic Interchange included	$27 million	$653 million	9.6%	610
Option 3: Limit Mail-Service Incentives	$8.5 million	$206 million	3.0%	192
Option 4: Require PBM Disclosure	$17 million	$475 million	7.0%	389
Option 5: Require Fiduciary Responsibility	$8.7 million	$209 million	3.1%	196
Assuming Disclosure required	$27 million	$693 million	10.2%	597

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[1] Source: PricewaterhouseCoopers, 2004

PA1 Ward.

Proposed Amendments to HB 1332 2-9-05

Page 1, line 1, after "A" replace the remainder of the bill with "concurrent resolution directing the Legislative Council to study the pharmacy benefits management industry.

WHEREAS, it is the legislative responsibility to review existing laws to ensure that they address the problems they are intended to rectify; and

WHEREAS, the Fifty-Ninth Legislative Assembly considered, but did not adopt, House Bill 1332, based in part on questions about relationships between health insurers, health benefit plans, health maintenance organizations, and pharmacy benefit managers with respect to the distribution of prescription drugs, pharmacy networks, pricing, costs, revenue, taxes, negotiating strategies and market share in the pharmacy benefits management industry.

NOW, THEREFORE, BE IT RESOLVED BY THE HOUSE OF REPRESENTATIVES OF NORTH DAKOTA, THE SENATE CONCURRING THEREIN:

That the Legislative Council study the pharmacy benefits management industry; the extent of competition in the marketplace for health insurance and prescription drugs; whether protecting the confidentiality of trade secret or proprietary information has a positive or negative impact on prices; ownership interest or affiliation between insurance companies and pharmacy benefits management companies, and whether such relationships are good for the consumer; the impact of disclosure of information regarding relationships between pharmacy benefits management companies and their customers; the use of various cost containment methods by PBM's including, but not limited to, the extent to which PBM's promote the use of generic drugs; the actual impact of the use of PBM techniques on community pharmacies; the price consumers actually pay for prescription drugs in North Dakota; and an assessment of the constitutionality and legality of imposing statutory restrictions on PBMs; and

BE IT FURTHER RESOLVED, that the Legislative Council report its findings and recommendations, together with any legislation required to implement the recommendations, to the Sixtieth Legislative Assembly."

Proposed Amendments to HB 1332

Hoghouse
Pat Ward

Remove pages 1-7, replace with, "the Legislative Council shall study the pharmacy benefits management industry; relationships between health insurers, health benefit plans, health maintenance organizations, and pharmacy benefit managers with respect to the distribution of prescription drugs, pharmacy networks, pricing, costs, revenue, taxes, negotiating strategies and market share in the pharmacy benefits management industry; the use of trade secret or proprietary information and its impact on prices; ownership interest or affiliation between insurance companies and pharmacy benefits management companies, and whether such relationships are good for the consumer; the impact of disclosure of information regarding relationships between pharmacy benefits management companies and their customers; use of generic drugs versus therapeutic equivalents by the pharmacy benefits management industry.

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ZUGER KIRMIS & SMITH

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January 27, 2005

House IBL-PBM Subcommittee

Dear Representatives Kasper, Vigesaa, Thorpe, Amerman, and Dosch:

It is my understanding that you have been appointed by Chairman Kieser to serve on a subcommittee to study the issue of PBMs in North Dakota which has been raised by the proponents of HB 1332. As you know, I represent Medco Health Solutions, Inc. in opposition to this bill. I am willing to give you any help that I can in trying to convince you to kill this bill.

I am enclosing a letter from the Federal Trade Commission to a California legislator who asked questions regarding the competition in the industry when a similar bill was presented in California, Item 1. This FTC letter clearly shows that there is vigorous competition in the PBM industry, that employers are sophisticated in negotiating contracts with PBMs, and that the result of such protectionist legislation may well be to cause overall drug costs to consumers to go up significantly in this country. Also, reading between the lines in the FTC report, one can see that there is already considerable regulation of this industry by federal agencies, antitrusts laws, and other laws already in place. The lawsuits alluded to by the proponents of the bill against people in this industry also point out another form of regulation of the industry available to the public, state attorneys general, and to class action lawyers.

I am also enclosing copies of various items for your use: Item 2 is a graph showing that the number of independent pharmacies has stayed fairly constant in North Dakota, even though there has been a slight growth in chain pharmacies. We believe that this shows that the changing dynamics in the pharmacy marketplace are not having an adverse impact on patient access to local pharmacies. I think the bigger question is the threat to the viability of the independent pharmacy from the chain drug stores and large retailers like Wal-Mart or Costco getting into the pharmacy business.

Item 3 is the Price Waterhouse Coopers' report referenced in my testimony. I did include the projected increased costs to North Dakota with my testimony at the hearing, but that is attached again as Item 4.

Item 5 is the chart I referenced in my testimony showing the slowing trend in the cost for prescription drug expenditures. As I testified, the reason for the growth in overall drug expenditures is the aging of the baby boomers and the simple fact that more people are using more drugs than ever.

Finally, our own U.S. Senator Byron Dorgan has asked the government accounting office to look into the effect of using PBMs to manage federal employees health benefits. I am attaching the lengthy report from the GAO to Senator Dorgan. What GAO found was that the PBMs reviewed produced savings for health plans by obtaining drug price discounts from retail pharmacies and dispensing drugs at lower costs through mail order pharmacies, passing on certain manufacturer rebates to the plans, and operating drug utilization control programs. The average price PBMs obtained from retail pharmacies for 14 brand named drugs was about 18 percent below the average price paid by consumers without third party coverage.

Item 7 is an analysis of the District of Columbia decision and why the disclosure requirements imposed on PBMs are unconstitutional because of the unlawful taking of trade secrets.

I will also get you actual copies of the District of Columbia and Maine Court decisions. Please let me know if you need any additional information. We would be more than happy to meet with your subcommittee at your convenience.

Sincerely,

Pat Ward

Patrick J. Ward

Enclosures
c: Vicki Knighton
Peter Harty
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Testimony of Patrick Ward in Response to Proposed
Insurance Department Amendments to HB 1332

House Industry, Business and Labor Committee February 14, 2005

Chairman Keiser and Members of the House IBL Committee. I represent Medco Health Solutions, Inc., a large national pharmacy benefits management company which does business in North Dakota. We oppose HB 1332.

- For what it's worth, it's ***probably*** better than as introduced, but I still don't think we like it, so I'm inclined to continue to oppose even if amended to this form.
- The process as this point seems unfair; late Friday we get the proposed amendments for the first time, and have to be back to the table Monday morning. Suffice it to say, getting input from my clients at Medco and their competitors over the weekend was a difficult to sporadic process at best. Most people have job descriptions that don't include working through the weekend.
- What's the process for today at the committee meeting? Presumably, since Representative Kasper worked with Commissioner Poolman's office to get these amendments, Representative Kasper is likely going to offer this as a substitute, which will then be voted on.
- This short time table points again to another reason for the study bill I have proposed. We support the study amendment.
- Section 26.1-27.1-04 regarding prohibited practices a PBM should be able to substitute a lower price generic or a therapeutically equivalent drug. The language proposed uses "and." There is a difference between generic and

therapeutically equivalent drugs (such as the Lipitor to Zocor example given in some of the testimony) which does not involve the substitution of a generic drug for a branded one. In the same paragraph, it seems quite silly to require disclosure of financial information where the substitution is being made for medical reasons. If the prescriber and a pharmacist agree that for medical reasons, the patient should receive a different drug, then what difference does it make to the plan or the patient what economic factors might be involved.

- Subsection 2 of the prohibited practice section is simply unnecessary. There is really no testimony provided at the hearing that this is a problem that our Legislature needs to step in and address.
- Likewise the requirements in subparagraph 3 dealing with discrimination on the basis of co-payments or days of supplies seems to be designed to eliminate mail order pharmacies which really can reduce the cost to the consumer of co-payments and the health plan of the prescriptions themselves. Some health plans require mail because mail is cheaper. It strikes me that this may be an unconstitutional attempt to restrain commerce. This would be economic protectionism at its worst because it would require everyone to pay more just to protect the retail pharmacy. Actuarial analysis on similar language in other states has pegged the cost at about a 1% increase in costs. If the purpose of this is to try to keep down expenditures for prescription drugs, this is the wrong headed way of going about it.

- Subparagraph 4 regarding record keeping requirements seems to be an intrusion into basic freedom of contract. It also seems unnecessary. Once again, I don't recall any testimony that this is a problem in North Dakota.
- Subsection 26.1-27.1-05 regarding the contents of pharmacy benefits management agreements, is a new provision that my clients have not seen any where else in the country. This is currently the approach that is taken, but do we want to freeze it into law and avoid a future innovation. Sophisticated commercial parties come up with new ideas and approaches all the time.
- The provision regarding providing a three year history of rebates and other retrospective utilization discounts received by the PBM again enacts into law a misunderstanding of what's really going on. Rebates are proprietary trade secrets and it is the essence of the competitive advantage given to PBMs when competing with others for business. This would enact a statute mandating disclosure to prospective customers with absolutely no confidentiality provisions. It would result in an unconstitutional taking of information similar to the Maine and District of Columbia trial court opinions. Secondly, every deal with every client is different and every plan design that a client uses is different. Three years of relevant history may have nothing to do with the plan design the employer is thinking of implementing.
- It would be unfair to begin regulating specific pharmacy benefits management business practices until you've completed the study and are sure you're doing the right thing. People complain about lack of competition for BC/BS, you don't want to do anything that pushes competition out of the state. For example, Medco and

Express Scripts haven't written any new business in SD subject to the new law, nor has Medco written any in ME. If you force competitors out of the marketplace, then who have you helped?

- **So here are the three elements, I think we could all live with:**
  - Study resolution as we drafted it. We are willing to work with whomever through the interim; the FTC study of whether PBMs' ownership of mail service pharmacies presents a conflict of interest will be completed later this year (June, if I remember correctly) and a definitive report issued; the ME & DC lawsuits will likely be concluded so the legal issues will be resolved, etc. In two years, with the benefit of a thorough and thoughtful study, evaluating all the evidence and arguments, would be the time to revisit the question of whether there should be some regulation of pharmacy benefit management business practices, rather than rushing through language that affected people have had less than one business day to review.
  - Require PBMs license up as TPAs (proposed 26.1-27.1-02 in the proposed amended bill that Rod sent to me); this at least gives the Insurance Commissioner some jurisdiction over all PBMs that do business in the state, and there's at least some level of oversight. Medco just got a TPA license. Caremark Express would likely not object.
  - Disclosure of ownership interests to the Commissioner (proposed 26.1-27.1-03). This way the state begins to at least get some information

related to BC/BS's ownership interest in Prime Therapeutics, which is one of the acknowledged concerns.

Patrick Ward testimony in opposition to Engrossed HB 1332
Senate IBL committee
March 7, 2005

Chairman Mutch and members of the Senate IBL committee. My name is Patrick Ward. I am an attorney with Zuger Kirmis and Smith law firm in Bismarck. I represent Medco Health Solutions in opposition to this bill. Peter Harty of Medco will also testify today.

This bill is an attempt by one profession, North Dakota pharmacists, to freeze out competition in the pharmacy business by placing restrictions on pharmacy benefit companies, PBM's, and by limiting mail service pharmacies from their competitive advantages over local pharmacies, all at the expense and detriment of the consumer. The PBM issue and mail service pharmacies have been investigated by the FTC and GAO and both have concluded that consumers benefit from mail service and PBM's. In addition, a few states have passed legislation that placed similar restrictions on PBM's and courts in those states, Maine and D.C., both of which have issued injunctions against those statutes.

All industries and professions in North Dakota face outside competition. In the law business we see Minneapolis and other big city law firms opening offices in North Dakota. In the insurance business there are now internet and direct writers like GEICO and Progressive that do not use local agents. Will you pass legislation requiring insurance to be sold through a local agent? Will you ban outside law firms from coming in? Neither should you place restriction on freedom of contract in the pharmacy business. To do so will lessen consumer choices and drive up prices for an already

expensive product.

You will not see any consumers supporting this bill today.

PBM's have no objection to registration as a TPA. For that reason I propose the following amendments to Engrossed HB 1332. These amendments remove the restrictions on contracts and mail service pharmacies which frequently provide discounts on co-pays or other benefits to consumers.

Page 2, remove line 18

Page 4, remove lines 7-16

You need to decide today whether to amend or kill this bill. It is unnecessary and protectionist legislation and should be killed. Peter Harty will provide more information and answer any questions you may have.

Patrick J. Ward
March 9, 2005

Proposed Amendments to Engrossed HB 1332

Page 1, line 1, after "A" replace the remainder of the bill with "concurrent resolution directing the Legislative Council to study the pharmacy benefits management industry.

WHEREAS, it is the legislative responsibility to review existing laws to ensure that they address the problems they are intended to rectify; and

WHEREAS, the Fifty-Ninth Legislative Assembly considered, but did not adopt, House Bill 1332, based in part on questions about relationships between health insurers, health benefit plans, health maintenance organizations, and pharmacy benefit managers with respect to the distribution of prescription drugs, pharmacy networks, pricing, costs, revenue, taxes, negotiating strategies and market share in the pharmacy benefits management industry.

NOW, THEREFORE, BE IT RESOLVED BY THE SENATE OF NORTH DAKOTA, THE HOUSE OF REPRESENTATIVE CONCURRING THEREIN:

That the Legislative Council study the pharmacy benefits management industry; the extent of competition in the marketplace for health insurance and prescription drugs; whether protecting the confidentiality of trade secret or proprietary information has a positive or negative impact on prices; ownership interest or affiliation between insurance companies and pharmacy benefits management companies, and whether such relationships are good for the consumer; the impact of disclosure of information regarding relationships between pharmacy benefits management companies and their customers; the use of various cost containment methods by PBM's including, but not limited to, the extent to which PBM's promote the use of generic drugs; the actual impact of the use of PBM techniques on community pharmacies; the price consumers actually pay for prescription drugs in North Dakota; and an assessment of the constitutionality and legality of imposing statutory restrictions on PBMs; and

BE IT FURTHER RESOLVED, that the Legislative Council report its findings and recommendations, together with any legislation required to implement the recommendations, to the Sixtieth Legislative Assembly."

Supplemental Background Information

Submitted by Medco Health Solutions, Inc.

In Opposition to HB 1332

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UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
Washington, DC 20580

Bureau of Competition
Bureau of Economics
Office of Policy Planning

September 3, 2004

Assembly Member Greg Aghazarian
State Capital, Room 2130
Sacramento, CA 95814

Dear Assemblyman Aghazarian:

The staffs of the Federal Trade Commission's Office of Policy Planning, Bureau of Competition, and Bureau of Economics are pleased to respond to your requests for comments on the competitive effects of California Assembly Bill No. 1960 ("AB 1960").[1] AB 1960 requires pharmacy benefit managers (PBMs) to make specified disclosures to "purchasers" and "prospective purchasers" with regard to their revenues and drug formularies.[2] AB 1960 also requires PBMs to make specified disclosures to prescribers and consumers, and sets certain requirements for PBM contracts, formularies, and staffing.[3] In your letter dated May 6, 2004,

[1] This letter expresses the views of the Federal Trade Commission's Office of Policy Planning, Bureau of Competition, and Bureau of Economics. The letter does not necessarily represent the views of the Federal Trade Commission (Commission) or of any individual Commissioner. The Commission has, however, voted to authorize us to submit these comments.

[2] AB 1960 defines a "purchaser" as "any person who enters into an agreement with a pharmacy benefits manager for the provision of pharmacy benefit management services," and a "prospective purchaser" as "any person to whom a pharmacy benefits manager offers to provide pharmacy benefits management services." AB 1960 § 1 (150000)(d)-(e).

[3] AB 1960 does not formally define "prescribers," but the context makes it clear that it is the health care professional who originally prescribed the pharmaceutical in question. AB 1960 § 1 (150007)(a).

you asked us to analyze the competitive implications of AB 1960 and discuss whether it is likely to "result in the increased cost of pharmaceutical care for consumers."

AB 1960 has been amended seven times since its introduction, but the bill's fundamental objectives (increasing cost transparency in transactions between PBMs and their health plan clients, providing more information to consumers and prescribers with respect to certain drug substitutions,[4] and ensuring that realized cost savings are passed on to consumers) do not appear to have changed.[5]

We believe that AB 1960, if enacted, may have the unintended consequences of limiting competition, thus increasing the cost of pharmaceuticals and ultimately decreasing the number of Americans with insurance coverage for pharmaceuticals. Specifically, we believe that AB 1960 may make it more difficult for PBMs to generate cost savings (including rebates) and may well make those cost savings smaller. To the extent that AB 1960 increases the cost of pharmaceuticals, it may result in an increase in health insurance premiums and reduced availability of insurance coverage for pharmaceuticals.

Although AB 1960 appears likely to discourage drug substitutions that may be aimed only at increasing PBM profitability, it does so by making all substitutions more difficult, time-consuming, and expensive. Drug substitutions can save money for consumers without placing their health at risk. As a recent Food and Drug Administration ("FDA") white paper noted, use of generic drugs can "significantly reduce overall health care costs" by providing "medicines that are just as safe and effective as their brand-name counterparts."[6] California already requires prior prescriber approval for therapeutic interchange, thus limiting the risk associated with substitution to a lower-cost alternative brand name drug. To the extent AB 1960 makes generic substitution and therapeutic interchange more difficult, it again has the potential to increase health insurance premiums and restrict the availability of insurance coverage for pharmaceuticals. Finally, we do not believe AB 1960 will materially increase the probability that realized cost savings (including rebates) are passed on to consumers.

[4] Drug substitution encompasses generic substitution and therapeutic interchange (or clinical interchange). *See* page 6 *infra*. Different disclosure is required, depending on the type of drug substitution at issue. *Id.*

[5] This letter refers to the version of AB 1960 voted on favorably by the Senate on August 24, 2004, and the Assembly on August 25, 2004. We note that the amendments made to AB 1960 since its introduction have lessened the bill's likely anticompetitive effects. Generally, in the spectrum of PBM regulation, disclosure-based regulations such as AB 1960 are likely to raise fewer competitive concerns than regulation that imposes greater restrictions on PBM contracts, such as mandating that rebates be returned to purchasers or consumers, or requiring that PBMs enter into a fiduciary relationship with purchasers.

[6] Food and Drug Administration, NEW FDA INITIATIVE ON "IMPROVING ACCESS TO GENERIC DRUGS," (June 12, 2003), available at http://www.fda.gov/oc/initiatives/generics/whitepaper.html.

In this letter, we focus on cost transparency, drug substitution, and whether cost savings are being passed on to consumers. We do not address other provisions in AB 1960.

Interest and Experience of the Federal Trade Commission

The Federal Trade Commission (Commission) is charged by statute with preventing unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce.[7] Pursuant to this statutory mandate, the Commission seeks to identify business practices and regulations that impede competition without offering countervailing benefits to consumers. For several decades, the Commission and its staff have investigated the competitive effects of restrictions on the business practices of health care providers.[8] The Commission has brought numerous enforcement actions against entities involved in the pharmaceutical industry,[9] and the Commission and its staff have issued reports and studies regarding various aspects of the pharmaceutical industry.[10]

The Commission also has extensive recent experience with PBMs. On April 8, 2004, Commission staff commented on proposed legislation in Rhode Island directly affecting PBMs.[11] Earlier this year, the Commission investigated the competitive implications of a proposed merger between Caremark and AdvancePCS.[12] On June 26, 2003, the Commission and Department of Justice Antitrust Division (Division) held a half-day of hearings on PBMs, as part of their Hearings on Health Care and Competition Law and Policy (Health Care Hearings).[13] The

[7] Federal Trade Commission Act, 15 U.S.C. § 45.

[8] *See* Federal Trade Commission, *FTC Antitrust Actions in Health Care Services and Products*, available at http://www.ftc.gov/bc/hcupdate031024.pdf.

[9] *See* Federal Trade Commission, *FTC Antitrust Actions in Pharmaceutical Services and Products*, available at http://www.ftc.gov/bc/0310rxupdate.pdf.

[10] *See* Federal Trade Commission, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION (July, 2002); David Reiffen and Michael R. Ward, GENERIC DRUG INDUSTRY DYNAMICS, Federal Trade Commission Bureau of Economics Working Paper No. 248 (Feb. 2002), available at http://www.ftc.gov/be/econwork.htm; Roy Levy, THE PHARMACEUTICAL INDUSTRY: COMPETITIVE AND ANTITRUST ISSUES IN AN ENVIRONMENT OF CHANGE, Federal Trade Commission Bureau of Economics Staff Report (March 1999), available at http://www.ftc.gov/reports/pharmaceutical/drugrep.pdf.

[11] Letter from FTC staff to Patrick C. Lynch, Attorney General and Juan M. Pichardo, Deputy Senate Majority Leader, State of Rhode Island and Providence Plantations, April 8, 2004, available at http://www.ftc.gov/os/2004/04/ribills.pdf.

[12] Statement of the Federal Trade Commission, *In re Caremark Rx, Inc./AdvancePCS*, File No. 0310239 (Feb. 11, 2004) available at http://www.ftc.gov/os/caselist/0310239/040211ftcstatement0310239.pdf.

[13] Health Care Hearings, June 26, 2003. http://www.ftc.gov/ogc/healthcarehearings/030626ftctrans.pdf. *See also* http://www.ftc.gov/ogc/healthcarehearings/030626agenda.htm. All subsequent references to the hearings will identify a panelist, affiliation, and transcript page. Affiliations are as of the date of the hearing.

report jointly issued by the Commission and the Division on July 23, 2004, addressed the issues raised by PBMs as well.[14] Finally, Commission staff currently are conducting a Congressionally mandated study on the cost implications of PBM use of mail order pharmacies.[15]

Description of AB 1960

AB 1960 requires PBMs to disclose the following information to purchasers and prospective purchasers of PBM services: the aggregate amount of rebates received for drug benefits specific to the purchaser or prospective purchaser; aggregate rebates for each therapeutic class of pharmaceuticals specific to the purchaser or prospective purchaser; nature and amount of revenue received from pharmaceutical manufacturers and labelers for drug benefits related to the purchaser or prospective purchaser; administrative fees charged to the purchaser; and arrangements with providers, pharmacists and other entities to encourage formulary compliance or manage prescription drug benefits.[16] AB 1960 also requires PBMs to disclose drug utilization information to purchasers (but not prospective purchasers). AB 1960 provides that a PBM need not make these disclosures unless the purchaser or prospective purchaser agrees to protect the confidentiality of any proprietary information.[17] AB 1960 excludes health plans and health insurers that provide pharmacy benefit management services to their own enrollees from these disclosure requirements.

AB 1960 also imposes disclosure requirements to prescribers and patients before a PBM may substitute one medication for another. AB 1960 requires a PBM that is requesting authorization from a prescriber to substitute a medication to disclose a range of information, including the cost savings (if any) to the purchaser; the difference (if any) in the consumer co-payment; the existence of any payments received by the PBM as a result of the substitution; the circumstances (if any) under which the existing prescription would be covered; the circumstances under which health care costs arising from the change in medications will be compensated; and any known differences in potential effects on health and human safety of the new medication.[18]

[14] Federal Trade Commission and Department of Justice, IMPROVING HEALTH CARE: A DOSE OF COMPETITION Chapter 7 (2004), available at http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf.

[15] Federal Trade Commission, *Pharmacy Benefit Manager Conflict of Interest Study Public Notice*, March 26, 2004, available at http://www.ftc.gov/os/2004/03/040326pnpbm.pdf.

[16] AB 1960 §§ 150001, 150002. This information is to be provided to the purchaser no less frequently than quarterly. A PBM is not required to disclose discounts associated with prescription drugs purchased for sale and distribution through the PBM's mail order pharmacy. AB 1960 §§ 150001 (c), 150002 (c).

[17] AB 1960 § 150003 (b).

[18] AB 1960 § 150006 (a). California law prohibits the dispensing of a prescription pharmaceutical without a valid prescription. Although California law permits pharmacies to substitute a generic equivalent for a brand name drug in certain circumstances (*see* CA. BUS. & PROF'L CODE § 4073) a pharmacy may not dispense to a patient a different drug than the one prescribed without prescriber approval. Combined with this existing approval

AB 1960 states that this information need not be provided to the health care provider in five circumstances, including substitution of a generic equivalent of the prescribed medication.[19]

AB 1960 also prohibits a PBM from making any drug substitution unless certain information is communicated to the consumer, including the identity of the proposed and current medication, the difference (if any) in the consumer co-payment, the circumstances (if any) under which the existing prescription would be covered, the circumstances under which health care costs arising from the change in medications will be compensated, and any potential side effects of the new medication.[20] AB 1960 provides no circumstances where PBMs are not required to make consumer disclosures when there is a drug substitution. Thus, we interpret AB 1960 to require that this information be disclosed to consumers even when a bio-equivalent generic drug is substituted for a brand-name drug. The bill also requires a PBM to monitor the health effects on patients of medication substitutions requested by the PBM, and report the results of this monitoring on a quarterly basis to the PBM's Pharmacy and Therapeutics Committee.[21]

AB 1960 states that the PBM should reverse any drug substitution upon written or oral instructions from a prescriber or consumer, unless the prescribed drug is no longer on the purchaser's formulary or the consumer is unwilling to pay any higher applicable co-payment associated with the prescribed drug.[22]

Finally, AB 1960 requires PBM contracts to address a number of issues, including the amount of revenues, rebates and discounts identified previously that will be passed on to the purchaser, any administrative fees charged by the PBM, and the conditions under which an audit of the contract for PBM services may be conducted.[23]

Background on PBMs

There are approximately 60 PBMs operating in the United States today. There are three large independent, full-service PBMs with national scope: Medco, Express Scripts, and Caremark. Some large insurers manage pharmacy benefits internally. A few PBMs are owned by large retail supermarket/pharmacy chains. In addition, there are many smaller privately held

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requirement, § 150006 (a) has the effect of requiring disclosures to prescribers whenever a PBM wants to effect a therapeutic interchange.

19 AB 1960 § 150006 (b)(1).

20 AB 1960 § 150006 (d).

21 AB 1960 § 150007.

22 AB 1960 § 150006 (e).

23 AB 1960 § 150004.

PBMs. The relative size and ranking of these companies varies according to the measure used. The three large national PBMs are the major players in many markets, but anywhere from one-third to one-half of the market is made up of the other PBMs listed above. In our most recent antitrust investigation in the PBM industry, we found the competition between PBMs for contracts with plan sponsors to be "vigorous."[24]

PBMs manage the pharmacy benefits of group health plan sponsors. At the Health Care Hearings, one panelist estimated that ninety-five percent of patients with prescription drug insurance coverage receive their benefits through a PBM.[25] A PBM's contract with group health plan sponsors specifies the amount that plan sponsors will pay per prescription of each drug, and the charges for the variety of PBM services that plan sponsors may utilize.

One important tool used by PBMs to manage pharmacy benefits is the formulary, which is a list of PBM-approved drugs for treating various diseases and conditions. PBMs use the formulary to guide drug substitution (both generic substitution and therapeutic interchange) in an effort to reduce costs. Generic substitution is the dispensing of a bio-equivalent generic drug product that contains the same active ingredient(s) as the brand-name drug and is, among other things, chemically identical in strength, concentration, dosage form, and route of administration as the substituted brand-name product. Generally, generic substitution is allowed without prior prescriber authorization.[26] Therapeutic interchange involves substitution of a therapeutically equivalent, but pharmacologically distinct, drug product for the drug product referred to on the consumer's prescription (*e.g.*, two brand-name drug products that treat the same ailment). As noted *supra*, California requires prior prescriber authorization before a pharmacist is allowed to interchange one brand-name drug for another. Therapeutic interchange allows a PBM to encourage implementation of its formulary, by steering utilization toward or away from a particular pharmaceutical.

Because the formulary affects the mix of drugs used by enrollees in a plan, its design can significantly affect the cost to the plan sponsor. Because generic drugs are substantially less expensive than their brand-name counterparts, generic substitution lowers prescription drug costs. Further, preferential placement on a formulary, accompanied with reduced co-payments, can cause a drug product to obtain higher market share within a drug plan. Accordingly,

[24] Commission Statement, *supra* note 12.

[25] John Richardson, The Health Strategies Consultancy, Health Care Hearings, *supra* note 13, at 8.

[26] Indeed, nearly all state pharmacy assistance programs require generic substitution. *See* The Commonwealth Fund, State Pharmacy Assistance Programs Provide Lessons for Reducing Costs and Improving Patient Safety (Feb. 12, 2004), available at http://www.cmwf.org/newsroom/newsroom_show.htm?doc_id=223655. Further, some states require pharmacists to make generic substitutions unless the consumer objects or the prescription specifically states "dispense as written." *See, e.g.*, MINN. STAT. Chapter 151.21 (2003).

competition between pharmaceutical companies for preferred placement on the formulary can lead to lower drug prices.

PBMs also enter into contracts with pharmaceutical manufacturers.[27] The contract often provides that the pharmaceutical manufacturer will pay a rebate, based on some combination of a percentage of a reference price, achieving certain specified sales or market share targets, and preferred placement of certain drug products on the PBM's formulary. These rebates are either paid to the group health plan sponsor, retained by the PBM, or shared between them depending on the specifics of the contract between these parties.[28]

Group health plan sponsors generally procure PBM services through a bidding process. They typically issue requests for proposals to several PBMs and then evaluate the proposals based on costs and the package of services offered by each bidder. Plan sponsors or their consultants conduct these bidding processes, which may go through multiple iterations.

PBMs compete on price and non-price dimensions. One survey of plan sponsors using PBM services showed that the financial terms of the bid (such as the reimbursement rate and dispensing fee paid to pharmacies, the rebates paid to plan sponsors based on formulary drugs utilized, mail order pricing, and administrative fees) often were the key determinants in the selection of the winning bid.[29] This study also found that plan sponsors were concerned about non-price dimensions of service, such as plan design, the extent of the retail network, and mail order components. These terms and features are balanced against each other and the particular mix of terms and features is driven by the needs of the plan sponsor. For example, at the Health Care Hearings, panelists stated that some health plan sponsors want to maximize generic substitution, whereas others want to maximize rebates from manufacturers.[30] Panelists also

[27] PBMs also enter into contracts with retail pharmacies to create a retail network. The contract generally specifies the amount the PBM will reimburse the pharmacy for dispensing a prescribed pharmaceutical, expressed as a discount from a reference price plus a dispensing fee. Because AB 1960 does not target the relationship between PBMs and retail pharmacies, such issues are not discussed in this letter. An extensive discussion of these issues is found in the Letter from FTC staff to Patrick C. Lynch, Attorney General and Juan M. Pichardo, Deputy Senate Majority Leader, State of Rhode Island and Providence Plantations, *supra* note 11.

[28] John Richardson, Health Strategies Consultancy, Health Care Hearings, *supra* note 13, at 23-24 (PBMs "can be paid through administrative fees, share of rebates, or some combination."); Thomas M. Boudreau, Express Scripts, Health Care Hearings, *supra* note 13, at 124.

[29] *See* Health Care Financing Administration, Study of Pharmaceutical Benefit Management, June 2001, available at http://www.cms.gov/researchers/reports/2001/cms.pdf.

[30] Thomas M. Boudreau, Express Scripts, Health Care Hearings, *supra* note 13, at 65; Anthony Barrueta, Kaiser Foundation Health Plan, Inc., Health Care Hearings, *supra* note 13, at 105.

noted that some plan sponsors want to receive all rebates from manufacturers, while others allow the PBM to retain the rebates – and many plan sponsors fall somewhere in-between.[31]

The General Accounting Office released a study in January 2003 that examined the effects of PBMs on the Federal Employees Health Benefits Program, enrollees, and pharmacies.[32] The report considered the prescription benefits programs offered within three health plans available to federal government employees. The study compared prices that three types of customers paid for 14 brand name drugs and 4 generic drugs: (1) cash-paying customers, who buy at retail pharmacies; (2) health plan sponsors and their enrollees, who buy at retail pharmacies; and (3) health plan sponsors and their enrollees, who buy from a PBM's mail order facility. The study found that the lowest average prices for 30-day supplies were obtained when the drug was purchased through the PBM's mail order pharmacy, and that cash-paying customers at retail pharmacies paid the highest prices.[33]

Likely Effects of AB 1960

One of the primary goals of AB 1960 is to provide purchasers of PBM services with

[31] John Richardson, The Health Strategies Consultancy, Health Care Hearings, *supra* note 13, at 18 ("A lot of PBMs don't retain any of the rebates; others retain a portion in addition to whatever percent of the revenue they will keep as their administrative fees. So again, that's going to differ in each arrangement that is out there."); John Dicken, General Accounting Office, Health Care Hearings, *supra* note 13, at 40 ("of those contracts – not all, but some – would have the PBMs retaining some portion of those rebates to cover their administrative services."); Thomas M. Boudreau, Express Scripts, Health Care Hearings, *supra* note 13, at 58-59.

[32] *See* General Accounting Office, *Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies*, available at http://www.gao.gov/cgi-bin/getrpt?GAO-03-196. See also Sara Fisher Ellison and Christopher M. Snyder, *Countervailing Power in Wholesale Pharmaceuticals*, MIT Working Paper 01-27 July 2001, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=277290. ("buyers of wholesale drugs that can use restrictive formularies obtain substantially lower prices than buyers without this ability.")

[33] Similar cost savings for PBM clients have been reported in another study. See Cindy Parks Thomas et al., *Impact of Health Plan Design And Management On Retirees' Prescription Drug Use And Spending, 2001*, Health Affairs Web Exclusive W2-408, December 4, 2002, available at http://content.healthaffairs.org/cgi/reprint/hlthaff.w2.408v1.

We note the filing of a lawsuit alleging that the largest PBMs have violated California state law by receiving rebates from pharmaceutical manufacturers that did not benefit employers and/or consumers but instead increased PBM profits and overall health care costs. *See* First Amended Representative Action and Complaint for Violation of the Unfair Competition Law, APSCME v. AdvancePCS, *et al.*, Superior Court of the State of California, case No. BC292227 (Apr. 4, 2003) at ¶ 4. We also note that the United States, along with 20 states (including California), recently announced a settlement of claims for injunctive relief and state unfair trade practices against Medco Health Solutions, Inc., and that New York recently filed a lawsuit against Express Scripts alleging various forms of misconduct relating to pharmaceutical pricing practices.

detailed information about the cost structure of the PBMs with whom they do business.[34] In the overwhelming majority of markets, however, consumers have limited or no information about the cost structure of those with whom they do business. More importantly, in general, consumers do not need such information to make efficient purchasing decisions. Instead, consumers make purchasing decisions based on the price and value of goods and services, without regard to a vendor's costs of production. AB 1960 thus holds PBMs to a standard that does not apply to other industries.

AB 1960 also requires PBMs to disclose certain financial information to purchasers, prospective purchasers, and prescribers. AB 1960 specifies that rebate information may be provided in a somewhat aggregated form to purchasers and prospective purchasers and does not have to be provided unless purchasers and prospective purchasers agree to keep the information confidential. No such confidentiality restrictions apply to the disclosure of information to prescribers. Thus, financial information disclosed by PBMs to prescribers may become public, and a knowledgeable pharmaceutical manufacturer might well be able to use this information to calculate the rebate a competitor was offering. If pharmaceutical manufacturers learn the exact amount of the rebates offered by their competitors (either because the safeguards on subsequent disclosure by purchasers and prospective purchasers are insufficient or because the mandated disclosure to prescribers provides sufficient information for pharmaceutical manufacturers to calculate these amounts) then tacit collusion among manufacturers is more feasible. Consequently, the required disclosures may lead to higher prices for PBM services and pharmaceuticals.

Inclusion in a PBM formulary offers pharmaceutical manufacturers the prospect of substantially increased sales opportunities. Whenever PBMs have a credible threat to exclude pharmaceutical manufacturers from their formulary, manufacturers have a powerful incentive to bid aggressively. Willingness to bid aggressively, however, is affected by the degree of transparency with respect to the terms that pharmaceutical companies offer PBMs. Whenever competitors know the actual prices charged by other firms, tacit collusion – and thus higher prices – may be more likely.[35] It is for this reason that California law requires the state to use sealed bids to procure desired goods and services whose value exceeds $25,000.[36]

[34] Although it may seem that rebates are revenues received by the PBMs from manufacturers, they are frequently booked as reductions in the cost of sales.

[35] *See, e.g.*, Svend Albaek *et al.*, *Government Assisted Oligopoly Coordination? A Concrete Case*, 45 J. INDUS. ECON. 429 (1997).

[36] *See* http://www.pd.dgs.ca.gov/sell2state/default.htm.

When group health plan sponsors contract with PBMs, they know the price of the services they are obtaining. AB 1960 is premised on the belief that greater transparency with regard to the PBM's costs, which are affected by the rebates they are able to secure, will allow group health plan sponsors to ensure they are "getting the best deal." From the purchaser's perspective, there is no functional difference between a higher list price coupled with a rebate and a lower list price. We also note that some health plan sponsors are large, sophisticated, repeat-purchasers of health care services, and many use a bidding process to decide which PBM they will contract with. It is possible that AB 1960 may provide some additional information to these plan sponsors about the revenue streams obtained by PBMs, but it does not necessarily follow that this would make the PBMs compete more aggressively to do business with this plan sponsor. Indeed, to the extent AB 1960 makes tacit collusion more likely, these plan sponsors may end up with "worse" contractual terms.

AB 1960 may also inadvertently increase health care costs in another manner. As noted previously, AB 1960 excludes health plans and health insurers that provide pharmacy benefit management services to their own enrollees from the disclosure requirements. To the extent the disclosures mandated by AB 1960 chill the willingness of pharmaceutical manufacturers to offer substantial rebates to non-integrated PBMs, or otherwise increase non-integrated PBMs' costs, AB 1960 ultimately will increase health plans' and health insurers' costs of administering pharmacy benefits through non-integrated PBMs. In this way, AB 1960 will encourage health plans and health insurers to bring "in-house" the management of pharmacy benefits. To the extent that AB 1960 causes firms that would prefer to turn to the market for PBM services to instead provide such services internally, AB 1960 will induce inefficiency and may well increase the cost of PBM services. As before, increases in the cost of PBM services may well lead to increases in health insurance premiums and reductions in the availability of insurance coverage for pharmaceuticals.

There do not appear to be any significant barriers to negotiation between health plan sponsors and PBMs over all the terms of their agreement, including how PBMs are to be paid for their services and the disposition of any rebates.[37] At the Health Care Hearings, one panelist suggested that many health plan sponsors have decided to allow PBMs to keep rebates in exchange for lower administrative fees.[38] We are informed that one major PBM voluntarily discloses extensive information regarding rebates and administrative fees.[39] Press reports indicate that some PBMs have made formal promises to inform their customers about all rebates they receive from drug manufacturers, and a coalition of major employers are attempting to bypass PBMs entirely, and negotiate with pharmaceutical manufacturers directly.[40]

As these developments indicate, vigorous competition in the marketplace for PBMs is more likely to arrive at an economically efficient level of transparency than regulation of those terms. Just as competitive forces encourage PBMs to offer their best price and service combinations to health plan sponsors in order to gain access to subscribers, competition also encourages disclosure of the information group health plan sponsors require to decide which PBM to contract with, including but not limited to the magnitude of any rebates the PBMs might receive, the circumstances under which those rebates will be paid, and how those rebates will be shared between PBMs and group health plan sponsors.

One of the central premises of AB 1960 is that information regarding a PBM's rebates from drug makers is relevant to a purchaser's decision-making process. However, if AB 1960 were to pass, insurers with integrated PBM services would not face the same disclosure requirements as independent (non-integrated) PBMs. In general, better informed purchasers are able to make better decisions, but more information is not necessarily better. For example, when only a subset of competitors are required to disclose certain financial information, purchasers may not be able to discern the true price of a service and may mistakenly choose a higher-priced option.[41] The different types of information potential purchasers would receive from integrated

[37] See Jack Calfee, American Enterprise Institute, Health Care Hearings, *supra* note 13, at 99; David Balto, White & Case, Health Care Hearings, *supra* note 13, at 99.

[38] See Anthony Barrueta, Kaiser Foundation Health Plan, Inc., Health Care Hearings, *supra* note 13, at 105.

[39] See Thomas M. Boudreau, Express Scripts, Health Care Hearings, *supra* note 13, at 103. *See also* http://www.express-scripts.com/client/business_principles.htm.

[40] *See* Milt Freudenheim, *Big Employers Joint Forces in Effort to Negotiate Lower Drug Prices*, N.Y. TIMES, June 12, 2004; Milt Freudenheim, *Critics Attack Secret Deals By Middlemen to Buy Drugs*, N.Y. TIMES, Dec. 20, 2003.

[41] A recent Commission staff report studied the impact of providing more detailed information to borrowers when a mortgage was obtained through a broker than when it was obtained through a direct lender. The study found that borrowers more frequently selected higher cost loans when given the choice between loans accompanied with more detailed information and loans without such information than when choosing between loans with the same baseline information. These results are consistent with the hypothesis that the additional information impaired

and non-integrated suppliers of PBM services is the type of asymmetry that could lead less-sophisticated purchasers mistakenly to choose higher cost services. Similarly, the mandated disclosure of information to prescibers and consumers prior to a drug substitution (and the absence of such disclosure if no such substitution is contemplated) may have the effect of misleading prescribers and consumers about the costs and benefits of continuing a currently prescribed drug compared to the proposed substitute.

AB 1960 also has a number of provisions that are likely to raise the costs of drug substitution. As noted previously, PBMs frequently use drug substitution to reduce costs and promote competition between branded drug makers. Instead of distinguishing between appropriate and inappropriate drug substitution and targeting the latter, AB 1960 imposes modest procedural barriers to drug substitution for a generic equivalent (by requiring disclosure to consumers and follow-up health monitoring) and substantial procedural barriers to drug substitution for a therapeutic equivalent (by requiring disclosure to consumers and prescribers, and follow-up health monitoring). These procedural barriers are likely to discourage both generic substitution and clinical interchange. To the extent AB 1960 makes safe and cost-reducing drug substitutions less probable, it is likely to increase the cost of pharmaceuticals, which in turn is likely to increase health insurance premiums and reduce the availability of insurance coverage for pharmaceuticals. Our concerns about AB 1960's impact on consumers and competition are far greater to the extent it has a material effect on the frequency of generic substitution.

As noted previously, generic substitution is encouraged by the FDA and widely recognized as safe, and California already requires prescriber approval for therapeutic interchange. As such, the disclosures mandated by AB 1960 are likely to prove unhelpful to most prescribers and consumers. More broadly, because current safeguards appear sufficient to protect consumers, AB 1960 is likely to increase costs to consumers without providing any countervailing benefits.

To the extent AB 1960 increases prices for pharmaceutical and health insurance and restricts the availability of insurance coverage for pharmaceuticals, the result is likely to be an increase in the number of Americans who do without pharmaceuticals and/or health insurance. As an article in *Health Affairs* last year noted, "when costs are high, people who cannot afford something find substitutes or do without. The higher the cost of health insurance, the more

consumers' ability to discern the low cost provider. James M. Lacko & Janis K. Pappalardo, THE EFFECT OF MORTGAGE BROKER COMPENSATION DISCLOSURES ON CONSUMERS AND COMPETITION: A CONTROLLED EXPERIMENT, at 8-9, Federal Trade Commission Bureau of Economics Staff Report, available at http://www.ftc.gov/os/2004/01/030123mortgagefullrpt.pdf (Feb. 2004).

people are uninsured. The higher the cost of pharmaceuticals, the more people skip doses or do not fill their prescriptions."[42]

Conclusion

AB 1960 is more likely to undermine competition than promote it. AB 1960's mandated disclosure of information may increase the cost of pharmaceuticals and health insurance premiums by attenuating competition between pharmaceutical companies and by raising the cost of generic substitution and clinical interchange. Any such cost increases are likely to undermine the ability of some consumers to obtain the pharmaceuticals and health insurance they need at a price they can afford. Any additional amendments to AB 1960 that have the effect of broadening and strengthening its provisions would be even more problematic from a competitive perspective.

[42] William Sage, David A. Hyman & Warren Greenberg, *Why Competition Law Matters to Health Care Quality*, 22 HEALTH AFFAIRS 31, 35 (March/April 2003). Although estimates of the elasticity of demand for health insurance coverage vary, the empirical evidence is clear that higher costs result in less coverage. *See* David M. Cutler, HEALTH CARE AND THE PUBLIC SECTOR, NBER Working Paper W8802, Table 5 http://papers.nber.org/papers/W8802.

Respectfully submitted,

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TESTIMONY SUBMITTED IN OPPOSITION TO ND HB 1332

HOUSE INDUSTRY, BUSINESS AND LABOR COMMITTEE

Submitted by:

Peter F. Harty
Vice President, Government Affairs and Policy
Medco Health Solutions, Inc.

January 25, 2005

Mr. Chairman, and members of the Committee, my name is Peter Harty and I am Vice President of Government Affairs and Policy for Medco Health Solutions, Inc., which is a pharmacy benefits management company, or "PBM." I would like to thank you for this opportunity to testify today regarding our opposition to House Bill 1332. We believe that the private marketplace is working, and there is no need for additional regulation in this area.

Medco is a leading provider of comprehensive, high-quality, affordable prescription drug care in the United States. We work with patients, pharmacists, physicians and health plan sponsors to improve the quality of pharmaceutical care provided to patients, while helping to control the growth in drug costs. We work under contract with health plan clients throughout the country that are providing prescription drug benefits for their members and employees, totaling more than 60 million covered lives. Our clients include very sophisticated health care purchasers, including:

- Fortune 500 corporations and smaller employers
- local, state and federal employee and retiree groups
- Blue Cross/Blue Shield plans
- unions, and
- insurance carriers and managed care plans.

Often assisted by benefits consulting firms, our customers design the voluntary benefit that they want to offer to their employees and/or members. That "plan design" includes such factors as members' cost-sharing in the form of deductibles and co-payments, use of mail service or retail pharmacies, the list of drugs to be covered under the plan, and the conditions under which drug substitution programs will be permitted. In a competitive bidding process, and again often with the assistance of consultants, the customers issue lengthy Requests for Proposals (RFPs) outlining the plan design, and

including any other factors that they deem to be important, which can – but does not always – include such issues as fiduciary responsibilities, disclosure of financial information, allocation of manufacturer rebates that the PBM receives pharmaceutical manufacturers, and other financial terms between the parties. Those PBMs that are interested in doing business on the terms outlined in the RFP submit bids, and a winner is ultimately selected, and a contract is negotiated between the parties, with the advice and counsel of their respective attorneys, addressing all of the key issues between the parties, including audit rights.

There is no such thing as a "form" contract in this area, as every deal is different. There is no need for the state to mandate a one-size-size-fits-all approach to issues such as fiduciary, disclosure and audits when the marketplace already can and does address those issues. What other private sector business has a statutory obligation to disclose its proprietary financial information to its customers as this bill would mandate?

The Federal Trade Commission has noted that there are approximately 60 PBMs – some standalone such as Medco, some owned by health plans such as Anthem, some owned by chain drugstores such as CVS, some national, some regional – competing in this market, and that competition among those PBMs for business is "vigorous."[1] In a letter regarding a PBM regulation bill in California (which Governor Schwarzenegger ultimately vetoed because of concerns that regulation would actually raise prescription drug costs without a benefit to consumers), the FTC further concluded that "[v]igorous

[1]Federal Trade Commission, *In re* Caremark Rx, Inc. / AdvancePCS, February 11, 2004

competition in the marketplace for PBMs is more likely to arrive at an economically efficient level of transparency than regulation of those terms."[2]

There is a growing body of objective, nonpartisan evidence documenting the savings that PBMs provide for their customers:

- The federal General Accounting Office (GAO) found that PBM retail prices for brand-name drugs were about 18% lower than the retail prices paid by patients without third-party coverage and generic prices were about 47% lower. At mail, PBMs provide even greater savings - about 27% and 53% for brand and generic drugs, respectively.[3]
- The Congressional Budget Office (CBO) estimated that PBMs could save between 25 and 30 percent if used to administer a Medicare drug benefit.[4]
- The Federal Trade Commission found that consumers with PBM-administered plan saved "substantially" on their drug costs as compared to cash paying customers.[5]
- PricewaterhouseCoopers estimated that PBMs reduced drug costs by 25% compared to retail prices for patients without coverage, and that total system-wide saving achieved by PBMs will reach $1.3 trillion over ten years.
- An analysis from the Heritage Foundation determined that PBMs provide value for patients by reducing costs and by promoting the better use of prescription drugs.[6]

Against this documented evidence of value that PBMs provide to their customers, what documented evidence of public harm is there that this bill would purport to address? We therefore respectfully request that you vote "no" on this bill. Thank you for your consideration of our views.

[2] Federal Trade Commission letter to Assembly Member Greg Aghazarian on California's AB1960, September 3, 2004

[3] GAO Report: Federal Employees' Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies (1/2003)

[4] CBO Cost Estimate: H.R. 4680. Medicare Rx 2000 Act (6/28/2000); in testimony one year later (6/8/2001), CBO provided updated savings estimates of 30 percent.

[5] PricewaterhouseCoopers Report: The Value of Pharmacy Benefit Management and the National Cost Impact of Proposed PBM Legislation (7/15/2004)

[6] Heritage Foundation Backgrounder: Compromising Quality: The High Cost of Government Drug Purchasing (5/25/2004)

TESTIMONY SUBMITTED IN OPPOSITION TO ND HB 1332

SENATE INDUSTRY, BUSINESS AND LABOR COMMITTEE

Submitted by:

Peter F. Harty
Vice President, Government Affairs and Policy
Medco Health Solutions, Inc.

March 7, 2005

Mr. Chairman, and members of the Committee, my name is Peter Harty and I am Vice President of Government Affairs and Policy for Medco Health Solutions, Inc., which is a pharmacy benefits management company, or "PBM." I would like to thank you for this opportunity to testify today regarding our opposition to House Bill 1332. We believe that the private marketplace is working, and there is no need for additional regulation in this area, and that this bill is likely to increase spending on prescription drugs in North Dakota by more than $200 MM over a ten-year period.

Medco is a leading provider of comprehensive, high-quality, affordable prescription drug care in the United States. We work with patients, pharmacists, physicians and health plan sponsors to improve the quality of pharmaceutical care provided to patients, while helping to control the growth in drug costs. We work under contract with health plan clients throughout the country that are providing prescription drug benefits for their members and employees, totaling more than 60 million covered lives. Our clients include very sophisticated health care purchasers, including:

- Fortune 500 corporations and smaller employers
- local, state and federal employee and retiree groups
- Blue Cross/Blue Shield plans
- unions, and
- insurance carriers and managed care plans.

Often assisted by benefits consulting firms, our customers – "covered entities" as defined in this bill – design the voluntary benefit that they want to offer to their employees and/or members. That "plan design" includes such factors as members' cost-sharing in the form of deductibles and co-payments, use of mail service or retail pharmacies, the list of drugs to be covered under the plan, and the conditions under which drug substitution programs will be permitted. In a competitive bidding process, and

again often with the assistance of consultants, the customers issue lengthy Requests for Proposals (RFPs) outlining the plan design, and including any other factors that they deem to be important, which can – but does not always – include such issues as fiduciary responsibilities, disclosure of financial information, allocation of manufacturer rebates that the PBM receives pharmaceutical manufacturers, and other financial terms between the parties. Those PBMs that are interested in doing business on the terms outlined in the RFP submit bids. In other words, the "covered entity" solicits bids from PBMs on the terms that the covered entity chooses; PBMs do not make "offers" to the covered entities as contemplated in proposed §26.1-27.1-05. Following the bid process, a winner is ultimately selected, and a contract is negotiated between the parties, with the advice and counsel of their respective attorneys, addressing all of the key issues between the parties, including audit rights.

There is no such thing as a "form" contract in this area, as every deal is different. There is no need for the state to mandate specific approaches to issues such as disclosure and audits when the marketplace already can and does address those issues.

The Federal Trade Commission has noted that there are approximately 60 PBMs – some standalone such as Medco, some owned by health plans such as Anthem, some owned by chain drugstores such as CVS, some national, some regional – competing in this market, and that competition among those PBMs for business is "vigorous."[1] In a letter regarding a PBM regulation bill in California (which Governor Schwarzenegger ultimately vetoed because of concerns that regulation would actually raise prescription drug costs without a benefit to consumers), the FTC further concluded that "[v]igorous

[1]Federal Trade Commission, *In re* Caremark Rx, Inc. / AdvancePCS, February 11, 2004

competition in the marketplace for PBMs is more likely to arrive at an economically efficient level of transparency than regulation of those terms."[2]

There is a growing body of objective, nonpartisan evidence documenting the savings that PBMs provide for their customers:

- The federal General Accounting Office (GAO) found that PBM retail prices for brand-name drugs were about 18% lower than the retail prices paid by patients without third-party coverage and generic prices were about 47% lower. At mail, PBMs provide even greater savings - about 27% and 53% for brand and generic drugs, respectively.[3]
- The Congressional Budget Office (CBO) estimated that PBMs could save between 25 and 30 percent if used to administer a Medicare drug benefit.[4]
- The Federal Trade Commission found that consumers with PBM-administered plan saved "substantially" on their drug costs as compared to cash paying customers.[5]
- PricewaterhouseCoopers estimated that PBMs reduced drug costs by 25% compared to retail prices for patients without coverage, and that total system-wide saving achieved by PBMs will reach $1.3 trillion over ten years.[6]
- An analysis from the Heritage Foundation determined that PBMs provide value for patients by reducing costs and by promoting the better use of prescription drugs.[7]

Against this documented evidence of value that PBMs provide to their customers, what documented evidence of public harm is there that this bill would purport to address?

At least one provision in this bill – proposed §26.1-27.1-04.3 ("Prohibited practices") is likely to ***increase*** spending on prescription drugs in North Dakota. By not allowing PBMs and their clients to use different copays or limitations on days supply,

[2] Federal Trade Commission letter to Assembly Member Greg Aghazarian on California's AB1960, September 3, 2004
[3] GAO Report: Federal Employees' Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies (1/2003)
[4] CBO Cost Estimate: H.R. 4680. Medicare Rx 2000 Act (6/28/2000); in testimony one year later (6/8/2001), CBO provided updated savings estimates of 30 percent.
[5] PricewaterhouseCoopers Report: The Value of Pharmacy Benefit Management and the National Cost Impact of Proposed PBM Legislation (7/15/2004)
[6] PricewaterhouseCoopers Report: The Value of Pharmacy Benefit Management and the National Cost Impact of Proposed PBM Legislation (7/15/2004)
[7] Heritage Foundation Backgrounder: Compromising Quality: The High Cost of Government Drug Purchasing (5/25/2004)

this bill would appear to effectively eliminate the use of mail service pharmacies. Our clients often choose to encourage their employees/members to purchase their maintenance medications – those taken for longer periods of time, generally for chronic conditions such as high blood pressure or high cholesterol – from our mail service pharmacies because they are more efficient and economical in general. Our clients encourage their employees/members to take advantage of this more economical channel by such tools as co-pay incentives or by limiting quantities or days of supply that can be purchased at traditional retail pharmacies. By eliminating the ability to use those incentives, this bill would likely increase spending on prescription drugs in this state by more than $200 MM over a ten-year period, representing a 3% increase, according to one estimate.[8]

We therefore respectfully request that you vote to recommend a "do not pass" on this bill. Thank you for your consideration of our views. I would be happy to answer any questions that members of the Committee might have.

[8] PricewaterhouseCoopers Report: The Value of Pharmacy Benefit Management and the National Cost Impact of Proposed PBM Legislation (7/15/2004)

Medco Health Solutions, Inc.
100 Parsons Pond Drive
Franklin Lakes, NJ 07417
Fax: 201-269-5262

www.medco.com/rph

medco

330000139
SOUTH POINTS PHARMACY
2400 32ND AVE S
FARGO, ND 58103

Medco Pharmacy Care Plus Network Enrollment Opportunity

Dear Owner:

Due to dramatic increases in prescription drug costs in recent years, plan sponsors are demanding reductions in prescription drug program costs. To achieve this objective, plan sponsors are selecting retail pharmacy networks based on discount. In effect, plan sponsors seeking reductions in program costs are being forced to choose between cost savings and member choice in retail pharmacy.

Medco has created a solution in the form of an alternative network that:

- Continues to allow patients their choice of pharmacy
- Reduces plan sponsors' prescription program costs
- Provides reasonable pharmacy reimbursement in today's marketplace

Plan sponsors have chosen; now it's up to you
Plan sponsors representing over $150 million in annual prescription drug purchases and more than 750,000 households have elected to move to the **Pharmacy Care Plus Network.** Medco is offering your pharmacy an opportunity to join the new **Pharmacy Care Plus Network** because your pharmacy is one of those which currently fills prescriptions for the 750,000 families that will exclusively use the **Pharmacy Care Plus Network.** Your pharmacy's participation will help to ensure that these and future members the ability to select the pharmacy of their choice.

A limited-time opportunity
Your pharmacy's ability to continue filling prescriptions for the 750,000 members and their families will end if you fail to sign and return the network agreement (see attached) by **February 28, 2005.** Please fax the signed agreement to **201 269 5262.** On **March 4, 2005,** we will notify 750,000 members as to which pharmacies are participating in the network. Pharmacies that choose not to sign the agreement as of **February 28, 2005,** will no longer be eligible to fill plan-supported prescriptions for these members and their families.

Sincerely,
Medco

Medco Health Solutions, Inc.
100 Parsons Pond Drive
Franklin Lakes, NJ 07417
Fax: 201-269-5262

www.medco.com/rph

medco

Pharmacy Care Plus Network™
Schedule PCP-01

PHARMACY agrees to participate in the Medco Health Solutions, Inc. ("Medco") ***Schedule PCP-01 Pharmacy Care Plus Network***™. The ***Schedule PCP-01 Pharmacy Care Plus Network***™ has a payment rate for the providing of Covered Services to Eligible Persons as follows:

a) Brand name drugs: equal to the lower of (i) PHARMACY's Usual and Customary Price or (ii) Average Wholesale Price minus (-) 15 percent plus a dispensing fee of $1.50.

b) Generic drugs: equal to the lowest of (i) PHARMACY's Usual and Customary Price or (ii) Average Wholesale Price minus (-) 30 percent plus a dispensing fee of $1.50 or (iii) MAC plus a dispensing of $1.50.

This schedule supplements and becomes a part of the Participating Pharmacy Agreement in effect between PHARMACY and MEDCO. PHARMACY evidences its agreement to participate in the ***Schedule PCP-01 Pharmacy Care Plus Network***™ by signing below where indicated or by providing Covered Services in accordance herewith.

Pharmacy Agrees to participate in this Medco Pharmacy Network.

Please Print Name

Signature Date

Contract #: 20030009
NCPDP #: 3503388
SOUTH POINTS PHARMACY
2400 32ND AVE S
FARGO, ND 58103
(701)234-9912

Medco Account #: 330000139

September 22, 2004

David B. Snow
Chairman, President, CEO, & Director
Medco Health Solutions, Inc.
100 Parsons Pond Drive
Franklin Lakes, NJ 07417

Dear Mr. Snow:

I am writing to you on behalf of the nation's community pharmacists, including the owners of 24,000 community pharmacies. We are very concerned about Medco Health Solutions' announcement regarding an addendum to your network pharmacy contracts that increases claims processing fees that Medco forces pharmacies to pay from three cents to ten cents per transaction using the TelePAID® system.

This is the latest, yet especially obnoxious, example of Medco dictating terms that restrict the level of service offered to customers, and arbitrarily limiting the ability of retail pharmacies to compete on a level playing field, including with Medco's mail order pharmacies.

The negative impact of your action on community pharmacies and the beneficiaries they serve would be substantial.

Perhaps you know that community pharmacies operate in a very competitive marketplace and earn modest profit margins. What may seem like insignificant pennies to a corporate giant like Medco, would amount to a significant reduction in net profit for the average small business community pharmacy. In contrast, it is estimated that this inappropriate action will yield an estimated $75-$100 million dollars a year to Medco.

If you allow this tripling of an already questionable burden on the community pharmacy, it will further erode the significantly compromised relationship between Medco and community pharmacy.

Consequently, I strongly urge you to revoke this latest edict. Perhaps one day pharmacy benefit managers, including Medco, would actually negotiate with pharmacies in an even-handed business like manner for the benefit of payors and beneficiaries.

If you would like to discuss this issue please contact me.

Sincerely,

Bruce Roberts, R.Ph.
Executive Vice President & CEO

Cc: Michael Freed, Esquire
William H. Wentz, Esquire
John M. Rector, Esquire

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
Washington, DC 20580

Office of Policy Planning
Bureau of Economics
Bureau of Competition

March 8, 2005

Senator Richard L. Brown
North Dakota Senate
State Capitol
600 East Boulevard
Bismark, ND 58505-0360

Dear Senator Brown:

The staffs of the Federal Trade Commission's Office of Policy Planning, Bureau of Competition, and Bureau of Economics[1] are pleased to respond to your requests for comments on the likely competitive effects of North Dakota House Bill 1332 ("HB 1332" or the "Bill") that would regulate the contractual relationships between pharmacy benefit managers ("PBMs") and "covered entities" – such as health plans and health insurers – and pharmacies.[2]

[1] This letter expresses the views of the Federal Trade Commission's Office of Policy Planning, Bureau of Competition, and Bureau of Economics. The letter does not necessarily represent the views of the Federal Trade Commission (Commission) or of any individual Commissioner. The Commission has, however, voted to authorize us to submit these comments.

[2] HB 1332 defines a covered entity as a "nonprofit hospital or a medical service corporation, a health insurer, a health benefit plan, a health maintenance organization, a health program administered by the state in a capacity of provider of health coverage, or an employer, a labor union, or other entity organized in the state which provides health coverage to covered individuals who are employed or reside in the state." HB 1332 § 26.1-27.1-01 (1). Covered entities do not include self-funded plans exempt from state regulation pursuant to ERISA, health plans "issued for federal employees," or health plans that provide "coverage only for accidental injury, specified disease, hospital indemnity, medicare supplement, disability income, long-term care, or other limited-benefit health insurance polic[ies] or contract[s]." *Id.*

In your letter dated January 19, 2005, you asked us to analyze the competitive implications of HB 1332 and discuss whether it "will likely result in the increased cost of pharmaceutical care for consumers." We believe that HB 1332, if enacted, may have the unintended consequence of increasing the price of pharmaceuticals and ultimately to decrease the number of North Dakotans with insurance coverage for pharmaceuticals. Specifically, we believe that HB 1332 may limit a PBM's ability to guide consumers to lower-cost pharmacies and would prohibit switching consumers to certain lower-priced drugs.[3]

Interest and Experience of the Federal Trade Commission

The Federal Trade Commission (Commission) is charged by statute with preventing unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce.[4] Pursuant to this statutory mandate, the Commission seeks to identify business practices and regulations that impede competition without offering countervailing benefits to consumers. For several decades, the Commission and its staff have investigated the competitive effects of restrictions on the business practices of health care providers.[5] The Commission has brought numerous enforcement actions against entities involved in the pharmaceutical industry,[6] and the Commission and its staff have issued reports and studies regarding various aspects of the pharmaceutical industry.[7]

The Commission also has extensive recent experience with PBMs. In 2004, Commission staff commented on proposed Rhode Island legislation that would have affected a PBM's ability to contract with pharmacies[8] and on proposed California legislation that would have required

[3] Although our comment is addressed only to these provisions, the Bill also regulates PBMs in other ways. *See* note 14, *infra*. We note that HB 1332 has been amended once by eliminating a requirement that PBMs act as fiduciaries to covered entities with which they contract and reducing the scope of a PBM's mandatory disclosure of financial information. These amendments eliminated other provisions that likely would have produced adverse competitive effects.

[4] Federal Trade Commission Act, 15 U.S.C. § 45.

[5] *See* Federal Trade Commission, *FTC Antitrust Actions in Health Care Services and Products* at http://www.ftc.gov/bc/healthcare031024.pdf.

[6] *See* Federal Trade Commission, *FTC Antitrust Actions in Pharmaceutical Services and Products*, at http://www.ftc.gov/bc/0310rxupdate.pdf.

[7] *See* Federal Trade Commission, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION (July 2002); David Reiffen and Michael R. Ward, GENERIC DRUG INDUSTRY DYNAMICS, Federal Trade Commission Bureau of Economics Working Paper No. 248 (Feb. 2002), *at* http://www.ftc.gov/be/econwork.htm; Roy Levy, THE PHARMACEUTICAL INDUSTRY: COMPETITIVE AND ANTITRUST ISSUES IN AN ENVIRONMENT OF CHANGE, Federal Trade Commission Bureau of Economics Staff Report (Mar. 1999), *at* http://www.ftc.gov/reports/pharmaceutical/drugrep.pdf.

[8] Letter from FTC staff to Patrick C. Lynch, Attorney General and Juan M. Pichardo, Deputy Senate Majority

PBMs to disclose certain information to covered entities and consumers related to a PBM's financial arrangements with pharmaceutical companies.[9] Also in 2004, the Commission investigated the competitive implications of a proposed merger between Caremark and AdvancePCS.[10] On June 26, 2003, the Commission and Department of Justice Antitrust Division (Division) held a half-day of hearings on PBMs, as part of their Hearings on Health Care and Competition Law and Policy (Health Care Hearings).[11] The report jointly issued by the Commission and the Division on July 23, 2004 addressed the issues raised by PBMs as well.[12] Finally, Congress has required the Commission to analyze the prices that plan sponsors and participants pay for pharmaceuticals dispensed through different distribution channels.[13]

Description of HB 1332's Provisions Related to Contracting with Retail Pharmacies and Restrictions on Certain Drug Substitutions

Although HB 1332 would regulate PBMs in several ways, this comment is directed only to certain provisions of the Bill that would restrict PBMs' contracting with pharmacies and that would prohibit certain drug substitutions.[14] Specifically, HB 1332 would prohibit a PBM from discriminating "on the basis copayments or days of supply" when contracting with pharmacies.[15] Further, it requires that "a contract must apply the same coinsurance, copayment, and deductible to covered drug prescriptions" to all pharmacies or pharmacists in a network.[16]

Leader, State of Rhode Island and Providence Plantations (Apr. 8, 2004), *at* http://www.ftc.gov/os/2004/04/ribills.pdf.

9 *See* Letter from FTC staff to Rep. Greg Aghazarian (Sept. 7, 2004), *at* http://www.ftc.gov/be/V040027.pdf.

10 Statement of the Federal Trade Commission, *In re Caremark Rx, Inc./AdvancePCS*, File No. 0310239 (Feb. 11, 2004), *at* http://www.ftc.gov/os/caselist/0310239/040211ftcstatement0310239.pdf.

11 Health Care Hearings, June 26, 2003, *at* http://www.ftc.gov/ogc/healthcarehearings/030626ftcmms.pdf. *See also* http://www.ftc.gov/ogc/healthcarehearings/030626agenda.htm. All subsequent references to the hearings will identify a panelist, affiliation, and transcript page. Affiliations are as of the date of the hearing.

12 Federal Trade Commission and Department of Justice, IMPROVING HEALTH CARE: A DOSE OF COMPETITION Chapter 7 (2004), *at* http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf.

13 Federal Trade Commission, *Pharmacy Benefit Manager Conflict of Interest Study Public Notice* (Mar. 26, 2004), *at* http://www.ftc.gov/os/2004/03/040326pbmfrn.pdf.

14 For example, HB 1332 would prohibit a PBM from excluding a pharmacy or pharmacist from one network "solely because the pharmacist or pharmacy declined to participate in another plan or network managed by the [PBM]." HB 1332 § 26.1-27.1.04(2). It also would require a PBM to offer covered entities contracting options that allow the covered entity to keep some, all, or none of the rebates collected by the PBM. *Id.* at § 26.1-27.1-05 (1). Further, any contract between a PBM and a covered entity must allow the covered entity to audit the PBM to "confirm that the benefit of rebates and other retrospective utilization discounts are being shared as required by the contract." *Id.* at § 26.1-27.1-05(2). This letter does not address any of these provisions.

15 HB 1332 § 26.1-27.1.04(3).

16 *Id.*

HB 1332 would allow the PBM to request the substitution of a "lower-priced generic or therapeutically equivalent drug" for a prescribed drug.[17] It is unclear in the Bill whether the term "therapeutically equivalent" drug refers to those drugs that are pharmaceutically equivalent or those that are pharmaceutically distinct, but are within the same therapeutic class.[18] To the extent that the Bill adopts the former narrower definition, HB 1332 would prohibit a PBM from requesting that the drug referred to in a patient's prescription be substituted for another drug that is designed to have similar therapeutic effects – but that is pharmaceutically distinct – unless the substitution is "for medical reasons that benefit the covered individual" and the prescribing physician approves the substitution.[19]

Background on PBMs

PBMs manage the pharmacy benefits of covered entities. At the Health Care Hearings, one panelist estimated that ninety-five percent of patients with prescription drug insurance coverage receive their benefits through a PBM.[20] There are approximately 60 PBMs operating in the United States today. There are three large, independent, full-service PBMs with national scope: Medco, Express Scripts, and Caremark. Some large insurers manage pharmacy benefits internally. A few PBMs are owned by large retail supermarket/pharmacy chains. In addition, there are many smaller, privately-held PBMs. The relative size and ranking of these companies varies according to the measure used. The three large national PBMs are the major players in many markets, but anywhere from one-third to one-half of the market is made up of the other types of PBMs listed above. In our most recent antitrust investigation in the PBM industry, the FTC found competition among PBMs for contracts with plan sponsors to be "vigorous."[21]

One important tool used by PBMs to manage pharmacy benefits is a formulary, which is a list of PBM-approved drugs for treating various diseases and conditions. Because a formulary affects the mix of drugs used by enrollees in a plan, its design significantly can affect the cost to the covered entity. Two procedures that PBMs use to attain better compliance with their formularies are generic substitution and therapeutic interchange.[22] Because generic drugs are

17 HB 1332 § 26.1-27.1.04(I)(a).

18 For example, the FDA defines therapeutically equivalent drugs to be those that are pharmaceutically equivalent and have the same therapeutic equivalence codes. *See* http://www.fda.gov/cder/drugsatfda/glossary.htm#T.

19 HB 1332 § 26.1-27.1.04(I)(b).

20 John Richardson, The Health Strategies Consultancy, Health Care Hearings, *supra* note 11, at 8.

21 Commission Statement, *supra* note 10.

22 Therapeutic interchange is the substitution of the drug product referred to on the consumer's prescription with a drug that is designed to have similar therapeutic effects, but is pharmaceutically different (i.e., two brand-name drug products that treat the same ailment). *See* R. Berdman & D. Blumenthal, eds., DESCRIPTION AND

typically substantially less expensive than their brand-name counterparts, generic substitution lowers prescription drug costs. Therapeutic interchange also has the potential of increasing the utilization of less expensive brand name drugs.

Preferential placement on a formulary, accompanied with reduced co-payments, can give a drug product a higher market share within a drug plan. Pharmaceutical companies compete by offering rebates and other financial rewards based on some combination of a percentage of a reference price, achieving certain specified sales or market share targets, and preferred placement of certain drug products on a PBM's formulary. These rebates are either paid to the covered entity, retained by the PBM, or shared between them depending on the specifics of the contract between these parties.[23] Rebates can lead to lower health care costs.[24]

PBMs also enter into contracts with retail pharmacies to create a retail network. The contract generally specifies the amount the PBM will reimburse the pharmacy for dispensing a prescribed pharmaceutical, expressed as a discount from a reference price plus a dispensing fee. By forming an exclusive network, a PBM is able to guide a covered entity's participants to certain pharmacies. The promise of increased customer volume creates an incentive for pharmacies to bid aggressively with lower drug prices in exchange for membership in a network.[25] Pharmacies will be willing to compete more vigorously for inclusion in a network as the exclusivity of the network and the number of pharmacies in the relevant market increases.

Likely Effects of HB 1332

HB 1332 limits PBMs' freedom in contracting with retail pharmacies and prohibits certain drug substitutions. These provisions are likely to lead to higher prices for pharmaceuticals and health insurance, which in turn is likely to increase the number of North Dakotans who go without pharmaceuticals and/or health insurance. As a recent article in *Health*

ANALYSIS OF THE VA NATIONAL FORMULARY (Institute of Medicine June 2000), *at* www.nap.edu/books/0309069866/html.

[23] John Richardson, Health Strategies Consultancy, Health Care Hearings, *supra* note 11, at 23-24 (PBMs "can be paid through administrative fees, share of rebates, or some combination."); Thomas M. Boudreau, Express Scripts, Health Care Hearings, *supra* note 11, at 124.

[24] *See* General Accounting Office, *Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies* at 11 (Jan. 2003) ("GAO Report") (noting that rebates passed through to health plans reduced those plans' annual spending on prescription drugs by three percent to nine percent), *at* http://www.gao.gov/cgi-bin/getrpt?GAO-03-196.

[25] For example, the GAO Report noted that when Blue Cross Blue Shield introduced a plan with a smaller network of retail pharmacies, it included deeper discounts in its retail pharmacy payments. *See* GAO Report at 11. An extensive discussion of these issues is found in the Letter from FTC staff to Patrick C. Lynch, Attorney General and Juan M. Pichardo, Deputy Senate Majority Leader, State of Rhode Island and Providence Plantations, *supra* note 8.

Affairs noted, "when costs are high, people who cannot afford something find substitutes or do without. The higher the cost of health insurance, the more people are uninsured. The higher the cost of pharmaceuticals, the more people skip doses or do not fill their prescriptions."[26] We provide details on our concerns below.

A. Restrictions on Contracting with Pharmacies

HB 1332 would prohibit PBMs from charging different copayments, coinsurance, or deductibles at various pharmacies within a plan's pharmacy network.[27] An important element of the design of pharmacy benefit plans administered by PBMs, however, is the determination of how the price for drugs will be split between the covered entity and its participants. This price sharing is achieved through the copayments, coinsurance, or deductibles that the participant pays to the pharmacy at the time the drug is dispensed.

Both a GAO study and an academic article reported that the prices charged to covered entities can vary substantially across different types of pharmacies.[28] This Bill, however, would prevent covered entities from designing benefit plans to encourage participants to use network pharmacies that provide drugs to the plan at a lower cost than other network pharmacies. Participants ultimately make the decision about where the drugs will be dispensed, but the covered entity bears most of the cost of the purchase. To encourage the participant to make efficient decisions, covered entities must be free to design plans that align its and the participants' interests.

The uniform copayments required by HB 1332, however, will prevent that alignment of interests and will likely generate inefficient decisions and higher drug costs. Under the Bill, participants would be less likely to use low-cost pharmacies than if they had been allowed to share in the cost savings via a lower copayment. Both the participants and the covered entity will miss out on the savings they could have shared from using the low-cost pharmacies. Only the high-cost pharmacies will benefit. A potential secondary effect of this uniform copayment

[26] William Sage, David A. Hyman & Warren Greenberg, *Why Competition Law Matters to Health Care Quality*, 22 HEALTH AFFAIRS 31, 35 (March/April 2003). Although estimates of the elasticity of demand for health insurance coverage vary, the empirical evidence is clear that higher costs result in less coverage. *See* David M. Cutler, HEALTH CARE AND THE PUBLIC SECTOR, NBER Working Paper W8802, Table 5 (Feb. 2002), *at* http://papers.nber.org/papers/W8802.

[27] HB 1332 § 26.1-27.1-04(3).

[28] The study found that the lowest average prices for 30-day supplies were obtained when the drug was purchased through the PBM's mail order pharmacy, and that cash-paying customers at retail pharmacies paid the highest prices. *See* GAO Report. Similar cost savings for PBM clients have been reported in another study. *See* Cindy Parks Thomas et al., *Impact of Health Plan Design And Management On Retirees' Prescription Drug Use And Spending, 2001*, Health Affairs Web Exclusive W2-408 (Dec. 4, 2002), *at* http://content.healthaffairs.org/cgi/reprint/hlthaff.w2.408v1.

structure is that low-cost pharmacies may lose the incentive to offer lower prices to covered entities. Pharmacies would not want to offer lower prices because doing so would generate no more sales than offering a high price under the legislation, since the final decision makers – the participants – are shielded from the price differences.

B. Prohibitions on Certain Drug Substitutions

HB 1332 may limit a PBM's ability to effect certain drug substitutions. It is unclear in the Bill whether "therapeutically equivalent" drugs are those that are pharmaceutically equivalent or those that are pharmaceutically distinct, but are within the same therapeutic class. To the extent that the Bill adopts the former narrower definition, HB1332 substantially would impair a PBM's ability to engage in price-reducing therapeutic interchange. Although North Dakota already requires physician approval before one branded drug may be switched for another,[29] HB 1332 further would limit substitutions to those that are "for medical reasons that benefit the covered individual." Consequently, the Bill would prevent a PBM from switching a prescription for one brand-name drug with a less expensive brand-name drug that is designed to have similar therapeutic effects, but that is pharmaceutically distinct, unless the switch was for medical reasons. To the extent HB 1332 makes safe and cost-reducing drug substitutions less common, it is likely to increase the cost of pharmaceuticals, which in turn is likely to increase health insurance premiums and reduce the availability of insurance coverage for pharmaceuticals.[30]

At the same time, it is unclear how the additional requirements in HB 1332 are likely to provide consumers with any additional countervailing benefits, because, as noted above, North Dakota requires prior prescriber authorization before a pharmacist is allowed to substitute one brand-name drug for another. Thus, existing safeguards appear sufficient to protect consumers from inappropriate therapeutic interchange.

[29] *See* N.D. CENT. CODE § 19-02.1-02(14) (prohibiting "Dispensing or causing to be dispensed a different drug or brand of drug in place of the drug or brand of drug ordered or prescribed without the express permission in each case of the person ordering or prescribing").

[30] Additionally, HB 1332 may reduce the value to a pharmaceutical company of securing a preferred spot on a PBM's formulary. When PBMs can use the formulary to guide consumers from one branded drug to another they can promote competition between pharmaceutical manufacturers, which is likely to result in reduced drug prices and/or insurance premiums. To the extent that HB 1332 reduces a PBM's ability to use therapeutic interchange, pharmaceutical companies may compete less vigorously for inclusion on the formulary, which could lead to higher drug prices.

Conclusion

HB 1332 is likely to limit a PBM's ability to reduce the cost of prescription drugs without providing consumers any additional protections. Any such cost increases are likely to undermine the ability of some consumers to obtain the pharmaceuticals and health insurance they need at a price they can afford. Accordingly, we would urge the North Dakota legislature not to adopt HB 1332.

Respectfully submitted,

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participants – are shielded from the price differences.

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UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
Washington, DC 20580

Bureau of Competition
Bureau of Economics
Office of Policy Planning

September 7, 2004

Assembly Member Greg Aghazarian
State Capitol, Room 2130
Sacramento, CA 95814

Dear Assemblyman Aghazarian:

The staffs of the Federal Trade Commission's Office of Policy Planning, Bureau of Competition, and Bureau of Economics are pleased to respond to your requests for comments on the competitive effects of California Assembly Bill No. 1960 ("AB 1960").[1] AB 1960 requires pharmacy benefit managers (PBMs) to make specified disclosures to "purchasers" and "prospective purchasers" with regard to their revenues and drug formularies.[2] AB 1960 also requires PBMs to make specified disclosures to prescribers and consumers, and sets certain requirements for PBM contracts, formularies, and staffing.[3] In your letter dated May 6, 2004, you asked us to analyze the competitive implications of AB 1960 and discuss whether it is likely to "result in the increased cost of pharmaceutical care for consumers."

[1] This letter expresses the views of the Federal Trade Commission's Office of Policy Planning, Bureau of Competition, and Bureau of Economics. The letter does not necessarily represent the views of the Federal Trade Commission (Commission) or of any individual Commissioner. The Commission has, however, voted to authorize us to submit these comments.

[2] AB 1960 defines a "purchaser" as "any person who enters into an agreement with a pharmacy benefits manager for the provision of pharmacy benefit management services," and a "prospective purchaser" as "any person to whom a pharmacy benefits manager offers to provide pharmacy benefits management services." AB 1960 § 1 (150000)(d)-(e).

[3] AB 1960 does not formally define "prescribers," but the context makes it clear that it is the health care professional who originally prescribed the pharmaceutical in question. AB 1960 § 1 (150007)(a).

AB 1960 has been amended seven times since its introduction, but the bill's fundamental objectives (increasing cost transparency in transactions between PBMs and their health plan clients, providing more information to consumers and prescribers with respect to certain drug substitutions,[4] and ensuring that realized cost savings are passed on to consumers) do not appear to have changed.[5]

We believe that AB 1960, if enacted, may have the unintended consequences of limiting competition, thus increasing the cost of pharmaceuticals and ultimately decreasing the number of Americans with insurance coverage for pharmaceuticals. Specifically, we believe that AB 1960 may make it more difficult for PBMs to generate cost savings (including rebates) and may well make those cost savings smaller. To the extent that AB 1960 increases the cost of pharmaceuticals, it may result in an increase in health insurance premiums and reduced availability of insurance coverage for pharmaceuticals.

Although AB 1960 appears likely to discourage drug substitutions that may be aimed only at increasing PBM profitability, it does so by making all substitutions more difficult, time-consuming, and expensive. Drug substitutions can save money for consumers without placing their health at risk. As a recent Food and Drug Administration ("FDA") white paper noted, use of generic drugs can "significantly reduce overall health care costs" by providing "medicines that are just as safe and effective as their brand-name counterparts."[6] California already requires prior prescriber approval for therapeutic interchange, thus limiting the risk associated with substitution to a lower-cost alternative brand name drug. To the extent AB 1960 makes generic substitution and therapeutic interchange more difficult, it again has the potential to increase health insurance premiums and restrict the availability of insurance coverage for pharmaceuticals. Finally, we do not believe AB 1960 will materially increase the probability that realized cost savings (including rebates) are passed on to consumers.

In this letter, we focus on cost transparency, drug substitution, and whether cost savings are being passed on to consumers. We do not address other provisions in AB 1960.

[4] Drug substitution encompasses generic substitution and therapeutic interchange (or clinical interchange). *See* page 6 *infra*. Different disclosure is required, depending on the type of drug substitution at issue. *Id.*

[5] This letter refers to the version of AB 1960 voted on favorably by the Senate on August 24, 2004, and the Assembly on August 25, 2004. We note that the amendments made to AB 1960 since its introduction have lessened the bill's likely anticompetitive effects. Generally, in the spectrum of PBM regulation, disclosure-based regulations such as AB 1960 are likely to raise fewer competitive concerns than regulation that imposes greater restrictions on PBM contracts, such as mandating that rebates be returned to purchasers or consumers, or requiring that PBMs enter into a fiduciary relationship with purchasers.

[6] Food and Drug Administration, NEW FDA INITIATIVE ON "IMPROVING ACCESS TO GENERIC DRUGS," (June 12, 2003), available at http://www.fda.gov/oc/initiatives/generics/whitepaper.html.

Interest and Experience of the Federal Trade Commission

The Federal Trade Commission (Commission) is charged by statute with preventing unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce.[7] Pursuant to this statutory mandate, the Commission seeks to identify business practices and regulations that impede competition without offering countervailing benefits to consumers. For several decades, the Commission and its staff have investigated the competitive effects of restrictions on the business practices of health care providers.[8] The Commission has brought numerous enforcement actions against entities involved in the pharmaceutical industry,[9] and the Commission and its staff have issued reports and studies regarding various aspects of the pharmaceutical industry.[10]

The Commission also has extensive recent experience with PBMs. On April 8, 2004, Commission staff commented on proposed legislation in Rhode Island directly affecting PBMs.[11] Earlier this year, the Commission investigated the competitive implications of a proposed merger between Caremark and AdvancePCS.[12] On June 26, 2003, the Commission and Department of Justice Antitrust Division (Division) held a half-day of hearings on PBMs, as part of their Hearings on Health Care and Competition Law and Policy (Health Care Hearings).[13] The report jointly issued by the Commission and the Division on July 23, 2004, addressed the issues raised by PBMs as well.[14] Finally, Commission staff currently are conducting a

[7] Federal Trade Commission Act, 15 U.S.C. § 45.

[8] *See* Federal Trade Commission, *FTC Antitrust Actions in Health Care Services and Products*, available at http://www.ftc.gov/bc/hcupdate031024.pdf.

[9] *See* Federal Trade Commission, *FTC Antitrust Actions in Pharmaceutical Services and Products*, available at http://www.ftc.gov/bc/0310rxupdate.pdf.

[10] *See* Federal Trade Commission, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION (July, 2002); David Reiffen and Michael R. Ward, GENERIC DRUG INDUSTRY DYNAMICS, Federal Trade Commission Bureau of Economics Working Paper No. 248 (Feb. 2002), available at http://www.ftc.gov/be/econwork.htm; Roy Levy, THE PHARMACEUTICAL INDUSTRY: COMPETITIVE AND ANTITRUST ISSUES IN AN ENVIRONMENT OF CHANGE, Federal Trade Commission Bureau of Economics Staff Report (March 1999), available at http://www.ftc.gov/reports/pharmaceutical/drugrep.pdf.

[11] Letter from FTC staff to Patrick C. Lynch, Attorney General and Juan M. Pichardo, Deputy Senate Majority Leader, State of Rhode Island and Providence Plantations, April 8, 2004, available at http://www.ftc.gov/os/2004/04/ribills.pdf.

[12] Statement of the Federal Trade Commission, *In re Caremark Rx, Inc./AdvancePCS*, File No. 0310239 (Feb. 11, 2004) available at http://www.ftc.gov/os/caselist/0310239/040211ftcstatement0310239.pdf.

[13] Health Care Hearings, June 26, 2003. http://www.ftc.gov/ogc/healthcarehearings/030626ftctrans.pdf. *See also* http://www.ftc.gov/ogc/healthcarehearings/03062526agenda.htm. All subsequent references to the hearings will identify a panelist, affiliation, and transcript page. Affiliations are as of the date of the hearing.

[14] Federal Trade Commission and Department of Justice, IMPROVING HEALTH CARE: A DOSE OF COMPETITION Chapter 7 (2004), available at http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf.

Congressionally mandated study on the cost implications of PBM use of mail order pharmacies.[15]

Description of AB 1960

AB 1960 requires PBMs to disclose the following information to purchasers and prospective purchasers of PBM services: the aggregate amount of rebates received for drug benefits specific to the purchaser or prospective purchaser; aggregate rebates for each therapeutic class of pharmaceuticals specific to the purchaser or prospective purchaser; nature and amount of revenue received from pharmaceutical manufacturers and labelers for drug benefits related to the purchaser or prospective purchaser; administrative fees charged to the purchaser; and arrangements with providers, pharmacists and other entities to encourage formulary compliance or manage prescription drug benefits.[16] AB 1960 also requires PBMs to disclose drug utilization information to purchasers (but not prospective purchasers). AB 1960 provides that a PBM need not make these disclosures unless the purchaser or prospective purchaser agrees to protect the confidentiality of any proprietary information.[17] AB 1960 excludes health plans and health insurers that provide pharmacy benefit management services to their own enrollees from these disclosure requirements.

AB 1960 also imposes disclosure requirements to prescribers and patients before a PBM may substitute one medication for another. AB 1960 requires a PBM that is requesting authorization from a prescriber to substitute a medication to disclose a range of information, including the cost savings (if any) to the purchaser; the difference (if any) in the consumer co-payment; the existence of any payments received by the PBM as a result of the substitution; the circumstances (if any) under which the existing prescription would be covered; the circumstances under which health care costs arising from the change in medications will be compensated; and any known differences in potential effects on health and human safety of the new medication.[18] AB 1960 states that this information need not be provided to the health care

[15] Federal Trade Commission, *Pharmacy Benefit Manager Conflict of Interest Study Public Notice*, March 26, 2004, available at http://www.ftc.gov/os/2004/03/040326pnpbm.pdf.

[16] AB 1960 §§ 150001, 150002. This information is to be provided to the purchaser no less frequently than quarterly. A PBM is not required to disclose discounts associated with prescription drugs purchased for sale and distribution through the PBM's mail order pharmacy. AB 1960 §§ 150001 (c), 150002 (c).

[17] AB 1960 § 150003 (b).

[18] AB 1960 § 150006 (a). California law prohibits the dispensing of a prescription pharmaceutical without a valid prescription. Although California law permits pharmacies to substitute a generic equivalent for a brand name drug in certain circumstances (*see* CA. BUS. & PROF'L CODE § 4073) a pharmacy may not dispense to a patient a different drug than the one prescribed without prescriber approval. Combined with this existing approval requirement, § 150006 (a) has the effect of requiring disclosures to prescribers whenever a PBM wants to effect a therapeutic interchange.

provider in five circumstances, including substitution of a generic equivalent of the prescribed medication.[19]

AB 1960 also prohibits a PBM from making any drug substitution unless certain information is communicated to the consumer, including the identity of the proposed and current medication, the difference (if any) in the consumer co-payment, the circumstances (if any) under which the existing prescription would be covered, the circumstances under which health care costs arising from the change in medications will be compensated, and any potential side effects of the new medication.[20] AB 1960 provides no circumstances where PBMs are not required to make consumer disclosures when there is a drug substitution. Thus, we interpret AB 1960 to require that this information be disclosed to consumers even when a bio-equivalent generic drug is substituted for a brand-name drug. The bill also requires a PBM to monitor the health effects on patients of medication substitutions requested by the PBM, and report the results of this monitoring on a quarterly basis to the PBM's Pharmacy and Therapeutics Committee.[21]

AB 1960 states that the PBM should reverse any drug substitution upon written or oral instructions from a prescriber or consumer, unless the prescribed drug is no longer on the purchaser's formulary or the consumer is unwilling to pay any higher applicable co-payment associated with the prescribed drug.[22]

Finally, AB 1960 requires PBM contracts to address a number of issues, including the amount of revenues, rebates and discounts identified previously that will be passed on to the purchaser, any administrative fees charged by the PBM, and the conditions under which an audit of the contract for PBM services may be conducted.[23]

Background on PBMs

There are approximately 60 PBMs operating in the United States today. There are three large independent, full-service PBMs with national scope: Medco, Express Scripts, and Caremark. Some large insurers manage pharmacy benefits internally. A few PBMs are owned by large retail supermarket/pharmacy chains. In addition, there are many smaller privately held PBMs. The relative size and ranking of these companies varies according to the measure used. The three large national PBMs are the major players in many markets, but anywhere from one-third to one-half of the market is made up of the other PBMs listed above. In our most recent

19 AB 1960 § 150006 (b)(1).

20 AB 1960 § 150006 (d).

21 AB 1960 § 150007.

22 AB 1960 § 150006 (e).

23 AB 1960 § 150004.

antitrust investigation in the PBM industry, we found the competition between PBMs for contracts with plan sponsors to be "vigorous."[24]

PBMs manage the pharmacy benefits of group health plan sponsors. At the Health Care Hearings, one panelist estimated that ninety-five percent of patients with prescription drug insurance coverage receive their benefits through a PBM.[25] A PBM's contract with group health plan sponsors specifies the amount that plan sponsors will pay per prescription of each drug, and the charges for the variety of PBM services that plan sponsors may utilize.

One important tool used by PBMs to manage pharmacy benefits is the formulary, which is a list of PBM-approved drugs for treating various diseases and conditions. PBMs use the formulary to guide drug substitution (both generic substitution and therapeutic interchange) in an effort to reduce costs. Generic substitution is the dispensing of a bio-equivalent generic drug product that contains the same active ingredient(s) as the brand-name drug and is, among other things, chemically identical in strength, concentration, dosage form, and route of administration as the substituted brand-name product. Generally, generic substitution is allowed without prior prescriber authorization.[26] Therapeutic interchange involves substitution of a therapeutically equivalent, but pharmacologically distinct, drug product for the drug product referred to on the consumer's prescription (*e.g.*, two brand-name drug products that treat the same ailment). As noted *supra,* California requires prior prescriber authorization before a pharmacist is allowed to interchange one brand-name drug for another. Therapeutic interchange allows a PBM to encourage implementation of its formulary, by steering utilization toward or away from a particular pharmaceutical.

Because the formulary affects the mix of drugs used by enrollees in a plan, its design can significantly affect the cost to the plan sponsor. Because generic drugs are substantially less expensive than their brand-name counterparts, generic substitution lowers prescription drug costs. Further, preferential placement on a formulary, accompanied with reduced co-payments, can cause a drug product to obtain higher market share within a drug plan. Accordingly, competition between pharmaceutical companies for preferred placement on the formulary can lead to lower drug prices.

PBMs also enter into contracts with pharmaceutical manufacturers.[27] The contract often

[24] Commission Statement, *supra* note 12.

[25] John Richardson, The Health Strategies Consultancy, Health Care Hearings, *supra* note 13, at 8.

[26] Indeed, nearly all state pharmacy assistance programs require generic substitution. *See* The Commonwealth Fund, State Pharmacy Assistance Programs Provide Lessons for Reducing Costs and Improving Patient Safety (Feb. 12, 2004), available at http://www.cmwf.org/newsroom/newsroom_show.htm?doc_id=223655. Further, some states require pharmacists to make generic substitutions unless the consumer objects or the prescription specifically states "dispense as written." *See, e.g.*, MINN. STAT. Chapter 151.21 (2003).

[27] PBMs also enter into contracts with retail pharmacies to create a retail network. The contract generally

provides that the pharmaceutical manufacturer will pay a rebate, based on some combination of a percentage of a reference price, achieving certain specified sales or market share targets, and preferred placement of certain drug products on the PBM's formulary. These rebates are either paid to the group health plan sponsor, retained by the PBM, or shared between them depending on the specifics of the contract between these parties.[28]

Group health plan sponsors generally procure PBM services through a bidding process. They typically issue requests for proposals to several PBMs and then evaluate the proposals based on costs and the package of services offered by each bidder. Plan sponsors or their consultants conduct these bidding processes, which may go through multiple iterations.

PBMs compete on price and non-price dimensions. One survey of plan sponsors using PBM services showed that the financial terms of the bid (such as the reimbursement rate and dispensing fee paid to pharmacies, the rebates paid to plan sponsors based on formulary drugs utilized, mail order pricing, and administrative fees) often were the key determinants in the selection of the winning bid.[29] This study also found that plan sponsors were concerned about non-price dimensions of service, such as plan design, the extent of the retail network, and mail order components. These terms and features are balanced against each other and the particular mix of terms and features is driven by the needs of the plan sponsor. For example, at the Health Care Hearings, panelists stated that some health plan sponsors want to maximize generic substitution, whereas others want to maximize rebates from manufacturers.[30] Panelists also noted that some plan sponsors want to receive all rebates from manufacturers, while others allow the PBM to retain the rebates – and many plan sponsors fall somewhere in-between.[31]

specifies the amount the PBM will reimburse the pharmacy for dispensing a prescribed pharmaceutical, expressed as a discount from a reference price plus a dispensing fee. Because AB 1960 does not target the relationship between PBMs and retail pharmacies, such issues are not discussed in this letter. An extensive discussion of these issues is found in the Letter from FTC staff to Patrick C. Lynch, Attorney General and Juan M. Pichardo, Deputy Senate Majority Leader, State of Rhode Island and Providence Plantations, *supra* note 11.

[28] John Richardson, Health Strategies Consultancy, Health Care Hearings, *supra* note 13, at 23-24 (PBMs "can be paid through administrative fees, share of rebates, or some combination."); Thomas M. Boudreau, Express Scripts, Health Care Hearings, *supra* note 13, at 124.

[29] *See* Health Care Financing Administration, Study of Pharmaceutical Benefit Management, June 2001, available at http://www.cms.gov/researchers/reports/2001/cms.pdf.

[30] Thomas M. Boudreau, Express Scripts, Health Care Hearings, *supra* note 13, at 65; Anthony Barrueta, Kaiser Foundation Health Plan, Inc., Health Care Hearings, *supra* note 13, at 105.

[31] John Richardson, The Health Strategies Consultancy, Health Care Hearings, *supra* note 13, at 18 ("A lot of PBMs don't retain any of the rebates; others retain a portion in addition to whatever percent of the revenue they will keep as their administrative fees. So again, that's going to differ in each arrangement that is out there."); John Dicken, General Accounting Office, Health Care Hearings, *supra* note 13, at 40 ("of those contracts -- not all, but some -- would have the PBMs retaining some portion of those rebates to cover their administrative services."); Thomas M. Boudreau, Express Scripts, Health Care Hearings, *supra* note 13, at 58-59.

The Government Accountability Office (formerly the General Accounting Office) released a study in January 2003 that examined the effects of PBMs on the Federal Employees Health Benefits Program, enrollees, and pharmacies.[32] The report considered the prescription benefits programs offered within three health plans available to federal government employees. The study compared prices that three types of customers paid for 14 brand name drugs and 4 generic drugs: (1) cash-paying customers, who buy at retail pharmacies; (2) health plan sponsors and their enrollees, who buy at retail pharmacies; and (3) health plan sponsors and their enrollees, who buy from a PBM's mail order facility. The study found that the lowest average prices for 30-day supplies were obtained when the drug was purchased through the PBM's mail order pharmacy, and that cash-paying customers at retail pharmacies paid the highest prices.[33]

Likely Effects of AB 1960

One of the primary goals of AB 1960 is to provide purchasers of PBM services with detailed information about the cost structure of the PBMs with whom they do business.[34] In the overwhelming majority of markets, however, consumers have limited or no information about the cost structure of those with whom they do business. More importantly, in general, consumers do not need such information to make efficient purchasing decisions. Instead, consumers make purchasing decisions based on the price and value of goods and services, without regard to a vendor's costs of production. AB 1960 thus holds PBMs to a standard that does not apply to other industries.

[32] *See* General Accounting Office, *Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies*, available at http://www.gao.gov/cgi-bin/getrpt?GAO-03-196. *See also* Sara Fisher Ellison and Christopher M. Snyder, *Countervailing Power in Wholesale Pharmaceuticals*, MIT Working Paper 01-27 July 2001, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=277290. ("buyers of wholesale drugs that can use restrictive formularies obtain substantially lower prices than buyers without this ability.")

[33] Similar cost savings for PBM clients have been reported in another study. *See* Cindy Parks Thomas et al., *Impact of Health Plan Design And Management On Retirees' Prescription Drug Use And Spending, 2001*, Health Affairs Web Exclusive W2-408, December 4, 2002, available at http://content.healthaffairs.org/cgi/reprint/hlthaff.w2.408v1.

We note the filing of a lawsuit alleging that the largest PBMs have violated California state law by receiving rebates from pharmaceutical manufacturers that did not benefit employers and/or consumers but instead increased PBM profits and overall health care costs. *See* First Amended Representative Action and Complaint for Violation of the Unfair Competition Law, AFSCME v. AdvancePCS, *et al.*, Superior Court of the State of California, case No. BC292227 (Apr. 4, 2003) at ¶ 4. We also note that the United States, along with 20 states (including California), recently announced a settlement of claims for injunctive relief and state unfair trade practices against Medco Health Solutions, Inc., and that New York recently filed a lawsuit against Express Scripts alleging various forms of misconduct relating to pharmaceutical pricing practices.

[34] Although it may seem that rebates are revenues received by the PBMs from manufacturers, they are frequently booked as reductions in the cost of sales.

AB 1960 also requires PBMs to disclose certain financial information to purchasers, prospective purchasers, and prescribers. AB 1960 specifies that rebate information may be provided in a somewhat aggregated form to purchasers and prospective purchasers and does not have to be provided unless purchasers and prospective purchasers agree to keep the information confidential. No such confidentiality restrictions apply to the disclosure of information to prescribers. Thus, financial information disclosed by PBMs to prescribers may become public, and a knowledgeable pharmaceutical manufacturer might well be able to use this information to calculate the rebate a competitor was offering. If pharmaceutical manufacturers learn the exact amount of the rebates offered by their competitors (either because the safeguards on subsequent disclosure by purchasers and prospective purchasers are insufficient or because the mandated disclosure to prescribers provides sufficient information for pharmaceutical manufacturers to calculate these amounts) then tacit collusion among manufacturers is more feasible. Consequently, the required disclosures may lead to higher prices for PBM services and pharmaceuticals.

Inclusion in a PBM formulary offers pharmaceutical manufacturers the prospect of substantially increased sales opportunities. Whenever PBMs have a credible threat to exclude pharmaceutical manufacturers from their formulary, manufacturers have a powerful incentive to bid aggressively. Willingness to bid aggressively, however, is affected by the degree of transparency with respect to the terms that pharmaceutical companies offer PBMs. Whenever competitors know the actual prices charged by other firms, tacit collusion – and thus higher prices – may be more likely.[35] It is for this reason that California law requires the state to use sealed bids to procure desired goods and services whose value exceeds $25,000.[36]

When group health plan sponsors contract with PBMs, they know the price of the services they are obtaining. AB 1960 is premised on the belief that greater transparency with regard to the PBM's costs, which are affected by the rebates they are able to secure, will allow group health plan sponsors to ensure they are "getting the best deal." From the purchaser's perspective, there is no functional difference between a higher list price coupled with a rebate and a lower list price. We also note that some health plan sponsors are large, sophisticated, repeat-purchasers of health care services, and many use a bidding process to decide which PBM they will contract with. It is possible that AB 1960 may provide some additional information to these plan sponsors about the revenue streams obtained by PBMs, but it does not necessarily follow that this would make the PBMs compete more aggressively to do business with this plan sponsor. Indeed, to the extent AB 1960 makes tacit collusion more likely, these plan sponsors may end up with "worse" contractual terms.

35 *See, e.g.*, Svend Albaek *et al.*, *Government Assisted Oligopoly Coordination? A Concrete Case*, 45 J. INDUS. ECON. 429 (1997).

36 *See* http://www.pd.dgs.ca.gov/sell2state/default.htm.

AB 1960 may also inadvertently increase health care costs in another manner. As noted previously, AB 1960 excludes health plans and health insurers that provide pharmacy benefit management services to their own enrollees from the disclosure requirements. To the extent the disclosures mandated by AB 1960 chill the willingness of pharmaceutical manufacturers to offer substantial rebates to non-integrated PBMs, or otherwise increase non-integrated PBMs' costs, AB 1960 ultimately will increase health plans' and health insurers' costs of administering pharmacy benefits through non-integrated PBMs. In this way, AB 1960 will encourage health plans and health insurers to bring "in-house" the management of pharmacy benefits. To the extent that AB 1960 causes firms that would prefer to turn to the market for PBM services to instead provide such services internally, AB 1960 will induce inefficiency and may well increase the cost of PBM services. As before, increases in the cost of PBM services may well lead to increases in health insurance premiums and reductions in the availability of insurance coverage for pharmaceuticals.

There do not appear to be any significant barriers to negotiation between health plan sponsors and PBMs over all the terms of their agreement, including how PBMs are to be paid for their services and the disposition of any rebates.[37] At the Health Care Hearings, one panelist suggested that many health plan sponsors have decided to allow PBMs to keep rebates in exchange for lower administrative fees.[38] We are informed that one major PBM voluntarily discloses extensive information regarding rebates and administrative fees.[39] Press reports indicate that some PBMs have made formal promises to inform their customers about all rebates they receive from drug manufacturers, and a coalition of major employers are attempting to bypass PBMs entirely, and negotiate with pharmaceutical manufacturers directly.[40]

As these developments indicate, vigorous competition in the marketplace for PBMs is more likely to arrive at an economically efficient level of transparency than regulation of those terms. Just as competitive forces encourage PBMs to offer their best price and service combinations to health plan sponsors in order to gain access to subscribers, competition also encourages disclosure of the information group health plan sponsors require to decide which PBM to contract with, including but not limited to the magnitude of any rebates the PBMs might receive, the circumstances under which those rebates will be paid, and how those rebates will be shared between PBMs and group health plan sponsors.

[37] *See* Jack Calfee, American Enterprise Institute, Health Care Hearings, *supra* note 13, at 99; David Balto, White & Case, Health Care Hearings, *supra* note 13, at 99.

[38] *See* Anthony Barrueta, Kaiser Foundation Health Plan, Inc., Health Care Hearings, *supra* note 13, at 105.

[39] *See* Thomas M. Boudreau, Express Scripts, Health Care Hearings, *supra* note 13, at 103. *See also* http://www.express-scripts.com/client/business_principles.htm.

[40] *See* Milt Freudenheim, *Big Employers Joint Forces in Effort to Negotiate Lower Drug Prices*, N.Y. TIMES, June 12, 2004; Milt Freudenheim, *Critics Attack Secret Deals By Middlemen to Buy Drugs*, N.Y. TIMES, Dec. 20, 2003.

One of the central premises of AB 1960 is that information regarding a PBM's rebates from drug makers is relevant to a purchaser's decision-making process. However, if AB 1960 were to pass, insurers with integrated PBM services would not face the same disclosure requirements as independent (non-integrated) PBMs. In general, better informed purchasers are able to make better decisions, but more information is not necessarily better. For example, when only a subset of competitors are required to disclose certain financial information, purchasers may not be able to discern the true price of a service and may mistakenly choose a higher-priced option.[41] The different types of information potential purchasers would receive from integrated and non-integrated suppliers of PBM services is the type of asymmetry that could lead less-sophisticated purchasers mistakenly to choose higher cost services. Similarly, the mandated disclosure of information to prescibers and consumers prior to a drug substitution (and the absence of such disclosure if no such substitution is contemplated) may have the effect of misleading prescribers and consumers about the costs and benefits of continuing a currently prescribed drug compared to the proposed substitute.

AB 1960 also has a number of provisions that are likely to raise the costs of drug substitution. As noted previously, PBMs frequently use drug substitution to reduce costs and promote competition between branded drug makers. Instead of distinguishing between appropriate and inappropriate drug substitution and targeting the latter, AB 1960 imposes modest procedural barriers to drug substitution for a generic equivalent (by requiring disclosure to consumers and follow-up health monitoring) and substantial procedural barriers to drug substitution for a therapeutic equivalent (by requiring disclosure to consumers and prescribers, and follow-up health monitoring). These procedural barriers are likely to discourage both generic substitution and clinical interchange. To the extent AB 1960 makes safe and cost-reducing drug substitutions less probable, it is likely to increase the cost of pharmaceuticals, which in turn is likely to increase health insurance premiums and reduce the availability of insurance coverage for pharmaceuticals. Our concerns about AB 1960's impact on consumers and competition are far greater to the extent it has a material effect on the frequency of generic substitution.

As noted previously, generic substitution is encouraged by the FDA and widely recognized as safe, and California already requires prescriber approval for therapeutic

[41] A recent Commission staff report studied the impact of providing more detailed information to borrowers when a mortgage was obtained through a broker than when it was obtained through a direct lender. The study found that borrowers more frequently selected higher cost loans when given the choice between loans accompanied with more detailed information and loans without such information than when choosing between loans with the same baseline information. These results are consistent with the hypothesis that the additional information impaired consumers' ability to discern the low cost provider. James M. Lacko & Janis K. Pappalardo, THE EFFECT OF MORTGAGE BROKER COMPENSATION DISCLOSURES ON CONSUMERS AND COMPETITION: A CONTROLLED EXPERIMENT, at 8-9, Federal Trade Commission Bureau of Economics Staff Report, available at http://www.ftc.gov/os/2004/01/030123mortgagefullrpt.pdf (Feb. 2004).

interchange. As such, the disclosures mandated by AB 1960 are likely to prove unhelpful to most prescribers and consumers. More broadly, because current safeguards appear sufficient to protect consumers, AB 1960 is likely to increase costs to consumers without providing any countervailing benefits.

To the extent AB 1960 increases prices for pharmaceutical and health insurance and restricts the availability of insurance coverage for pharmaceuticals, the result is likely to be an increase in the number of Americans who do without pharmaceuticals and/or health insurance. As an article in *Health Affairs* last year noted, "when costs are high, people who cannot afford something find substitutes or do without. The higher the cost of health insurance, the more people are uninsured. The higher the cost of pharmaceuticals, the more people skip doses or do not fill their prescriptions."[42]

Conclusion

AB 1960 is more likely to undermine competition than promote it. AB 1960's mandated disclosure of information may increase the cost of pharmaceuticals and health insurance premiums by attenuating competition between pharmaceutical companies and by raising the cost of generic substitution and clinical interchange. Any such cost increases are likely to undermine the ability of some consumers to obtain the pharmaceuticals and health insurance they need at a price they can afford. Any additional amendments to AB 1960 that have the effect of broadening and strengthening its provisions would be even more problematic from a competitive perspective.

[42] William Sage, David A. Hyman & Warren Greenburg, *Why Competition Law Matters to Health Care Quality*, 22 HEALTH AFFAIRS 31, 35 (March/April 2003). Although estimates of the elasticity of demand for health insurance coverage vary, the empirical evidence is clear that higher costs result in less coverage. *See* David M. Cutler, HEALTH CARE AND THE PUBLIC SECTOR, NBER Working Paper W8802, Table 5 http://papers.nber.org/papers/W8802.

Respectfully submitted,

Susan A. Creighton, Director
Bureau of Competition

Luke M. Froeb, Director
Bureau of Economics

Maureen K. Ohlhausen, Acting Director
Office of Policy Planning

David A. Hyman
Special Counsel

R/x^x

a prescription benefits management company

Dear Network Pharmacy Provider,

June 22, 2004

As a network pharmacy provider for R/x^x Pharmacy Solutions, Inc., I would like to first of all thank you for providing pharmacy services for our clients. Secondly, I would like to introduce myself as the new Vice President/General Manager, Kirk Huffaker, RPh.

R/x^x Pharmacy Solutions was founded in 1999 and has experienced many changes and enhancements to our business over the years. Because the majority of our network contracts date back to 1999, we are in the process of updating them in order to ensure continuity among the network. This updated information will be very important as we enhance and update our web-based pharmacy network look up tool.

I realize that your pharmacy is a provider for many different PBM networks across the country and it is very important that R/x^x is able to promote your pharmacy as part of our national network.

Accompanying this cover letter, please find a copy of the updated pharmacy network agreement. I would ask that you fill in the information on page two (2) of the contract and fax back page two (2) only to 1-866-251-3309. If you have updated your contract information with us within the past 12 months, please disregard this update notification.

Again, thank you being a valued provider in the R/x^x Pharmacy Solutions network and please feel free to e-mail or call me with any questions.

Best Regards,

Kirk Huffaker, R.Ph.
Vice President/General Manager
kirkh@imxinc.com
866-251-3317

Rx Pharmacy Solutions, Inc.
HMO AND PPO PHARMACY NETWORK AGREEMENT

This Agreement is effective the day of _____ 2004, between Rx Pharmacy Solutions, Inc. (hereinafter referred to as "Rx") and the undersigned pharmacy provider (hereinafter referred to as "Participant").

AGREEMENT

In consideration of the mutual covenants, agreements and conditions hereinafter set forth, Rx and Participant agree as follows:

PHARMACY SERVICES.

1.1 Participant agrees to provide pharmacy services to plan members of the HMO and PPO Pharmacy Networks of Rx through those pharmacy locations comprising all or a part of its pharmacy chain (as identified by attachment to this Agreement) pursuant to the contracts entered into between Rx and any third party payor (hereinafter referred to as "Plan Sponsor").

1.2 Rx may, from time to time, request Participant to designate one or more of its pharmacies to participate in Plan Sponsor Contracts of Rx which are not generally applicable to the entire Pharmacy Network of Rx.

1.3 Participant shall provide to all eligible plan members prescription drugs and other related and appropriate items pursuant to lawful prescriptions presented by such plan members to Participant.

PRICING.

2.1 Reimbursement rates for all branded product prescriptions provided shall be the lower of AWP less 15% plus $1.75 dispensing fee (or) usual and customary charges.

2.2 Reimbursement rates for all generic product prescriptions provided shall be the lower of MAC or AWP less 38% plus a $ 2.00 dispensing fee (or) usual and customary charges.

2.3 When the reimbursement rate is lower than a plan member's co-payment, Participant shall be reimbursed the lesser of the plan member's co-payment or the usual and customary.

2.4 Reimbursement rates are subject to change, from time to time, upon written notice by Rx to Participant.

Rx Pharmacy Solutions, Inc All rights reserved ©2004 03-19-04

LICENSE. *R/x*^{x} grants to Participant a non-exclusive, non-transferable license to utilize trademarks owned by *R/x*^{x} during the term of this Agreement.

TERMS AND CONDITIONS. The parties to this Agreement are subject to "Exhibit A"- *R/x*^{x} Standard Terms and Conditions, which is attached hereto and incorporated by this reference. Within fifteen (15) days of the effective date of this Agreement, Participant agrees that all pharmacies identified as part of this Agreement shall be equipped with and programmed for the on-line adjudication of *R/x*^{x}*'s* claims.

IN WITNESS WHEREOF, the parties have entered into this Agreement effective as of the day and year first above written.

For *R/x*^{x}:

By: Kirk Huffaker, R.Ph.

Title: VicePresident/General Manager

Signature:

Date:

For Participant:

Name:

By:

Title:

Signature:

Address:

NCPDP:

Tax ID:

Telephone No.:

Fax No.:

Date:

R/x^{x} Pharmacy Solutions, Inc All rights reserved ©2004 03-19-04

EXHIBIT "A"

R/x[x] STANDARD TERMS AND CONDITIONS

1. PHARMACY SERVICES. Participant agrees to provide pharmacy services pursuant to the terms of each contract entered into between *R/x*[x] and any third-party payor ("Plan Sponsor"). In each instance Participant shall provide to all eligible plan members of such Plan Sponsor, prescription drugs and other related and appropriate items pursuant to lawful prescriptions presented by such plan member to Participant. Participant hereby agrees to participate in each Plan Sponsor Contract entered into by *R/x*[x] in accordance with its terms, unless Participant notifies *R/x*[x] in writing within ten(10) days of notification of the terms of a specific Plan Sponsor Contract that it elects not to participate in such Plan Sponsor Contract.

2. PARTICIPANT'S COVENANTS AND UNDERTAKINGS.

2.1 Claims Submission. All claims processing shall be provided by one or more claims processors (collectively hereinafter referred to as the "Processor") selected by *R/x*[x]. All adjudication of *R/x*[x] claims and related data processing services shall be provided by Processor. Participant agrees to submit claims "on-line". In doing so, Participant may incur costs for claims processing equipment, computer software licenses, telephone lines, and other services, all of which shall be borne by Participant. *R/x*[x] makes no warranties, expressed or implied, as to the data processing and claims adjudication services provided by Processor, and specifically disclaims any implied warranties of merchantability and fitness for a particular purpose.

2.2 Compliance with Laws. Participant shall comply with all applicable local, state, and federal laws, rules, and regulations affecting the practice of the profession of pharmacy and the operations of pharmacies, including, but not limited to, having a licensed pharmacist at each of Participant's participating pharmacies available during business hours for plan member consultation, and at all times holding a valid permit to operate its participating pharmacies within the jurisdiction where Participant's pharmacies are located. Nothing herein shall be construed to require Participant to render professional services or dispense medications if, in the pharmacist's professional judgment, such service or medication should not be rendered or dispensed. Participant assumes full and complete legal responsibility for liability arising out of the practice of the profession of pharmacy.

2.3 Scope of Services. Participant shall be required to collect from each eligible plan member any co-pay or ancillary charge which the Plan Sponsor Contract of *R/x*[x] requires as a cost containment measure, and may be required to (i) offer twenty-four (24) hour-a-day, seven (7) day-a-week emergency service, (ii) maintain patient profiles on each eligible plan member, (iii) offer pharmacy counseling services to eligible plan members, (iv) participate in drug utilization reviews, peer review, and other quality assessment and assurance programs, and (v) provide such additional and ancillary services as *R/x*[x] may,

from time to time, uniformly and reasonably impose upon all Participants by advance written notice.

2.4 Record Keeping. Participant shall comply with complete and proper prescription drug record keeping practices, including maintaining (manually, electronically, or otherwise) legible and timely notations on all new and refill prescription orders regarding the quantity dispensed, identification of the dispensed product by manufacturer, the date dispensed with identification of the dispensing pharmacist, and all refill authorizations, if any, by date of authorization and identification of person authorizing the refills or as required or permitted by the state pharmacy regulatory authorities. Each Participant shall grant on-site access to prescription dispensing records as requested by *Rx*[x] utilization review auditors for purposes of performing drug utilization reviews and quality assessment and assurance activities.

3. LICENSE. Subject to the terms and conditions of this Agreement, *Rx*[x] grants to Participant a non-exclusive, non-transferable license to utilize the trademarks, including, but not limited to, the *Rx*[x] trademark during the term of this Agreement. *Rx*[x] retains full and exclusive ownership rights to the use, reproduction, or distribution of the trademarks to any person or entity.

4. TERM. This Agreement shall be effective as of the date first above written, and shall continue in full force and effect unless terminated upon ninety (90) days advance written notice by either party, unless sooner terminated as hereinafter provided following a material breach of this Agreement or for good cause shown.

5. TERMINATION. This Agreement may be terminated for cause upon written notice at any time. For purposes of this Agreement, cause shall be defined as a material breach of the terms and conditions of this Agreement, Participant's election not to participate in any Plan Sponsor Contracts, submission of fraudulent claims or failure to withdraw claims made for prescriptions not filled, or for other good cause shown. Upon termination of this Agreement for any reason, Participant shall return all *Rx*[x] materials in it possession or control forthwith.

6. INDEMNIFICATION. Participant shall indemnify, hold harmless, and defend *Rx*[x] from any and all claims, losses, or expenses incurred or suffered by *Rx*[x] arising out of or resulting from the entering into or performance of this Agreement. *Rx*[x] does not practice the profession of pharmacy. Therefore, Participant further agrees to indemnify and hold harmless *Rx*[x] from any liability which *Rx*[x] may suffer as a consequence of the entering into or performance of this Agreement constituting the failure to comply with the requirements of the practice of the profession of pharmacy. Participant agrees to obtain and maintain at its own liability insurance protection throughout the term hereof, including general public liability, products liability and professional liability, with loss limits of not less than one million dollars ($1,000,000) per occurrence, naming *Rx*[x] as an additional insured upon *Rx*[x] request if Participant can do so without additional charge or premium, and to provide a certificate of such insurance to *Rx*[x] upon request. Further, *Rx*[x] shall have no liability with respect to the payment to Participant for pharmacy services rendered

to eligible plan members. Participant shall look exclusively to the Plan Sponsor for all such compensation for services rendered.

7. INDEPENDENT CONTRACTOR. The parties hereto are independent contractors with respect to one another and nothing herein contained shall be construed to constitute *Rx*[x] and Participant as joint ventures, partners, employer/employee, principal/agent, or any other relationship whatsoever.

8. NON-EXCLUSIVITY. Participant is entitled to participate in the *Rx*[x] network upon entering into this Agreement. However, nothing herein contained shall be construed to restrict Participant's entitlement to participate in any other network of pharmacies providing the same or similar services, or any number of such networks, or from entering into any other contract of any nature whatsoever for providing pharmacy services.

9. ASSIGNMENT. Neither this Agreement nor any rights transferred to Participant hereunder may be assigned or transferred, consensually or by operation of law, without the prior written consent of *Rx*[x], which may be granted or withheld at *Rx*[x]'s sole and exclusive discretion. However, if the Participant shall be transferred to a new owner, whether by transfer of stock or controlling ownership interest in any entity which owns the Participant, *Rx*[x]'s consent to an assignment to such transferee shall not be unreasonably withheld.

10. MARKETING. Participant authorizes *Rx*[x] to use its name, location, and telephone number in any marketing or solicitation materials to be developed and utilized by *Rx*[x] in the development, marketing and sales of pharmacy benefit services.

11. ARBITRATION. Any and all controversies and claims arising out of or related to this Agreement or breach hereof shall be settled by binding arbitration by the American Arbitration Association in Phoenix, Arizona upon the application of either party. The arbitration proceeding shall be conducted in accordance with the rules then prevailing of the American Arbitration Association or its successor. Each party shall select one arbitrator and the two so selected shall select a third, and failing the selection of an arbitrator by either party, or a third arbitrator by the two so selected, the arbitrator or arbitrators shall be selected by the American Arbitration Association. Compensation of the arbitrators shall be borne equally by the parties. Judgment upon award by the majority of arbitrators may be filed in a court of competent jurisdiction.

12. NOTICES. Notices shall be deemed given upon confirmed facsimile transmission, five (5) days after deposit in the United States mail, first class postage prepaid, or upon receipt if mailed certified mail, return receipt requested, to the party at the address set forth below, or at such other address as either party shall provide to the other by similar notice:

If to *Rx*[x]: 1600 West Broadway Road
Suite 300
Tempe, AZ 85282

If to Participant: To the address set forth beneath Participant's signature.

13. MISCELLANEOUS. This Agreement constitutes the entire agreement between the Participant and *Rx*[x] with respect to the subject matter contained herein and shall supersede all prior written or oral agreements. This Agreement may be modified only in writing if signed by both parties to this Agreement. This Agreement shall be governed and construed in accordance with the laws of the State of Arizona.

Rx[x] Pharmacy Solutions, Inc All rights reserved ©2004 03-19-04

WELLPOINT
PHARMACY MANAGEMENT®

PHARMACY PROVIDER AGREEMENT

THIS AGREEMENT is entered into this _____ day of _____, 2004, by and between Professional Claim Services, a New York Corporation, d/b/a WellPoint Pharmacy Management (hereinafter referred to as "WPM"), an affiliate of WellPoint Health Networks, Inc. and , a (corporation, partnership or proprietorship), (hereinafter referred to as "PHARMACY").

WHEREAS, WPM provides administrative services as herein defined to certain third party payors such as Blue Cross and/or Blue Shield plans, employers, insurance carriers, health care service plans, third party administrators, and other party payors, (hereinafter collectively referred to as "Payors"), and

WHEREAS, WPM has established a nationwide pharmacy network ("WellPoint National Network"), and

WHEREAS, WPM administers, on behalf of Payors, certain Managed Prescription Drug Benefit Contracts for the purchase of Covered Prescriptions, and

WHEREAS, PHARMACY desires to participate in the WellPoint National Network as a provider of Covered Prescriptions and/or Covered Services to Covered Members, and

WHEREAS, WPM and PHARMACY recognize as a mutual objective continuing efforts toward the goal of access, cost containment, and the delivery of quality pharmacy services;

NOW, THEREFORE, in consideration of the premises and the mutual promises and covenants herein contained, the parties hereto agree as follows:

ARTICLE 1
DEFINITIONS

1.1 Anniversary Date.
The term "Anniversary Date" shall mean the first day of the next month following the Effective Date of this Agreement.

1.2 Affiliate.
The term "Affiliate" shall mean a corporation or other organization owned or controlled, either controlling directly or through a parent or subsidiary corporation(s), by WPM, or under common control with WPM.

1.3. Agreement.
The term "Agreement" shall mean this Agreement and all additions and or modifications and Program and Pharmacy Operations Manuals of WPM.

1.4 Average Wholesale Price.
The term "Average Wholesale Price" or "AWP" shall mean the average wholesale price published by a readily available commercial source selected by WPM, such as MediSpan or First Data Bank, for drugs and medical supplies, and shall be based upon product cost reimbursement at the time of dispensing as determined by WPM.

1.5 Co-payment or Co-pay.
The terms "Co-payment" or "Co-pay" shall mean the amount(s) required to be paid by a Covered Member in accordance with requirements set forth in the Covered Member's Managed Prescription Drug Benefit Contract and this Agreement.

1.6 Compound Prescriptions.
The term "Compound Prescriptions" shall mean a mixture of two or more ingredients when at least one of the ingredients in the preparation is a federal Legend Drug or state restricted drug in a therapeutic amount. It excludes the addition of only water or flavoring to any preparation. Further, "Compound Prescriptions" shall refer to a compound preparation not administered by infusion.

1.7 Covered Prescriptions and Covered Services.
The terms "Covered Prescriptions" and "Covered Services" shall mean a prescription of federal Legend Drugs and/or insulin covered under a Covered Member's Managed Prescription Drug Benefit Contract, as indicated by WPM's on-line system. The term "Covered Prescription" does not include any prescription specifically excluded from coverage by the applicable Managed Prescription Drug Benefit Contract.

1.8 Covered Member.
The term "Covered Member" shall mean an individual or dependent or spouse of an individual who is eligible to receive Covered Services from PHARMACY by virtue of this Agreement and are properly enrolled under a Payor's Managed Prescription Drug Benefit Contract or under an Affiliate or Other Payor's covered benefit plan. The term "Covered Member" is inclusive of the terms "policyholder," "subscriber," "insured" or any other term used to describe an individual eligible to receive Covered Services under a Managed Prescription Drug Benefit Contract.

1.9 Covered Member Reimbursement Program.
The term "Covered Member Reimbursement Program" shall mean a program for the delivery of Covered Services under a Managed Prescription Drug Benefit Contract, whereby PHARMACY agrees to collect the full amount allowed for Covered Services rendered from the Covered Member and provide WPM and/or the Covered Member with such data as may be necessary for the subsequent filing of a claim and reimbursement of the Covered Member as provided under the Covered Member's Managed Prescription Drug Benefit Contract.

Further, for outpatient benefit plans that cover only generic drugs, PHARMACY shall charge Covered Members no more than an amount determined in accordance with the applicable

pricing schedule for brand name drugs and the Covered Member shall be responsible for no more than 100% of such negotiated fee.

1.10 Covered Quantity.
The term "Covered Quantity" shall mean a quantity of a Covered Prescription as permitted by the Covered Member's Managed Prescription Drug Benefit Contract.

1.11 Covered Refills.
The term "Covered Refills" shall mean refills of a Covered Quantity of a Covered Prescription as allowed by law and the Managed Prescription Drug Benefit Contract and authorized by a prescribing physician, up to one (1) year from the date of the original Covered Prescription.

1.12 Customary and Reasonable Charges.
The term "Customary and Reasonable Charges" shall mean those amounts which PHARMACY normally charges its regular private customers for comparable Covered Prescriptions/Covered Services, including any offered discounts.

1.13 Dispensing Fee.
The term "Dispensing Fee" shall mean the amount, other than the Average Wholesale Price minus a discount and any applicable incentives determined by WPM as compensation to PHARMACY for providing Covered Services.

1.14 Drug Utilization Review.
The term "Drug Utilization Review" shall mean the process whereby the therapeutic effects and cost effectiveness of various drug therapies are reviewed, monitored and acted upon within the scope of this Agreement.

1.15 Electronic Network.
The term "Electronic Network" shall mean the system designed by WPM for the verification of Covered Member Eligibility and the collection of data, drug utilization and/or claims at the time a Covered Service is rendered.

1.16 Formulary.
The term "Formulary" shall mean a list of drugs and medical supplies, the use of which is encouraged or mandated by a particular Payor's Managed Prescription Drug Benefit Contract.

1.17 Generic Drug.
The term "Generic Drug" shall mean a drug identified by its chemical or generic name, as determined by the United States Adopted Names Council, and refers to a drug product having the same active ingredients as a higher cost brand or trade name product. WPM may, with notice to PHARMACY, cause a brand name product to be treated as a Generic Drug for purposes of this Agreement.

1.18 Legend Drug.
The term "Legend Drug" shall mean a drug which, in accordance with federal and/or state law, can be dispensed only pursuant to a prescription and which is required by law to bear the legend "Caution – federal and/or state law prohibits dispensing without prescription" or other similar language.

1.19 Managed Prescription Drug Benefit Contract.
The term "Managed Prescription Drug Benefit Contract" shall mean a contract, endorsement, or other agreement or program and any changes or additions thereto as may be made from time to time which, by its terms, provides coverage for health care/professional services, Covered Prescriptions and/or supplies to Covered Members, or otherwise provide access to drugs pursuant to agreed upon terms.

1.20 Maximum Allowable Cost.
The terms "Maximum Allowable Cost" or "MAC" shall mean the highest amount adopted and amended by WPM, at which WPM will reimburse PHARMACY for a specific drug. WPM will review and update its MAC lists as it deems necessary to reflect changes in market pricing. Single source Generic Drugs may be added to the MAC list per market conditions, as determined by WPM.

1.21 Network.
The term "Network" shall mean the national pharmacy network ("WellPoint National Network") and any state specific networks obtained by acquisition or otherwise deemed necessary by WPM for purposes of complying with state law.

1.22 Other Payors.
The term "Other Payors" shall mean persons or entities utilizing the WellPoint National Network pursuant to a contract with WPM, including without limitation, any Blue Cross and/or Blue Shield plan, self-administered or self-insured programs providing health care benefits, or employers, or insurers.

1.23 Prior Authorization.
The term "Prior Authorization" shall mean the select Covered Prescriptions, identified by the Electronic Network, that are not payable unless certain clinical criteria are met as determined by WPM.

1.24 Program Requirements.
The term "Program Requirements" shall mean those criteria and specifications established by WPM which are used to determine PHARMACY's eligibility to participate in the WellPoint National Network. Such Program Requirements shall include, but shall not be limited to, credentialing and audit policies, and procedures and programs designed by WPM.

ARTICLE 2
RELATIONSHIP OF THE PARTIES

2.1 Independent Entities.
WPM and PHARMACY are independent entities, and nothing in this Agreement shall be interpreted to create any relationship other than that of independent parties contracting with each other for the sole purpose of carrying out the provisions of this Agreement. In the

performance of the obligations of this Agreement, regarding any services rendered under this Agreement, by either party or its agents, servants, or employees, each party is at all times acting and performing as an independent contractor with respect to the other party, and no party shall have or exercise any control or direction over the method by which the other party shall perform such work or render or perform such services and functions. It is further expressly agreed that no work, act, commission or omission of any party, its agents, servants or employees, pursuant to the terms and conditions of this Agreement, shall be construed to make or render any party, its agents, servants or employees, an agent, servant, representative, or employee of, or joint venture with, the other party.

2.2 Other Payor Arrangements.
PHARMACY agrees that each arrangement by which PHARMACY performs services for Covered Members, enrollees, employees, dependents and other beneficiaries who are covered by an Affiliate or by an Other Payor that utilizes the WellPoint National Network shall constitute an independent legal relationship between PHARMACY and that Affiliate or Other Payor.

2.3 Rights and Remedies of Other Parties.
This is an Agreement between WPM and PHARMACY only. It shall not be interpreted to create any rights or remedies in favor of any other party, including any Covered Member, except as otherwise provided herein.

ARTICLE 3
RESPONSIBILITIES AND OBLIGATIONS OF PHARMACY

3.1 Service Availability.
PHARMACY shall be a provider of Covered Services to all Covered Members pursuant to the terms of this Agreement and the Covered Member's Managed Prescription Drug Benefit Contract, during all normal hours of operations of PHARMACY.

3.2 Eligibility Verification.
PHARMACY agrees to determine, as a condition precedent to providing Covered Services, the eligibility of each Covered Member by requesting a current WPM or Affiliate identification card or by requesting Covered Member's identification number and verifying eligibility using the on-line Electronic Network.

3.3 Claims Submission.
PHARMACY shall submit all claims with National Drug Code ("NDC") numbers, through the Electronic Network in the format required by WPM for Covered Services rendered to Covered Members under the Managed Prescription Drug Benefit Contract no later than 72 hours after the date of service. PHARMACY shall not charge more than the amount agreed to between WPM and PHARMACY as set forth hereunder.

3.4 Co-payments.
Upon the Covered Member's presentation of his or her WPM or Payor identification card and the Covered Member's receipt of the Covered Prescription or Covered Refill, PHARMACY shall collect and retain from the Covered Member the Co-payment for each Covered Quantity

of a Covered Prescription or Covered Refill. The amount of such Co-payment shall be the amount provided for in the Covered Member's Managed Prescription Drug Benefit Contract applicable to the Covered Member. PHARMACY shall have full responsibility for the collection of such Co-payment, as well as the collection of any other charge(s) designated as a Covered Member's financial responsibility in accordance with the terms of the Managed Prescription Drug Benefit Contract applicable to each individual Covered Member. PHARMACY shall not discount Covered Member Co-payment.

PHARMACY agrees to request reimbursement from Covered Members only for the amount of the applicable Co-payment or deductible for Covered Services, the amount for services which are not Covered Services, and for the difference between the payment and the PHARMACY's charge where the Covered Member refuses to allow substitution of lower cost generic equivalents, if permitted under the terms of the Covered Member's Managed Prescription Drug Benefit Contract. Further, in the event the Covered Member is enrolled in a heath care service plan, PHARMACY shall not, to the extent prohibited by law, maintain any action at law or equity against a Covered Member to collect sums owed to PHARMACY.

3.5 Payment in Full.
PHARMACY agrees to furnish Covered Services to Covered Members, to submit all claims via the Electronic Network to WPM for reimbursement of Covered Services, and to accept payment as provided in this Agreement as payment in full.

3.6 Program Requirements.
PHARMACY agrees to comply with the Program Requirements established by WPM and further agrees that WPM has sole discretion to amend and modify the Program Requirements from time to time. Such Program Requirements may include, without limitation, the administration of any drug utilization evaluation activities, Prior Authorizations, quality of care review, audit and grievance resolution procedures conducted by or on behalf of WPM. Further, PHARMACY shall meet utilization standards as established by WPM.

3.7 Lowest Cost Drugs.
PHARMACY agrees to dispense the lowest cost drug that PHARMACY then has in stock, consistent with the orders of the prescriber, the requirements of law and the professional judgment of PHARMACY.

3.8 Generic Substitution.
PHARMACY agrees to promote, and where not specifically prohibited by a prescribing physician, utilize generic products when and if available for substitution for equivalent brand name products. All generic products utilized must be in compliance with applicable federal and state requirements including those of the Federal Food and Drug Administration. WPM may encourage physicians to permit generic substitution as a means of cost containment whenever, in the judgment of such physicians, such substitution would not jeopardize the health of the Covered Members or specifically be prohibited by the prescriber.

3.9 Mandatory Generic Programs.
Unless provided by Payor's plan and as permitted by law, PHARMACY agrees to dispense, for applicable mandatory generic programs, brand name multi-source federal Legend Drugs only if medically necessary as determined by the prescribing physician and if the prescription is

written in the physician's own handwriting as DAW ("Dispense as Written") and entered into the Electronic Network as "DAW-1." A Covered Member's or PHARMACY's selection of a brand name multi-source product does not constitute medical necessity. The PHARMACY or Covered Member shall be liable for the difference between the average of the AWP of the multi-source product or MAC, whichever is lower, and the AWP of the brand name drug for any non-DAW-1 multi-source product dispensed as brand.

In connection with outpatient pharmacy benefit plans that cover only generic drugs, PHARMACY will charge Covered Members no more than an amount determined in accordance with the appropriate Contracted Rate fee schedule for brand name drugs, and the Covered Member shall be responsible for no more than 100% of that negotiated fee.

3.10 Non-Formulary Drugs.
Unless provided by Payor's plan and as permitted by law, PHARMACY shall dispense, for applicable formulary programs, non-formulary federal Legend Drugs only if medically necessary as determined by the prescribing physician and if the prescription is written in the physician's own handwriting as DAW ("Dispense as Written") and entered into the Electronic Networks as "DAW-1." Covered Member's or PHARMACY's selection of a non-formulary product does not constitute medical necessity and PHARMACY or Covered Member shall be liable for the AWP of the non-formulary drug in effect at the time of dispensing.

3.11 MAC Program.
PHARMACY shall comply with all of WPM's MAC and price control programs.

3.12 Operational Accuracy.
PHARMACY shall accurately submit all required data to WPM via the Electronic Network. PHARMACY shall enter the correct prescriber Drug Enforcement Agency ("DEA") number when submitting a claim for reimbursement. Should the prescriber's DEA number be entered incorrectly, PHARMACY shall, upon WPM's request, update its computer system to reflect the correct prescriber's DEA number. PHARMACY shall, however, be required to provide the correct DEA number when dispensing Schedule II drugs. Further, PHARMACY shall use and enter accurately on-line Electronic Network codes.

3.13 Cost Containment Efforts.
PHARMACY shall cooperate with cost containment efforts such as formularies, Prior Authorization programs, and Drug Utilization Reviews which promote prescribing and dispensing of appropriate and cost-effective therapeutic alternatives.

3.14 Prior Authorization.
If the Electronic Network message states "Prior Authorization Required," PHARMACY shall use best efforts to contact the prescribing physician. If the physician is not available, PHARMACY shall notify Covered Member and shall contact the WPM Prior Authorization desk to obtain a one-time emergency authorization. If the WPM's Prior Authorization desk is closed, PHARMACY may provide an emergency 72-hour supply.

3.15 Covered Member Reimbursement Program. PHARMACY shall keep in stock and furnish to Covered Members eligible under the Covered Members Reimbursement Programs WPM-supplied prescription drug claim forms and complete the PHARMACY portion of each claim

form, including data describing the Covered Service rendered or the Electronic Network assigned authorization code.

3.16 Non-Participating Pharmacy Affiliation.
PHARMACY shall not undermine Customary and Reasonable Charges or compound pricing as a component of the compensation set forth in this Agreement in any way, including, but not limited to: (a) owning, operating or affiliating with a non-participating pharmacy; or (b) separating cash and third party prescription business. Should WPM, at its sole discretion, determine that PHARMACY has taken actions to undermine Customary and Reasonable Charges or compound pricing, WPM shall immediately terminate PHARMACY from the WellPoint National Network.

3.17 Affiliate and Other Payor Services. PHARMACY agrees to provide, when the WellPoint National Network, is utilized by an Affiliate or Other Payor, services to Covered Members of that Affiliate in accordance with the terms of this Agreement and in all events, to look for payment only to the particular Affiliate or Other Payor that covers the particular services for which PHARMACY seeks to be compensated, except for applicable Co-payments or other obligations of Covered Members.

3.18 Insurance Claim Signature Log. PHARMACY shall maintain an Insurance Claim Log (Assignment and Disclaimer Statement) with an entry for each Covered Prescription for which a claim is submitted via the Electronic Network and retain this log, in date order, at the PHARMACY, for a period of not less than five (5) years from the date the prescription was dispensed, in the accepted National Council for Prescription Drug Programs ("NCPDP") standard format or in a form approved in writing by WPM, and make logs available for inspection and audit by an authorized representative or agent of WPM. PHARMACY shall not be entitled to payment of a claim for which there is not a signature of the Covered Member or authorized representative on this log.

3.19 Professional Judgment.
PHARMACY reserves the right to refuse to compound or dispense any Covered Prescription in the exercise of its professional judgment; provided, however, that PHARMACY shall remain solely liable to any and all persons and/or entities resulting therefrom. PHARMACY agrees to provide Covered Services to, and maintain a professional relationship with, Covered Members. PHARMACY shall be solely responsible for its professional services rendered.

3.20 Non-discrimination.
PHARMACY shall not discriminate against any Covered Member because of race, creed, color, religion, physical/mental handicap, sexual orientation, marital status or national origin/ancestry.

3.21 Representation of PHARMACY.
PHARMACY represents and agrees that it has, and shall have during each term of this Agreement, in full force and effect, all licenses, including Pharmacy State License and federal Drug Enforcement Agency License ("DEA"), permits, certifications, and other approvals required under federal, state and/or local law in regard to services provided under this Agreement. Further, PHARMACY represents and agrees that all its personnel who are employed or otherwise engaged by PHARMACY, directly or indirectly, to compound,

dispense or otherwise provide Covered Prescriptions or Covered Refills to Covered Members, are competent to do so and that all such personnel possess any and all licenses, permits, certifications and regulatory approvals required by law; that all such personnel shall perform only those services which they are legally authorized and permitted to perform; and that all such personnel shall perform their duties in accordance with all applicable, local, state and federal licensing requirements, as well as national, state and county standards of professional ethics and practice as may be applicable.

Further, PHARMACY represents and warrants that it and all applicable pharmacy personnel shall be legally authorized to dispense Covered Prescriptions for Medicare and Medicaid Covered Members. Should PHARMACY be excluded or prohibited from dispensing Covered Prescriptions for Medicare or Medicaid Covered Members, PHARMACY shall notify WPM immediately.

3.22 Computer System Upgrades.
PHARMACY shall maintain and upgrade PHARMACY's computer and software systems to accommodate and handle programs to meet industry standards such as mandatory generics, NCPDP file format for concurrent drug use review, and Prior Authorization and to meet current industry standards.

3.23 PHARMACY Changes.
PHARMACY shall notify WPM, in writing, thirty (30) days prior to implementation of changes in: name, location, ownership, licensure, general and professional liability insurance, and/or a reduction in the hours of operation. Prior notification of changes is required so that WPM may determine PHARMACY's compliance with WPM qualifications and contractual specifications. Ownership and location changes, as well as other changes, require prior written approval of WPM for continued PHARMACY participation. In the event PHARMACY provides notice to WPM pursuant to this Section 3.23, WPM may in its discretion, require that a new Agreement be executed.

3.24 Assumption of Liability.
PHARMACY shall be subject to the provisions of Section 11.4, and shall require any prospective successor to its interests to assume liability for any amounts for which PHARMACY is indebted to WPM, whether evidenced by a promissory note or otherwise. Such assumption of liability shall be one of the conditions for WPM's approval of any successor in interest as a participating PHARMACY. Such assumption of liability shall not release PHARMACY from the indebtedness unless an agreement to that effect is entered into between WPM and PHARMACY.

3.25 Notification of Legal Action.
PHARMACY shall notify WPM or its designated agent of any legal or administrative action filed against PHARMACY arising from this Agreement or otherwise which could affect the ability of PHARMACY to carry out of this Agreement within ten (10) days of such filing.

ARTICLE 4
RESPONSIBILITIES AND OBLIGATIONS OF WPM

4.1 Program Requirements.
WPM agrees that any material change of Program Requirements shall not be implemented without thirty (30) days written notice to PHARMACY.

4.2 Centers of Pharmaceutical Excellence.
WPM may designate certain pharmacies as Centers of Pharmaceutical Excellence and may refer Covered Members with specific medication needs to such pharmacies.

4.3 Third Parties Agreements.
WPM may enter into agreements with third parties which provide that specified services and responsibilities required of WPM in this Agreement are to be performed by subcontracting entities. PHARMACY will be advised of such subcontracting relationships when necessary to enable PHARMACY to perform its duties under this Agreement.

4.4 Pricing, Terms and Conditions.
WPM shall compensate PHARMACY according to the terms of Article 5 hereof. WPM is ultimately responsible for determining prices, terms and conditions of this Agreement, and for paying compensation pursuant to its terms. The responsibility for determining prices, terms and conditions has not and shall not be delegated.

4.5 Covered Member Identification.
WPM shall provide appropriate information to enable PHARMACY to identify Covered Members and determine Covered Services under each Payor's plan subject to this Agreement.

4.6 Managed Care Interventions.
WPM shall provide PHARMACY with appropriate information to participate in managed care interventions.

ARTICLE 5
COMPENSATION AND PAYMENT

5.1 Payment.
WPM shall, on behalf of Payor and pursuant to the terms of the agreements between Payor and WPM, pay PHARMACY for Covered Services rendered to Covered Members, less the per claim transmission fee due WPM netted from payment. Further, WPM or its designated agent shall deduct from its payments to PHARMACY the amount of any deductible and co-payment or co-insurance amounts required by the applicable Payor. Claims submitted by PHARMACY shall be paid once sufficient funds have been made available by Payor for the payment of such claims. In case of non-payment by a Payor, PHARMACY shall look solely to the Payor for payment.

5.2 Pricing Schedule.
The drug ingredient cost and professional Dispensing Fee paid to PHARMACY shall be at the rates set forth in the pricing Schedules attached hereto and incorporated by reference and/or at rates set forth in addenda specific to a Payor. PHARMACY agrees that WPM shall not be

required to pay for prescriptions and/or services that are not covered under the Covered Member's Managed Prescription Drug Benefit Contract.

5.3 Payment Processing Cycles.

WPM shall process or arrange to process all claims submitted for payment which are accurate, complete, and otherwise in compliance with this Agreement within thirty (30) days of receipt. WPM shall issue or arrange to issue checks for payment of claims at least twice a month. PHARMACY shall submit claims for compensation for Covered Services within ninety (90) days of the end of the month in which such Covered Services were provided. All claims should be submitted in the manner directed by WPM, and each such claim shall include an NDC number. For any taxable item, the claim shall also include the proper tax for the geographic area in which PHARMACY provided Covered Services to Covered Member, as designated by the Electronic Network. Should there be a difference between the tax amount indicated by the Electronic Network and the originally submitted tax amount, the Electronic Network tax amount shall prevail.

5.4 Full Compensation

PHARMACY shall accept the compensation set forth in pricing Schedules attached hereto and incorporated by reference and/or at rates set forth in addenda specific to a Payor, and/or any applicable deductible, co-payment or co-insurance amount, as payment in full for Covered Services rendered to Covered Members. PHARMACY shall not balance-bill a Covered Member. If PHARMACY receives any additional surcharge from a Covered Member, WPM shall require that PHARMACY promptly refund the amount thereof to the Covered Member or to WPM, as appropriate.

5.5 Errant Submissions.

WPM shall have a first lien in the amount of any indebtedness of PHARMACY to WPM. Indebtedness shall include, without limitation, the amount of any overpayment to PHARMACY by WPM or by a Covered Member (if WPM has reimbursed such overpayment to the Covered Member), and any amount determined to be due to WPM from PHARMACY under the audit program described in Article 7 hereof. WPM may set off such indebtedness against amounts due and payable to PHARMACY by WPM under this Agreement, under any other Agreement between PHARMACY and WPM of for any other reason. PHARMACY agrees to execute any financing statements or other documents required for WPM to perfect its lien under any state uniform commercial code or similar law.

5.6 Coordination of Benefits.

If a Covered Member is covered by more than one health plan, and Payor has primary responsibility according to federal or state laws and regulations, WPM shall pay the amounts due under this Agreement, once payment is received from Payor. If Payor is not primary under such federal or state laws and regulations, WPM shall nonetheless pay the amounts due under this Agreement as if Payor were primary. PHARMACY shall then cooperate with WPM in the recovery of money due from the primary health insurance plan. Payor shall be entitled to retain all such coordination of benefits recoveries. WPM will provide PHARMACY with thirty (30) days' notice prior to implementation of any changes to its procedures for coordination of benefits.

5.7 Other Payor Compensation.
WPM shall require that Other Payor(s) compensate PHARMACY in accordance with the terms of this Agreement and shall use its best efforts to ensure that such payment is made by any such Other Payor. In the event any such Other Payor fails to make required payments, PHARMACY may seek payment from the Covered Members (up to the rates specified herein) unless prohibited by applicable law. When an Other Payor utilizes the WellPoint National Network, PHARMACY shall follow such Other Payor's designated Drug Utilization Review requirements regarding the determination of medical necessity and appropriateness of services provided and other specified requirements.

ARTICLE 6
MAINTENANCE, INSPECTION, AND CONFIDENTIALTY OF RECORDS

6.1 Maintenance of Records.
PHARMACY agrees to maintain records as is required by WPM, by law or by appropriate regulatory authorities as such relate to Covered Services to be provided in accordance with this Agreement, for a period of no less than six (6) years following the termination of this Agreement. Should state law require records to be maintained for longer than six (6) years, the state law shall prevail.

6.2 Record Confidentiality.
PHARMACY and WPM agree that all Covered Member records shall be treated as confidential so as to comply with all state and federal laws regarding the confidentiality of Covered Member records and/or is prudent in accordance with applicable industry standards. Nothing herein is meant, however, or shall be construed, to limit the rights of WPM, or the rights of governmental authorities, to inspect and, at its/their own expense, copy at all reasonable times, any accounting, administrative, or Covered Member records maintained by PHARMACY pertaining to WPM's Program Requirements, Covered Prescriptions, or Covered Refills.

6.3 HIPAA Compliance.
The parties will endeavor to comply with all applicable regulations published pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPPA"), as of the effective enforcement date of each standard.

6.4 Access to Records.
WPM, and any and all applicable governmental authorities, shall have access at all reasonable times to PHARMACY's books, records and other papers which relate to Covered Prescriptions and Covered Refills compounded and/or dispensed by PHARMACY, billing records regarding Covered Prescriptions and Covered Refills, and payments received from, or on behalf of, Covered Members.

6.5 Record Duplication.
Any duplication of data or records shall be subject to federal or state laws concerning confidentiality and ownership of records. WPM will pay all costs for duplication of records pursuant to this Article 6.

6.6 Survival of Termination.
The provision of this Article 6 shall survive the termination of this Agreement.

ARTICLE 7
AUDITS

7.1 Audit Procedures.
PHARMACY agrees to fully cooperate with WPM in connection with the conducting by WPM of its audit programs then in effect, including audit by mail, in-house desk audits, drug utilization reviews and detection of claim submission errors. In connection therewith, PHARMACY will allow employees, agents, and independent contractors retained by WPM for the performance of such programs access to records pertaining to Covered Members, at reasonable times, at such locations, consistent with applicable law. WPM will, in conformity with its audit programs, conduct reviews periodically to determine that PHARMACY is collecting the correct Co-payment from the Covered Members and that PHARMACY is complying with the terms of this Agreement.

7.2 Notification.
Notwithstanding the foregoing, in addition to providing access for on-site inspection and/or audit by WPM, PHARMACY shall furnish WPM or its agents, within ten (10) calendar days of a written request therefore, information necessary to verify and substantiate compliance with the terms of this Agreement. For on-site audits, WPM shall notify PHARMACY in writing fourteen calendar (14) days prior to any such on-site audit.

7.3 Audit Deductions.
Pursuant to desk and/or on-site audits, deductions shall be made for, but not limited to, the following: billed for brand, dispensed generic; days' supply or quantity dispensed does not reflect the Covered Prescription order, ethical use, exceeds or is not in accordance with the Covered Member's Managed Prescription Drug Benefit Contract; missing hard copy prescriptions not retrieved and forwarded to WPM within fourteen (14) days of WPM's mailing a request for the same in writing to PHARMACY; physician Dispensed as Written ("DAW-1") not designated on Covered Prescription when billed as such; reason not specified on Covered Prescription when refill too early message is over-ridden; inappropriate DAW codes used or inaccurate DEA numbers submitted pursuant with compliance to Section 3.12 of this Agreement; formulary non-compliance; NDC number billed not in accordance with NDC number dispensed; NDC number of product or number of units billed does not reflect Covered Prescription order or Covered Member's Managed Prescription Drug Benefit Contract; claim billed as a compound or is not written and designated as a compound preparation; MAC program, compound upper limit or other cost containment programs.

7.4 Corrective Actions.
PHARMACY, shall, thereafter, within a reasonable period of time specified by WPM, but no more than thirty (30) days, take corrective action required by WPM, including remitting audit deduction amounts owed to WPM for the reasons set forth in Section 7.3 hereof or said amount shall be deducted from subsequent payments due PHARMACY. Further, PHARMACY shall cooperate and reply to any audit by mail request, within thirty (30) days of the request. Any

electronic signature challenged by the audit will be validated by a signed affidavit at the expense of PHARMACY.

7.5 Survival of Termination.
The provisions of this Article 7 shall survive the termination of this Agreement.

ARTICLE 8
INSURANCE AND INDEMNIFICATION

8.1 Insurance.
PHARMACY, at its sole cost and expense, shall procure and maintain policies of general and professional liability insurance and such other insurance as shall be necessary to insure it and its employees against any claim or claims for damages arising out of, or related to, alleged personal injuries or death occasioned directly or indirectly in connection with the performance of Covered Services and activities of PHARMACY, and/or the use of any facilities, equipment or supplies provided by PHARMACY. Each of such policies shall be amounts of at least one million dollars ($1,000,000.00) per occurrence and three million dollars ($3,000,000.00) annual aggregate, or provide such other evidence of financial responsibility as may be acceptable to WPM and shall name as an additional insured WPM, its successors and assignees. PHARMACY shall furnish WPM reasonable proof of such insurance as may be requested upon execution of this Agreement and/or at any reasonable time thereafter. This provision shall survive the termination of this Agreement.

8.2 Indemnification.
Neither WPM nor PHARMACY, nor any of their respective officers, directors, shareholders, employees or other agents, shall be liable to third parties for any act or omission of the other party under this Agreement.

ARTICLE 9
MARKETING, ADVERTISING AND PUBLICITY

9.1 Use of Names.
WPM has the right to use the name of PHARMACY only for the purposes of informing Covered Members or prospective Covered Members of the identity, location, business hours and services of PHARMACY and its status as participant in the WellPoint National Network under this Agreement. This right expires with the termination of this Agreement. Further, PHARMACY shall prominently display the provider window decal to be issued to PHARMACY by WPM.

9.2 Listing of Pharmacy.
PHARMACY agrees that WPM or Affiliates, may, in their sole discretion, list the name, address, telephone number of PHARMACY, and a description of its facilities and services, in directories or other material issued by WPM, or its Affiliates. Such directories may be revised as determined by WPM.

9.3 Unauthorized Use of Names.

Except as provided in Sections 9.1 and 9.2 hereof, WPM and PHARMACY each reserve the sole right to and the sole control of the use of their respective names and all symbols, trademarks, or service marks presently existing or hereafter established. This Agreement does not entitle WPM or PHARMACY to the unauthorized use of names, symbols, trademarks, or service marks of the other in advertising or promotional materials or otherwise without prior written consent of the other party. Consent may be withdrawn upon written notice and unauthorized usage must cease immediately upon written notice of the offended party, or upon termination of this Agreement, whichever occurs first.

9.4 Direct Marketing.

PHARMACY shall not directly market to or solicit Covered Members without written authorization from WPM and the applicable Payor. Such marketing and soliciting activities to Covered Members shall include without limitation direct marketing campaigns and solicitations via mail, telephone, internet or any other means available.

9.5 Survival of Termination.

The provisions of this Article 9 shall survive the termination of this Agreement.

ARTICLE 10
GOVERNING LAW AND DISPUTE RESOLUTION

10.1 Choice of Law.

This Agreement shall be construed, interpreted, and governed by the laws of the State of California.

10.2 Dispute Resolution.

If any dispute arising under this Agreement is not satisfactorily resolved by the parties themselves, WPM and PHARMACY agree to submit such dispute to binding arbitration. A written demand is necessary to initiate arbitration. Any such arbitration shall be held in the County of Los Angeles, California, and shall be conducted in accordance with the commercial rules of the American Arbitration Association.

ARTICLE 11
GENERAL PROVISIONS

11.1 Entire Agreement.

This Agreement, together will all exhibits, addenda, and schedules contains the entire Agreement between WPM and PHARMACY and supersedes all prior agreements between PHARMACY and WPM for the provision of Covered Services by PHARMACY. However, all existing pricing schedules and addenda shall be incorporated into this Agreement, except as provided for in Schedule 1 of this Agreement. This Agreement will be effective and binding on the parties only if the duly authorized signatures of the parties are affixed hereto where indicated on the signature page.

11.2 Amendments/Modifications.
This Agreement may be amended by WPM with not less than forty-five (45) calendar days' prior written notice to PHARMACY.

11.3 Administration of Agreement.
WPM and PHARMACY shall develop and implement mutually acceptable procedures necessary for the proper performance of this Agreement. In this regard, PHARMACY agrees to assist WPM in any way reasonably deemed necessary by WPM in connection with the utilization, quality assurance, and peer review programs which WPM establishes, to the extent that such programs relate to PHARMACY's provision of Covered Services in accordance with this Agreement.

11.4 Non-Assignability.
This Agreement, being intended to secure the services of PHARMACY, and the rights and obligations of PHARMACY described herein, shall not be assigned, subcontracted, delegated or transferred by PHARMACY without the prior written consent of WPM, the services of PHARMACY considered as unique and personal in nature. Any assignment, subcontract, delegation, or transfer, or any attempt by PHARMACY to assign, subcontract, delegate or transfer, any of its rights and/or obligations without the consent of WPM, its successors or assigns shall be void. However, nothing herein is meant, nor shall be construed, to prevent or hinder the assignment by WPM of this Agreement, its rights or any of its duties hereunder.

11.5 Non-Exclusivity.
The Agreement is non-exclusive, both parties having the right to enter into similar agreements with other parties.

11.6 Compliance with Laws and Regulations.
This Agreement will be interpreted and performed in compliance with all pertinent federal and state statutes and regulations. If this Agreement, or any part hereof, is found not to be in compliance with any pertinent federal or state statute or regulation, then the parties shall renegotiate the Agreement for the sole purpose of correcting the non-compliance.

11.7 Force Majeure.
The parties shall be excused, discharged, and released from performance under this Agreement to the extent that all or part of the Agreement cannot be performed due to causes which are outside the control of WPM and PHARMACY, and could not be avoided by the exercise of due care, including but not limited to acts of God, acts of a public enemy, acts of a sovereign nation or any state or political subdivision or any department or regulatory agency thereof or entity created thereby, acts of any person engaged in a subversive activity or sabotage, terrorist activity, fires, floods, earthquakes, explosions, strikes, slow-downs, lockouts or labor stoppage, freight embargoes, or by any enforceable law, regulation or order. The foregoing shall not be considered to be a waiver of any continuing obligations under this Agreement, and as soon as conditions cease, the party affected thereby shall fulfill its obligations as set forth under this Agreement.

11.8 Severability.
If any provision of this Agreement shall be invalid, illegal, or unenforceable by a court of competent jurisdiction, the remaining provisions hereof shall not in any way be affected or impaired thereby.

11.9 Waiver of Breach.
Waiver of breach of any provision of this Agreement shall not be deemed a waiver of any other breach of the same or a different provision.

11.10 Binding Effect.
Except as otherwise provided herein, this Agreement shall be binding upon and inure to the benefit of the parties, their agents, successors and permitted assigns unless otherwise set forth herein or agreed to in writing by the parties.

11.11 Notices.
Any notice required to be given pursuant to this Agreement shall be in writing, postage prepaid, and shall be sent via facsimile transmission or by United States first class mail or by certified or registered mail to the parties at the addresses indicated on the signature page of this Agreement (or such other addresses that the parties may hereafter designate). The notice shall be effective on the date the notice was mailed.

11.12 Headings.
The paragraph headings herein are for convenience purposes only and are not to be utilized in construction of the provisions of the Agreement.

ARTICLE 12
TERM AND TERMINATION

12.1 Term.
This Agreement shall be effective as of the Effective Date appearing on the signature page hereof, and shall continue in effect from year to year unless terminated by either party upon at least sixty (60) days' prior written notice to the other party. Termination shall have no effect upon the rights and obligations of the parties arising out of any transactions occurring prior to the effective date of such termination.

12.2 Termination with Cause.
This Agreement may be terminated at any time by either party for failure to comply with any terms or conditions herein stated or for any other just and sufficient cause provided, however, that thirty (30) days' prior written notice of such failure shall be given to the offending party and such party shall have the opportunity to cure such noncompliance during such thirty (30) day notice period.

12.3 Immediate Termination.
Either party may, subject to applicable state law, terminate this Agreement at any time if the other shall be adjudged a bankrupt; voluntarily files a petition in or for bankruptcy, reorganization or an arrangement with creditors; or makes a general assignment for the benefit

of creditors. WPM may immediately terminate this Agreement without notice at any time if PHARMACY fails to obtain and maintain any and/or all applicable licenses or to meet all requirements of applicable laws, fails to meet its obligations set forth herein or, in the sole discretion of WPM, fails to satisfactorily render services set forth in this Agreement.

12.4 Compound Prescriptions.
Compound Prescriptions billed to WPM at more than the PHARMACY's Customary and Reasonable Charge shall be sufficient grounds for immediate termination by WPM.

In Witness Whereof, the parties hereto have executed and delivered this Agreement, the day and year first written above. This Agreement shall become effective on the date executed by WPM ("Effective Date").

PHARMACY	PROFESSIONAL CLAIM SERVICES, INC. d.b.a. WellPoint Pharmacy Management
By: Signature	By: Signature
Print Name	Michael A. Nameth General Manager
Title	Post Office Box 4488 Woodland Hills, CA 91365-9709
Pharmacy Name	Date
Pharmacy Address	
City, State, Zip Code	
Phone Number	
Fax Number	
Email Address	
NCPDP Number	
Date	

EXHIBIT A
WELLPOINT MC and
SENIOR PASSPORT MEMBERS

PHARMACY agrees to provide services to WPM MC and Senior Passport Members in accordance with the following:

DEFINITIONS

A. "Covered Items" shall mean legend drugs which require a prescription under federal or state law and insulin and disposable syringes or needles necessary for the injection of insulin. Covered items do not include compound prescription medications.

B. "Senior Passport Members" shall mean individuals who have no prescription drug benefits under any federal, state or private programs. For purposes of this Exhibit A, WellPoint and Affiliates Members (hereafter referred to as WPM MC Members") shall mean individuals who have medical coverage through WPM and Affiliates but who have no prescription drug benefits.

RESPONSIBILITY OF PHARMACY

PHARMACY shall:

A. Provide WPM MC Members and Senior Passport Members with Covered Items in accordance with the professional judgment of PHARMACY. PHARMACY agrees to accept the rates set forth below as payment in full for Covered Items provided.

B. Verify that the individual who presents a WPM MC or Senior Passport card is the Member whose name is set forth on the card, and shall confirm such individual's WPM MC or Senior Passport eligibility through the Electronic Network.

C. Verify that the WPM MC Member or Senior Passport Member is not entitled to any insurance benefit, health plan benefit, or other benefit including, but not limited to, Medi-Cal or Medicare, which reimburses or pays the Member for prescription drugs, in whole or in part.

D. Submit information and data to WPM regarding Covered Items rendered through the Electronic Network in a format designated by WPM.

E. Look solely to WPM MC Members or Senior Passport Members for payment of all Covered Items proved to such Members and shall not seek, charge, collect or attempt to seek, charge or collect from WPM or an Affiliate any amounts due PHARMACY for Covered Items provided to a WPM MC Member or Senior Passport Member.

F. Dispense quantities of medication consistent with rational drug use in an amount not to exceed a thirty (30) day supply.

EXHIBIT B
FOR CALIFORNIA PHARMACIES PROCESSING CLAIMS FOR BLUE CROSS OF CALIFORNIA MEMBERS

WITNESSETH:

NOW THEREFORE, for services provided by California pharmacies to Covered Members of Blue Cross of California, the parties hereby agree as follows:

Article 3, Responsibilities and Obligations of PHARMACY, Section 3.3, Claims Submission, of the Agreement shall be deleted and replaced for California pharmacies only as follows:

> "PHARMACY shall submit claims for compensation for Covered Services within ninety (90) days of the end of the month in which such services were provided, and each such claim shall include an NDC number. All claims should be submitted in the manner directed by WPM. For any taxable item, the claim shall also include the proper tax for the geographic area in which PHARMACY provided Covered Services to Covered Member, as designated by the Electronic Network."

Article 3, Responsibilities and Obligations of PHARMACY, Section 3.27, California Regulations, shall be added to the Agreement as follows:

"3.27 California Regulations.

Pursuant to Title 22, Section 51002 of the California Code of Regulations, Medi-Cal managed care Covered Members are not responsible for the payment of prescription drugs covered under their pharmacy benefit. In the event PHARMACY cannot verify Medi-Cal eligibility or coverage, PHARMACY will be expected to contact WPM customer service for direction. Additionally, pursuant to Title 42, Section 447.20 of the Code of Federal Regulations, Medicare+Choice Covered Members with secondary coverage through Fee-for-Service (FFS) Medi-Cal are not responsible for any out of pocket expenses including their Co-pays. PHARMACY shall be responsible for billing the Co-pay amount directly to the FFS Medi-Cal processor, Electronic Data Systems ("EDS"). Further, PHARMACY agrees that WPM shall not be required to pay for prescriptions that are not covered under the Covered Member's pharmacy benefit."

Article 4, Responsibilities and Obligations of WellPoint, Section 4.7, California Health and Safety Code, which shall only apply with respect to services rendered in California, shall be added to the Agreement as follows:

"4.7 California Health and Safety Code.

WPM will comply with all requirements of California Health and Safety Code Section 1395.6. WPM's pharmacy networks may be sold, leased, transferred or conveyed to Other Payors, which may include workers' compensation insurers or automobile insurers. WPM will disclose upon initial signing of this Agreement and within thirty (30) days of receipt of a written request from PHARMACY a summary of all Other Payors currently eligible to pay the negotiated rates under this Agreement as a result of their arrangement with WPM. WPM requires such Other Payors to actively encourage Covered Members to use network participating providers when obtaining pharmaceutical care through the use of one or more of the following: reduced Co-

payments, reduced deductibles, premium discounts directly attributable to the use of a participating provider, financial penalties directly attributable to the non-use of a participating provider, providing Covered Members with the names, addresses and phone numbers of participating providers in advance of their selection of a pharmacy provider through the use of provider directories, toll-free telephone numbers and internet web site addresses. In the event WPM enters into an arrangement with an Other Payor that does not require such active encouragement of the use of the pharmacy networks, PHARMACY shall be allowed to decline to provide services to such Other Payor."

Article 7, Audits, Section 7.6, Audit Deductions, shall be added to the Agreement as follows:

"7.6 Audit Deductions.
Audit deductions shall be made for, but not limited to, the following:

- Billed for brand, dispensed generic;
- days supply or quantity dispensed does not reflect the prescription order, ethical use, exceeds or is not in accordance with the Covered Member's plan design;
- missing hard copy prescriptions not retrieved and forwarded to WPM within fourteen (14) days of WPM's mailing a request for the same in writing to PHARMACY;
- physician Dispensed As Written ("DAW-1") not designated on prescription when billed as such;
- non-formulary Dispensed As Written ("DAW") not designated on prescription when billed as such;
- reason not specified on prescription when refill too early message is over-ridden;
- inappropriate Blue Cross of California DAW codes used or inaccurate DEA numbers submitted;
- formulary non-compliance;
- NDC number billed not in accordance with NDC number dispensed;
- NDC number of product or number of units billed does not reflect prescription order or Covered Member's plan design;
- claim billed as a compound, but the prescription does not require compounding or is not written and designated as a compound prescription;
- MAC program, compound upper limit or other cost containment programs not followed."

Article 11, General Provisions, Section 11.11, Notices, shall be deleted in its entirety and replaced with the following:

"All notices relating to this Agreement shall be in writing, first class postage prepaid, and shall be sent by United States mail or by certified or registered mail to the parties at the addresses indicated on the signature page of this Agreement (or such other addresses that the parties may hereafter designate). All such notices shall be provided to the other party with at least a forty-five day time period from the effective date of said notice. The notice shall be effective on the date the notice was mailed."

EXHIBIT C
FOR PHARMACIES SERVICING BLUE CROSS
OF CALIFORNIA MEDI-CAL MEMBERS

WITNESSETH:

Article 13 set forth below is hereby added as Article 13 of the Agreement:

13.1 PHARMACY agrees to provide Covered Services to MMC Members pursuant to the terms of the Agreement and this Exhibit C.

13.2 PHARMACY agrees to make all its books and records, pertaining to the goods and services furnished under the terms of the Agreement, available for inspection, examination or copying:

(1) By the Department, the Department of Health & Human Services ("DHHS"), the Department of Corporations ("DOC) and WPM;
(2) At all reasonable times at PHARMACY's place of business or at such other mutually agreeable location in California;
(3) In a form maintained in accordance with the general standards applicable to such book or record keeping;
(4) For a term of at least five (5) years from the close of Department's fiscal year in which the Agreement was in effect.

13.3 PHARMACY agrees to maintain and make available to the Department, upon request, copies of all subcontracts and to ensure that all subcontracts are in writing and require the subcontractor to comply with the requirements of Section 14.2 herein.

13.4 PHARMACY shall meet all the applicable requirements of Chapters 3 and 4 of Subdivision 1, Division 3, of Title 22, California Code of Regulations, related to the services PHARMACY is required to perform.

13.5 PHARMACY agrees to cooperate with WPM in the preparation of all reports required by the Department, DHHS and DOC necessary to comply with MMC Program requirements.

13.6 This Agreement shall only become effective as to MMC Members under the MMC Program upon approval by the Department in writing or by operation of law. The parties agree the Department shall be notified in the event that this Agreement is terminated.

13.7 PHARMACY agrees to hold harmless the State of California and MMC Members in the event WPM cannot or will not pay for Covered Services performed by PHARMACY. If PHARMACY receives any additional surcharge from an MMC Member, WPM shall require that PHARMACY promptly refund the amount thereof to the MMC Member.

13.8 This Agreement shall be governed by and interpreted under the laws of the State of California, without reference to conflict of law principles, and in accordance with all laws, regulations, and contractual obligations of WPM.

13.9 PHARMACY agrees that any assignment or delegation of this Agreement shall be void unless prior approval is obtained from the Department.

13.10 Any Amendment to this Agreement shall be submitted to the Department for prior approval at least thirty (30) days before the effective date of any proposed changes governing compensation, services, or term. Proposed changes which are neither approved nor disapproved by the Department shall become effective by operation of law thirty (30) days after the Department has acknowledged receipt or upon the date specified in the amendment, whichever is later.

13.11 PHARMACY agrees to furnish the Department with the names of its officers and owners, stockholders owning more than ten percent (10%) of the stock issued by the PHARMACY and major creditors holding more than five percent (5%) of the debt of PHARMACY. The aforementioned information is public record on file with the Department.

13.12 In the event this Agreement is terminated, PHARMACY agrees to assist WPM in the transfer of MMC Program Member medical care including making available to the Department and WPM copies of medical records, patient files, and any other pertinent information held by PHARMACY necessary for efficient case management of MMC Program Members, as determined by the Director of the Department of Health Services. The parties acknowledge that the cost of reproduction required by this provision will not be billed to MMC Members, but will be borne by the Department.

The above provisions have been made to comply with the requirements of the California Department of Health Services' (the "Department") Medi-Cal Managed Care ("MMC") Program in order to provide Covered Services to persons assigned to WPM under the MMC Program.

EXHIBIT D
MEDICARE+CHOICE HMO (Senior Blue)

WITNESSETH:

This Exhibit is in effect for Covered Prescriptions provided to HealthNow New York, Inc. f/k/a Blue Cross and Blue Shield of Western New York, Inc. and New York Care Plus Insurance Company, Inc. d/b/a Blue Cross and Blue Shield of Western New York, Blue Shield of Northeastern New York ("Health Plan") Covered Members

1. Definitions. For the purposes of this Exhibit, the following terms shall have the meanings set forth therein:

a. "CMS" means the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services.

b. "Medicare+Choice Contract" means the agreement entered into between CMS and Payor pursuant to which Payor provides health care coverage to Medicare Covered Persons.

c. "Medicare+Choice Regulations" means those regulations promulgated by CMS at 42 C.F.R. § 422.100 et. seq., as amended.

d. "Medicare Covered Person" means an individual who is entitled to receive benefits pursuant to Title XVIII of the Social Security Act and is enrolled in Payors' plans pursuant to the Medicare Contract. The term "Covered Persons," "Members" or "Enrollees" in the Agreement shall include Medicare Covered Persons unless the context clearly indicates otherwise.

e. "Emergency Services" means covered inpatient and outpatient services that are: (a) furnished by a qualified provider, and (b) needed to evaluate or stabilize an emergency condition. "Emergency condition" means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent lay person with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in: (i) serious jeopardy to the health of the individual (or an unborn child); (ii) serious impairment to bodily functions; or (iii) serious dysfunction of any bodily organ or part.

f. "Urgently Needed Service" means covered services provided when a Medicare Covered Person is temporarily out-of-area (or, under unusual and extraordinary circumstances, provided when the Medicare Covered Person is in-area, but PHARMACY is temporarily unavailable or inaccessible) and such services are medically necessary and immediately required: (a) as a result of an unforeseen illness, injury or condition, and (b) it was not reasonably given the circumstances to obtain the services through the PHARMACY.

2. PHARMACY shall comply with all Medicare laws, regulations and CMS Instructions.

3. PHARMACY shall not deny, limit, or condition the furnishing of benefits to Medicare Covered Persons due to health status or source of payment.

4. Payor has agreed to provide and/or arrange access to Covered Services to Medicare Covered Persons in a manner described by CMS and Payor is accountable to CMS for adherence to

any functions or responsibilities related thereto. PHARMACY agrees that any services performed pursuant to this Exhibit shall be consistent and comply with the terms of the Medicare Contract. Payor shall inform PHARMACY of those functions and responsibilities as they affect the PHARMACY.

5. PHARMACY shall provide and/or arrange health care services in a manner consistent with professionally recognized standards of health care and in a culturally competent manner.

6. PHARMACY shall refrain from employing or contracting with any individual or any entity that employs or contracts with an individual who is excluded from participation in Medicare and/or Medicaid under Sections 1128 of the Social Security Act for the provision of any of the following services:

(i) health care;
(ii) utilization review;
(iii) medical social work; and
(iv) administrative services.

7. PHARMACY acknowledges and agrees that CMS, the U.S. Department of Health and Human Services ("HHS") and the Comptroller General may audit and evaluate any books, contracts, medical records, patient care documentation and other records or information of PHARMACY that pertain to any aspect of services performed or arranged, reconciliation of benefit liabilities and determination of amounts payable under the Agreement or as the Secretary of HHS may deem necessary to enforce its contract with Payor or this Exhibit. PHARMACY shall make available their premises, physical facilities and equipment, records relating to Medicare Covered Persons and any additional relevant information that CMS may require. The parties acknowledge that the right of CMS, HHS and the Comptroller General to inspect, evaluate and audit PHARMACY extends through six (6) years from the final date of the Medicare Contract or completion of an audit by CMS, HHS or the Comptroller General, whichever is longer, unless (1) CMS has determined that there is a special need to retain a particular record or group of records for a longer period and notifies Payor and/or PHARMACY at least thirty (30) days prior to the normal disposition date; (2) CMS determines that there is a reasonable possibility of fraud or similar fault by Payor or the PHARMACY, in which case the retention period may be extended for six (6) years from the date of any resulting final resolution of the termination, dispute or fraud or similar fault; or (3) CMS determines that there is a reasonable possibility of fraud, in which case it may inspect, evaluate, and audit Payor and/or PHARMACY at any time.

8. PHARMACY shall (a) safeguard the privacy of any records and information that identifies a particular Medicare Covered Person including, but not limited to, mental health records, medical records, and enrollment information so that information from, or copies of, such records may be released only to authorized individuals and unauthorized individuals are prevented from gaining access to or altering such records and information; (b) maintain the records and information in a timely and accurate manner; (c) ensure timely access by Medicare Covered Persons to such information that pertains to such Medicare Covered Person; and (d) abide by all federal and state laws regarding the confidentiality and disclosure for mental health records, medical records, other health information, and Medicare Covered Person information.

9. PHARMACY shall submit to Payor all data including, but not limited to, all medical records, necessary to characterize the content/purpose of each encounter with a Medicare Covered Persons. PHARMACY shall further ensure that the Chief Executive Officer of Provider shall (a) certify that any encounter data or any other information submitted to Payor pursuant or relevant to Payor's obligations under the Medicare Contract shall be complete, accurate, and truthful, (b) that Payor may rely upon such encounter data or other information in its submissions to CMS, and (c) to indemnify, defend and hold Payor harmless from any and all liability and costs, including, but not limited to, civil monetary penalties and reasonable attorneys fees, arising out of any false certification as described in (a) herein, and to contribute an appropriate share towards any liability incurred by Payor which partially arose from any such false certification.

10. Payor is required pursuant to the Medicare Contract to have an agreement with an independent quality review and improvement organization approved by CMS to monitor Payor's performance. PHARMACY agrees to comply with the activities of such independent quality review and improvement organization upon request by Payor.

11. PHARMACY shall cooperate with Payor's policies and procedures as promulgated by Payor including, but not limited to, quality improvement, utilization review activities and provider and/or enrollee appeals procedures.

12. PHARMACY acknowledges and understands that its credentials and certification shall be reviewed by Payor or its designee, from time to time, and that its performance shall be monitored by Payor or its designee on an ongoing basis.

13. To the extent that no prompt payment provision exists in the Agreement, PHARMACY shall pay all clean claims pursuant to New York State laws and regulations.

14. Except with respect to any applicable copayment, deductible or co-insurance, PHARMACY shall seek compensation or reimbursement for Covered Services from Payor only and PHARMACY shall not bill, charge, collect a deposit, seek compensation, recovery or attempt to obtain compensation or reimbursement from Medicare Covered Persons, CMS, or any other persons or entities acting on their behalf for any reason including, but not limited to, termination of this Agreement, Payor's insolvency, cessation of operations and/or failure to pay PHARMACY, unless:

(a) Payor has previously agreed that the service is not a Covered Service;

(b) PHARMACY has informed the Medicare Covered Person in advance of rendering a service that the service is not a Covered Service; and

(c) the Medicare Covered Person, in a written agreement, acknowledges that he/she is solely responsible for Payor's fee for such service.

PHARMACY agrees that, in the event that PHARMACY has not been given a list of Covered Services by Payor, and PHARMACY is uncertain as to whether a service is a Covered Service, PHARMACY shall make reasonable efforts to contact Payor and obtain a coverage determination prior to advising Medicare Covered Persons as to coverage liability for payment and prior to providing the service. PHARMACY shall indemnify and hold harmless Medicare Covered Persons, CMS and Payor from damages resulting from efforts to seek compensation for Covered Services to the extent prohibited by this provision.

15. In the event that the Agreement allows termination by any party without cause on less than sixty (60) days written notice, the notice required for termination without cause is hereby extended to not less than sixty (60) days written notice.

16. PHARMACY acknowledges that, pursuant to the Medicare Contract and Part 422 of the Code of Federal Regulations, PHARMACY is subject to certain laws that are applicable to individuals and entities receiving, in whole or part, federal funds. Therefore, PHARMACY shall comply with the terms of: (a) Title VI of the Civil Rights Act of 1964, as implemented by 45 C.F.R. Part 84; (b) the Age Discrimination Act of 1975, as implemented by 45 C.F.R. Part 91; (c) the Rehabilitation Act of 1973; (d) the Americans with Disabilities Act; (e) any other laws applicable to recipients of federal funds; and (f) all other applicable laws and regulations.

17. PHARMACY shall participate, cooperate and comply with Payor's and CMS' procedures for the resolution of Medicare Covered Person grievances and appeals.

18. To the extent that PHARMACY arranges for the provision of certain obligations required under the Agreement through other third parties ("Subcontractors"), all the terms and conditions of the Agreement and this Exhibit shall apply to such Subcontractors and PHARMACY shall ensure that such Subcontractors agree to and comply with all terms and conditions set forth in the Agreement and this Exhibit. PHARMACY agrees that all provisions of his/her/its agreements with Subcontractors shall be consistent with the terms of the Agreement and this Exhibit. Further, PHARMACY agrees to provide copies of such agreements to Payor upon request.

19. The parties agree that delegation of any of Payor's activities or responsibilities under the Medicare Contract to PHARMACY shall, to the extent necessary to comply with the Medicare+Choice Regulations, be governed by a separate schedule, which will be made a part of this Exhibit.

EXHIBIT E
FOR MARYLAND AND NEVADA PHARMACIES

WITNESSETH:

Now, therefore, for pharmacies in Maryland and Nevada, the parties hereby agree as follows:

Article 12, Term and Termination, Section 12.5, Termination without Cause, shall be added to the Agreement as follows:

"12.5 Termination without Cause.
Notwithstanding the foregoing, either party may terminate this Agreement by giving at least ninety (90) days prior written notice of the date of such termination to the other party."

EXHIBIT F
FOR SERVICES PROVIDED BY NEW JERSEY PHARMACIES TO MEMBERS COVERED UNDER FULLY INSURED BENEFIT PLANS

WITNESSETH:

NOW, THEREFORE, for services provided by New Jersey pharmacies to Covered Members under fully insured benefit plans, the parties hereby agree as follows:

Article 1, Definitions, Section 1.24, Clean Claim, shall be added to the Agreement as follows:

> "1.24 Clean Claim.
> Clean Claim shall mean a claim that has been submitted in accordance with Article 3 herein, and has no defect or impropriety, including any lack if required substantiating documentation, or particular circumstance requiring special treatment that otherwise prevents timely payment being made on the claim."

Article 3, Responsibilities and Obligations of PHARMACY, Section 3.1, Service Availability, of the Agreement shall include the following sentence at the end of the last sentence of the paragraph:

> "PHARMACY agrees to not differentiate or discriminate in the provision of Covered Services to Covered Members because of race, color, national origin, ancestry, religion, sex, marital status or age; and to render Covered Services in the same manner, in accordance with the same availability as offered PHARMACY's other patients."

Article 3, Responsibilities and Obligations of PHARMACY, Section 3.3, Claims Submission, of the Agreement shall be deleted and replaced with the following:

> "PHARMACY shall submit all claims through the on-line computer system established by WPM, and using best efforts to submit such claims within 72 hours after the date of service, but in no event later than sixty (60) days after the date of service when PHARMACY is not submitting the claims under an assignment of benefits from the Covered Member, or one hundred and eighty (180) days after the date of service when the PHARMACY is submitting the claim under an assignment of benefits from the Covered Member."

Article 3, Responsibilities and Obligations of PHARMACY, Section 3.4, Co-payments, of the Agreement shall include the following sentence at the end of the last sentence of the paragraph:

> "Furthermore, PHARMACY agrees that in no event, including nonpayment by WPM, insolvency of WPM, or breach of the Agreement, shall PHARMACY bill, charge, collect a deposit from, seek compensation, remuneration or reimbursement from, or have any recourse against Covered Member or person acting on behalf of Covered Member (other than WPM) for Covered Services provided under the Covered Member's Managed Prescription Drug Benefit Contract. This Section does not prohibit PHARMACY from collecting coinsurance, deductibles, or co-payments as required under the Covered Member's Managed Prescription Drug Benefit Contract, or from agreeing to continue services solely at the expense of the Covered Member, as long as PHARMACY has clearly informed the Covered Member that WPM may not cover or continue to cover a specific service or services."

Article 3, Responsibilities and Obligations of PHARMACY, Section 3.19, Professional Judgment, of the Agreement shall include the following sentence after the last sentence of the paragraph:

"Nothing herein exempts WPM from liability for WPM's negligent acts or conduct in the provision of its duties under this Agreement."

The first sentence of Article 3, Responsibilities and Obligations of PHARMACY, Section 3.21, Representation of PHARMACY, of the Agreement shall be deleted and replaced with the following:

"PHARMACY represents and agrees that it has, and shall have during each term of this Agreement, in full force and effect, all licenses, permits, certifications, and other approvals required under federal, state and/or local law in regard to services provided under this Agreement, and shall otherwise comply with all other federal, state and/or local laws in regard to services provided under the Agreement."

Article 3, Responsibilities and Obligations of PHARMACY, Section 3.26, Covered Member Communication, shall be added to the Agreement as follows:

"3.26 Covered Member Communication.
PHARMACY shall communicate openly with a Covered Member about all appropriate diagnostic testing and treatment options as appropriate to the scope of the PHARMACY's license."

The last sentence of Article 5, Compensation and Payment, Section 5.1, Payment, of the Agreement, shall be deleted and replaced with the following:

"WPM shall render payment for Clean Claims submitted by PHARMACY once sufficient funds have been made available by Payor for payment of such Clean Claims, but in no event later than i) thirty (30) calendar days after receipt of a Clean Claim by WPM, or ii) in the event of a claim under Medicare, the time established for the Federal Medicare program by 42 U.S.C. Section 1395u (c) (B) if earlier. In the event WPM fails to pay such a Clean Claim within these time limits, WPM shall include simple interest on the claim amount at the rate of ten (10) percent per year, which shall accrue beginning thirty (30) calendar days from the date all information and documentation required to process the claim is received by WPM. WPM shall add interest amounts payable in accordance with this Section to the claim amount, or render such interest amounts within fourteen (14) calendar days of the date the claim was paid."

Article 10, Governing Law and Dispute Resolution, Section 10.1, Choice of Law, of the Agreement is deleted and replaced with the following:

"This Agreement shall be construed in accordance with New Jersey law."

Article 10, Governing Law and Dispute Resolution, Section 10.2, Dispute Resolution, of the Agreement is deleted and replaced with the following:

"WPM and PHARMACY agree to meet and confer in good faith to resolve any problems or disputes that may arise under this Agreement. PHARMACY may initiate a formal review of any

complaint or grievance brought by PHARMACY by submitting the complaint or grievance to WPM in writing. WPM will review the complaint or grievance and communicate a written response to PHARMACY in accordance with the requirements of New Jersey law. Complaints or grievances brought by PHARMACY relating to payment of claims will be reviewed at no cost to the PHARMACY by a panel appointed by WPM, the Covered Members of which shall not be responsible for claims payment on a day to day basis, and a written response shall be communicated to PHARMACY within ten (10) business days after receipt of such complaint or grievance, or as otherwise required under New Jersey law. If any dispute, or complaint or grievance relating to payment of claims, arising under this Agreement is not satisfactorily resolved by the parties themselves, WPM and PHARMACY agree to submit such dispute, complaint or grievance to binding arbitration. The party wishing to initiate arbitration must notify the other party by written demand. Any such arbitration shall be held in New Jersey. Such arbitration shall be conducted in accordance with the commercial rules of the American Arbitration Association. The costs of the arbitration under this section shall be borne equally by the parities, and the results of the arbitration shall be issued no later than thirty (30) business days from the receipt by the arbitrator of all documentation necessary to complete its review."

Article 11, General Provisions, Section 11.3, Administration of Agreement, of the Agreement shall include the following after the last sentence:

"No provision in this Agreement or any references material shall require PHARMACY to violate the statutes or rules governing licensure of such PHARMACY in complying with the terms of such Agreement."

The last sentence of Article 11, General Provisions, Section 11.6, Compliance with Law and Regulations, of the Agreement shall be deleted and replaced with the following:

"In the event that any provision of this Agreement is determined to be in conflict with state or federal law, such provision will be deemed modified to the extent necessary to make it conform to the requirements of such law."

Article 12, Term and Termination, Sections 12.1, 12.2 and 12.3 of the Agreement shall be deleted and replaced with the following:

"12.1 This Agreement shall become effective as of the Effective Date appearing on the signature page hereof, and shall continue in effect from year to year unless terminated by the mutual written agreement of the parties.

a) Notwithstanding the foregoing, either party may terminate the Agreement without cause by giving to the other party at least ninety (90) days prior written notice of the date of termination.

b) WPM may immediately terminate this Agreement without notice at any time if PHARMACY (i) commits fraud, (ii) fails to meet its obligations under Article 3 above or otherwise breaches this Agreement, or (iii) in the sole discretion of WPM, represents an imminent danger to a Covered Member or the public health, safety and welfare.

c) Either party may, subject to applicable state law, terminate this Agreement at any time if the other party is adjudged bankrupt; voluntarily files a petition in or for bankruptcy,

reorganization or an arrangement with creditors; or makes a general assignment for the benefit of creditors by giving to the other party at least ninety (90) days prior written notice of the date of termination.

d) If WPM terminates this Agreement prior to the renewal date, other than pursuant to b) hereof, WPM shall provide PHARMACY with ninety (90) days prior written notice setting forth the reasons for termination ("Termination Notice"). Within ten (10) days of receipt of the Termination Notice, PHARMACY shall be entitled to request a hearing in writing with respect to the termination ("Hearing Request"). Within thirty (30) days of receipt of a Hearing Request, WPM shall hold a hearing before a panel appointed by WPM in accordance with N.J.A.C. 8:38A-4.9(b). The panel shall render a decision in writing within thirty (30) days of the close of the hearing, unless within such thirty (30) day period the panel provides notice to both PHARMACY and WPM of the need for an extension for rendering the decision.

e) In the event the Agreement terminates, PHARMACY agrees to continue to provide Covered Services under the terms of the Agreement, and at the contracted rates under the Agreement, to Covered Members for up to four (4) months following the date of termination when it is medically necessary for the Covered Member to continue such services, except as follows:

1) In the case of pregnancy of a Covered Member, medical necessity shall be deemed to have been demonstrated and coverage of services under the Agreement by the terminated PHARMACY shall continue to postpartum evaluation of the Covered Member, up to six (6) weeks after delivery;
2) In the case of post-operative care, coverage of services under the Agreement by the terminated PHARMACY shall continue for a period up to six (6) months;
3) In the case of oncological treatment, coverage of services under the Agreement by the terminated PHARMACY shall continue for a period up to one (1) year;
4) In the case of psychiatric treatment, coverage of services under the Agreement by the terminated PHARMACY shall continue for a period of up to one (1) year; and
5) In the event that the PHARMACY terminates the Agreement, coverage of services under the Agreement by the terminated PHARMACY shall continue for Covered Members who received services from the PHARMACY immediately prior to the date of termination for thirty (30) days following the date of termination, but for the remainder of the four (4) month period under e) only in cases were it is medically necessary to continue treatment with the terminated PHARMACY or in accordance with Items 1) through 4) above as they may apply.

Notwithstanding the forgoing under e), terminated PHARMACY shall not be required to continue to provide Covered Services under the Agreement in the event the Agreement terminates because i) WPM determines that PHARMACY is an imminent danger to one or more Covered Members or the public health, safety and welfare, ii) WPM determines that PHARMACY committed fraud, iii) WPM determines that PHARMACY breached the Agreement, or iv) PHARMACY is the subject of disciplinary action by any regulatory agency or board of the State of New Jersey.

f) PHARMACY's participation in the hearing process will not be deemed an abrogation of the PHARMACY's legal rights.

g) PHARMACY shall not be terminated or penalized solely for (i) acting as an advocate for a Covered Member seeking appropriate medically necessary health services, or (ii) for exercising his or her right to file a complaint, grievance or appeal, in accordance with procedures set forth in this Agreement.

h) Termination shall have no effect upon the rights and obligations of the parties arising out of any transactions occurring prior to the effective date of such termination."

Section 12.4, Compound Prescriptions, of the Agreement is re-numbered to be Section 12.2.

The foregoing Exhibit F is required to comply with New Jersey state law.

EXHIBIT G
FOR PHARMACIES LOCATED IN VIRGINIA

WITNESSETH:

Effective immediately for pharmacies located in Virginia, the parties hereby agree as follows:

Article 8, Section 8.2, Indemnification, shall be deleted in its entirety and replaced with the following:

PHARMACY hereby agrees that in no event, including, but not limited to nonpayment by Payor, the insolvency of the Payor or breach of this Agreement, shall PHARMACY bill, charge, collect a deposit from; seek compensation, remuneration or reimbursement from; or have any recourse against Covered Members or persons other than Payor for Covered Services provided pursuant to this Agreement. This provision shall not prohibit collection of any applicable Co-payments or deductibles billed in accordance with the terms of the Managed Prescription Drug Benefit contract. PHARMACY further agrees that (i) this provision shall survive the termination of this Agreement regardless of the cause giving rise to such termination and shall be construed to be for the benefit of the Payor's Covered Members and (ii) this provision supersedes any oral or written agreement to the contrary now existing or hereafter entered into between Payor and the Covered Member or persons acting on the Covered Member's behalf.

Except as specifically set forth herein, this notification will not change or affect the Agreement, which will otherwise remain in full force and effect.

EXHIBIT H
INDEPENDENT RETAIL PHARMACY QUESTIONNAIRE
(Please print or type)

Corporation Name

Contact Person

PHARMACY Name (If different)

Title

( )
Area Code Telephone Number

Address

( )
Area Code Fax Number

City

State Board of PHARMACY Registry No.

State Zip Code

NCPDP#

State Registry No. Expiration Date ATTACH A COPY OF STATE LICENSE.

PHARMACY DEA Number

Tax Identification No.

PHARMACY **Medicaid** Number

Provide the following information for all the owner(s) of the pharmacy. For stock owned companies, please list corporate officers. If needed, attach additional sheets. Include: Name and Title.

Software Vendor Information:

Vendor Name

Address

City, State, Zip Code

Contact Person

( )
Area Code Telephone Number

( )
Area Code Fax Number

Do you maintain professional liability and comprehensive general liability insurance:
YES ☐ NO ☐
If yes, what is:
the extent of coverage?

the name of your insurance carrier and broker (if applicable) ?

the expiration date? (copy of the insurance certificate required)

Is your pharmacy opened for business 24 hours a day? YES ☐ NO ☐
If no, please indicate your days and hours of operation below:

SUN **MON** **TUE** **WED**

THUR **FRI** **SAT**

Please provide details of PHARMACY's capabilities to provide:
24 Hour Services
Emergency
Services

Does your pharmacy provide:

DUR/Patient Counseling	YES ☐	NO ☐
Blood Pressure Monitoring	YES ☐	NO ☐
Compounding Services	YES ☐	NO ☐
Prescription Delivery Services	YES ☐	NO ☐

FOR OFFICE USE ONLY

Provider No.:
Date Entered:
Eff. Date:
Agr. Date:
Plan Code:
Agr. Code:
Processed by: **Date:**

WP 2004 09/04
Rev 9/15/04

SCHEDULE 1
COMPENSATION
WELLPOINT NATIONAL NETWORK

WPM, on behalf of Payor, or Covered Member (in a Covered Member Reimbursement Program) shall pay PHARMACY base compensation, for each Covered Prescription and Covered Refill provided to a Covered Member, at the lower of:

a. PHARMACY's Customary and Reasonable Charges; or

b. the lower of (1) 84% of the average wholesale price (AWP) of the Covered Prescription dispensed plus a Dispensing Fee of $1.85 for a brand and generic drugs, or (2) the Maximum Allowable Cost (MAC) of the Covered Prescription plus a Dispensing Fee of $1.85.

In addition to PHARMACY's receipt of the base compensation described above, PHARMACY shall be entitled to retain any co-pay amounts which exceed the above base compensation amount.

Taxes will be paid if the proper amount is electronically submitted in the tax field. Should there be a difference between the tax amount indicated by the Electronic Network and the originally submitted tax amount, the Electronic Network tax amount shall prevail.

EXPRESS SCRIPTS®
Creating the Future of Pharmacy
www.express-scripts.com

For Contract Questions:
866-296-9943

Network Enrollment Notification

Effective immediately, Express Scripts, Inc. (ESI) is consolidating networks that will include a 90-day at retail option for our clients.

Together we can create additional value for plan sponsors and their members with a network offering that encourages plan designs that incent generic use and low-cost brands.

Exhibit	Network
Exhibit #1000: A broad network (to include 90-day client option)	**Minimum** of 50,000 pharmacy locations **Important:** Member disruption will begin to occur and some members may not be able to go to your location(s) unless you accept the terms of the network enrollment form **Maximum** of 40,000 pharmacy locations
Exhibit #1001: The choice of a limited network (to include 90-day client option)	**Note:** Out-of-Network providers will either be excluded or members will pay higher copay differentials based on benefit design and retail location(s) participation (i.e., In-Network $5.00 and Out-of-Network $15.00) **Maximum** of 30,000 pharmacy locations
Exhibit #1001: A preferred / nonpreferred restricted network (to include 90-day client option)	**Note:** Out-of-Network providers will either by excluded or members will pay higher copay differentials based on benefit design and retail location(s) participation (i.e., In-Network $5.00 and Out-of-Network $15.00)

In addition to independent pharmacies contracting directly with Express Scripts, we recognize several Pharmacy Services Administrative Organizations (PSAOs) that contract, on behalf of independent pharmacies, for participation in our open and custom networks. There are cost efficiencies for Express Scripts and our clients when we work through PSAOs and we encourage you to review the attached list of PSAO organizations that ESI currently recognizes and ascertain whether the services they provide for independent pharmacies would be beneficial to your location.

Fax both Exhibits to 866.735.8559 by December 16, 2004.

Received Time Dec.10. 3:50PM

Express Scripts recognizes the following PSAOs:

AccessHealth
630 Morrison Road, #150
Gahanna, OH 43230

Please call us to learn AccessHealth can help you succeed in managed care pharmacy.
800-824-1763, option 3

FamilyCare & FamilyCare Plus
201 West St. John Street
P.O. Box 6052
Spartanburg, SC 29304
(864) 253-8600 ext. 7417
FamilyCare@qs1.com

Northeast Pharmacy Service Corporation
1661 Worcester Road
Suite 405
Framingham, MA 01701

(800) 532-3742

AWG
624 Westport Road
Kansas City, MO
64111

Leader Drug Stores
LeaderNET
(Cardinal Health)
7000 Cardinal Place
Dublin, OH 43017

For more information, please contact us at (888) 887-5323, or via email at LeaderNEThelpdesk@cardinal.com or on the web at Leaderdrug.com

United Drugs
National cooperative owned and operated by Independent Pharmacy Owners.
❖ *Third-party contractual relationships with national and regional managed care entities.*
For more information call 800-800-2988 or visit uniteddrugs.com

EPIC Pharmacy Network
6501 Mechanicsville Turnpike, Suite 103
Mechanicsville, VA 23111
(800) 876-3742

EPIC provides independent pharmacies with centralize 3rd party contracting, claims reconciliation, and accounts receivable services.

Major Value Pharmacy Network
740 Glasgow Ave.
Inglewood, CA 90301
(800) 227-4845 ext. 180

Yalonda Fotes, Manager

11/2004

Received Time Dec.10. 3:50PM

Express Scripts Pharmacy Enrollment Form

[redacted]mited and restricted networks will be open only to the maximum of 40,000 or 30,000 pharmacy stores, r[redacted]ctively, that have submitted the lowest reimbursement rates for that network.

Pharmacy Reimbursement Rates For Covered Medications. The lower of the Pharmacy's Usual and Customary Retail Price or the applicable rate below:

A limited network (not to exceed 40,000 locations)

	CONTRACT RATES	
	BRANDS Single-Source & Multi-Source** Brands and Generic Drugs without an ESI MAC	**GENERICS** Generic Drugs and Multi-Source Brands with an ESI MAC
30 Day	AWP - [ ] + $ [ ] (Minimum expected: AWP -16 +$1.00)	ESI MAC + $2.00
90 Day* ☐ Accept***	AWP - [ ] + $ [ ] (Minimum expected: AWP -20 + $1.00)	ESI MAC + $1.00

A restricted network (not to exceed 30,000 locations)

	CONTRACT RATES	
	BRANDS Single-Source & Multi-Source** Brands and Generic Drugs without an ESI MAC	**GENERICS** Generic Drugs and Multi-Source Brands with an ESI MAC
30 Day	AWP - [ ] + $ [ ] (Minimum expected: AWP -17 + $2.00)	ESI MAC + $2.00
90 Day* ☐ Accept***	AWP - [ ] + $ [ ] (Minimum expected: AWP -21 + $1.00)	ESI MAC + $1.00

*If client chooses a benefit design that covers excess days supply, then
30-day rate covers 1-83 days
90-day rate covers 84-90 days

**Multi-Source pricing depends on the DAW code utilized and design of the specific plan.

*** You **must** indicate your acceptance to participate in the 90 day network by checking the box above. If it is unchecked, your pharmacy will not be a participating provider for the 90 day component of the network

To the extent permitted by law, any disputes concerning this Agreement shall be resolve through arbitration.

ACCEPTED:

FAX: 866-735-8559

Pharmacy Name

Signature

Chain Code or NCPDP Number

Print Name

[redacted] Address

Title

[redacted], Zip Code

Date

11/2004

Received Time Dec.10. 3:50PM

Express Scripts Pharmacy Enrollment Form

ESI has created ExpressNet, which is an omnibus network that includes ESI's PerxSelect network, PERxCare network and Premier network, as well as the new 90-day networks described below. The rates set forth below shall supersede and replace all rates currently in effect between ESI and Provider effective on 11/1/2004 for the following networks: PERxSelect, PERxCare and Premier.

Pharmacy Reimbursement Rates For Covered Medications. The lower of the Pharmacy's Usual and Customary Retail Price or the applicable rate below:

A broad access network (50,000+ locations)

	CONTRACT RATES	
	BRANDS Single-Source & Multi-Source** Brands and Generic Drugs without an ESI MAC	**GENERICS** Generic Drugs and Multi-Source Brands with an ESI MAC
30 Day	AWP -16 + $2.00	ESI MAC + $2.00
90 Day*	AWP -19 + $1.00	ESI MAC + $1.00
Accept***		

* If client chooses a benefit design that covers excess days supply, then
30-day rate covers 1-83 days
90-day rate covers 84-90 days

**Multi-Source pricing depends on the DAW code utilized and design of the specific plan.

*** You **must** indicate your acceptance to participate in the 90 day network by checking the box above. If i is unchecked, your pharmacy will not be a participating provider for the 90 day component of the network.

To the extent permitted by law, any disputes concerning this Agreement shall be resolve through arbitration.

ACCEPTED:

Pharmacy Name

Chain Code or NCPDP Number

Street Address

City, State, Zip Code

Signature

Print Name

Title

Date

FAX Number: 866-735-8559

11/2004

Received Time Dec.10. 3:50PM

EXPRESS SCRIPTS
Charting the Future of Pharmacy

Pharmacy Benefit Managers

Vernon C. Rowen
Vice President
State Government Affairs
Express Scripts, Inc.

January 25, 2005

Pharmacy Benefit Managers (PBMs)

- Manage prescription drug benefits for 200 million Americans
- About 60 PBMs manage nearly 80 percent of prescription drug expenditures in U.S.
- PBM clients include health plans, employers, unions, and government programs such as state employee benefit plans
- PBMs can be stand-alone entities or subsidiaries of health plans or chain drug stores

Unique Role of PBMs

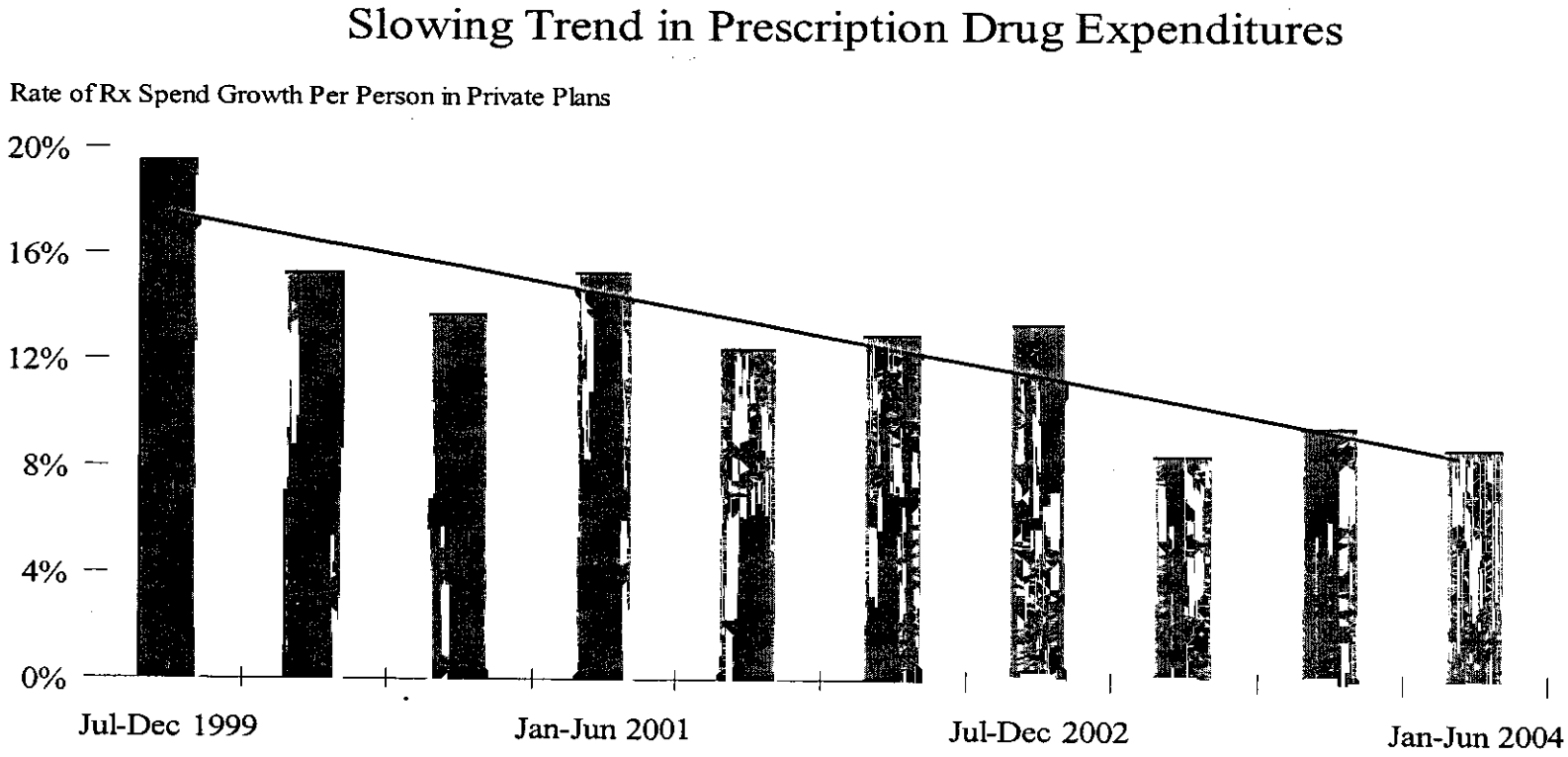
Only entities in the drug supply chain dedicated to *lowering cost* and *increasing quality*

- Advise plan sponsors on benefit design options
- Pool purchasing ability of millions of consumers to negotiate lower drug prices
- Link networks of pharmacies nationwide
- Use cost and quality management tools to make drug benefits safer and more affordable

History of PBMs

- Emerged in the 1980s to administer prescription drug insurance benefits
- Gradually expanded to include clinical services; mail service pharmacy also became prominent
- Significant growth in the 1990s as managed care organizations and self-insured employers turned to PBMs to administer their drug benefits
- Today: 60 PBMs compete vigorously in a well-developed market for PBM services

PBM Tools at Work: Decline in the Rate of Growth of Drug Expenditures



Center for Studying Health System Change, December, 2004

PBM Tools & Techniques

- Formulary Management
  - ✓ P&T Committees
  - ✓ Negotiated discounts
  - ✓ Tiered cost sharing
  - ✓ Generic substitution
  - ✓ Cost-effective products
  - ✓ Step therapy
- Drug utilization review (DUR)
- Mail-service and specialty pharmacies
- Patient compliance and disease management
- E-prescribing
- Pharmacy Networks

The PBM Marketplace Today

Perception: The PBM market is dominated by a few large companies

Reality:

- Many types of PBMs exist: large independent "stand-alones", health plan-sponsored PBMs, pharmacy-owned and regional PBMs, all offering different products and services
- The FTC, in approving a recent merger of two PBMs, found the competition between PBMs for contracts with plan sponsors to be 'vigorous'

The PBM Marketplace Today

Perception: PBM contracts are one-size-fits-all

Reality:

- PBMs have specialized offerings to meet individual plan sponsor's needs
- Plan sponsors are sophisticated and knowledgeable and often use brokers/consultants to assist and advise on RFP development and evaluation of bids
- Results in an inherent complexity in the market as different products are crafted to meet different needs

The Competitive Process for Business

- Plan sponsors request bids from many PBMs
- Sponsors have full discretion in requests
- Sponsors can, and do, request alternative pricing structures (e.g. per claim administrative fee, rebate share or rebate guarantee, etc.)
- Sponsors request custom-made products which include audit rights (64% of plan sponsors audited their PBM in the past year*)

*Source: EvergreenRe Survey, "64% of Health Plans Audit Their PBMs", April 20, 2004.

PBM Competition Benefits Plan Sponsors

- To remain competitive, PBMs work with pharmacies and manufacturers to deliver the best prices to sponsors
- Competition spurs innovation and development of new services as PBMs strive to differentiate themselves
- Motivated by competition for market share, PBMs will continue to seek better ways to serve their current clients:
  - Improved quality of service
  - Continual management of prescription drug costs

Value of PBMs—Increasing Evidence

Congressional Budget Office Study

PBMs have the potential to save as much as **30 percent** in total drug spending relative to unmanaged purchases of prescription drugs where PBMs can use their full range of price discounts and rebates, utilization control tools, and other tools for encouraging appropriate utilization (October 2002)

Value of PBMs—Increasing Evidence

General Accounting Office Study of FEHBP PBMs

- PBMs obtain discounted prices significantly below those paid by cash-paying customers
- PBMs obtain greater discounts from retail pharmacies than did state Medicaid programs
- PBMs provide enrollees generally unrestricted access to prescription drugs, cost savings, and other benefits
- PBMs provide enrollees access to broad retail pharmacy networks
- Enrollees benefit from PBM drug utilization review programs and customer service (January 2003)

Federal Trade Commission Conclusions on PBMs

- "[w]e found the competition between PBMs for contracts with plan sponsors to be 'vigorous.'" (Source: *In re* Caremark Rx, Inc. / AdvancePCS, February 11, 2004)
- "[v]igorous competition in the marketplace for PBMs is more likely to arrive at an economically efficient level of transparency than regulation of those terms." (Source: FTC letter to Assembly Member Greg Aghazarian on California's AB1960)
- Vigorous competition is also more likely to help ensure that gains from cost savings are passed on to consumers of health care services, either as lower premiums for health insurance, lower out-of-pocket costs…or improved services. (Source: Improving Health Care: A Dose of Competition, A Report by the FTC and DOJ, July 2004)

Value of PBMs—Increasing Evidence

Joint Federal Trade Commission (FTC) and Department of Justice (DoJ) Report

- "Vigorous competition in the marketplace for PBMs is more likely to arrive at an optimal level of transparency than regulation of those terms."
- "Consumers with prescription drug insurance administered by a PBM save substantially on their drug costs as compared to cash-paying customers."
- "The growth of PBMs is an important development in providing consumer access to prescription drugs."

Value of PBMs—Increasing Evidence

PricewaterhouseCoopers Study

- Pharmacy benefit management reduces prescription drug costs by 25 percent compared to retail purchases with no pharmacy benefit management
- Pharmacy benefit management will save $1.3 *trillion* in drug expenditures over the next 10 years
- Pharmacy benefit management will reduce costs by $268 per enrollee in private plans, or $53 billion in total in 2005.

Source: The Value of Pharmacy Benefit Management and the National Cost Impact of Proposed PBM Legislation, PricewaterhouseCoopers, June 2004

Summary

- PBMs play a unique role in holding down costs and increasing quality
- Growing body of evidence underscores PBMs' proven ability to deliver savings for plan sponsors and consumers
- The marketplace is working
- Restrictions on PBMs would impact all payers, public and private while providing no benefit to consumers

NDPhA
NORTH DAKOTA PHARMACISTS ASSOCIATION

January 18, 2005

Representative Don Vigesaa
Member
IBL Committee
P.O. Box 763
Cooperstown ND 58425-0763

Dear Representative Vigesaa:

On Tuesday, January 25, 2005 the IBL Committee will hear the arguments for HB 1332 that would regulate pharmacy benefit managers (PBMs) who choose to operate in North Dakota. On behalf of the 650 pharmacists who are members of this association, we write to request your support for HB 1332.

HB 1332 – the ***Employer's Right to Know*** bill - requires PBMs to disclose information about rebates, discounts, and other revenue streams to the employers who are sponsoring healthcare plans for their employees. This information is directly related to negotiations between PBMs and drug manufacturers for the products that become part of formularies in healthcare plans with a pharmacy benefit. *(Note: PBMs are third party administrators for the prescription drug benefit portion of a health plan).*

The concerns that motivated introduction of HB 1332, include:

- Escalating healthcare costs, especially prescription medications
- The myth that increases can be attributed to the pharmacy
- A myriad of litigation against PBMs in the past two years has uncovered numerous schemes being used by PBMs to retain rebates, discounts and other revenues rather than pass these savings on to the plan sponsors and, ultimately, consumers
- Mail order pharmacies owned by PBMs are diminishing the Patient's Right to Choose the pharmacy provider they prefer, by giving financial incentives to use the PBM's mail order rather than the local provider

With no regulation at the state or federal level, PBMs are free to continue with inappropriate business practices that have been identified as contributing to higher drug costs in the US. For example, the public employees group in Texas experienced a 245% increase in the cost of their pharmacy benefit over the past four years while under the administration of one of the largest PBMs in the country. And when they asked for detailed accounting of why this happened, they were told that information was proprietary and they could not have it. In fact, the PBM recently filed suit to keep the state of Texas in the dark.

A lawsuit against the PBM - Medco by 20 states and the US Justice Department was settled out of court last summer, with the PBM paying a $30 million penalty and agreeing to disclosure, notification, and passing through savings they had been keeping from the consumers in these twenty states. A second lawsuit by 19 states against Caremark (2nd largest PBM) alleges the same inappropriate business activities and seeks retribution for skyrocketing costs as well as future disclosure to guarantee consumer protection.

This is the type of activity we want to avoid in North Dakota. We are a sunshine state by tradition, and HB 1332 supports transparency while protecting the proprietary nature of the information by limiting access to the employers who sponsor the healthcare plans and the ND Insurance Department, which would provide oversight and regulations.

The concern about mail order is a real threat to pharmacies in North Dakota, and their ability to stay open so patients have access to their local pharmacist. In addition to the large national PBMs that operate in North Dakota who often mandate patients to use their mail order facilities in other states, the regional PBM – Prime Therapeutics, which is owned by the Blue Cross and Blue Shield organizations in six states (including ND and MN) opened their own mail order facility in Texas in 2004 and have been providing disincentives for patients to continue to use their local pharmacies. The situation has raised so much concern in Minnesota that it is under investigation by the Attorney General.

As lawmakers, you have seen the devastating impact on economies and lives as smaller communities loose businesses and jobs. You know that the economic impact of one business can be multiplied seven times in a community to fuel the engine that keeps the community alive. NORTH DAKOTA PHARMACIES ARE AT RISK and your community could be affected. Talk to your local pharmacist and get the details on PBMs, their schemes to keep substantial savings from reaching the consumer, and their quest to convert 90% of all Americans to their own mail order pharmacies in the future.

WE ASK YOUR SUPPORT FOR HB 1332. Thank you for your time and consideration. If you have questions at any time, please feel free to contact our office.

Sincerely,

Dr. Patricia A. Hill, Executive Vice President

cc:
Representative Clara Sue Price
Representative William Devlin
Senator Judy Lee
Senator Tom Fischer

Testimony before the House Industry, Business and Labor Committee
George Keiser, Chairman
January 25, 2005

RE: Support of HB 1332

Patricia A. Hill, PhD
Executive Vice President
ND Pharmacists Association

Good morning Mr. Chairman and members of the Committee. For the record my name is Patricia Hill. I am the Executive Vice President for the North Dakota Pharmacists Association and I am here in support of House Bill 1332.

We are all well aware of the healthcare crisis in this country, with escalating costs making it more difficult for employers to provide health plans for employees...and equally difficult for employees to bear additional expense with higher co pays or reduced coverage. As a public policy issue you search for ways to lower these costs so more of your constituents can access the services they need, or at least retain the coverage they currently have.

But increasing premiums, exceeding 20 percent annually, are a very real threat. That's why this bill is called the ***"Employers Right to Know"*** – giving employers who sponsor healthcare plans for their employees the opportunity to know every detail of the financial processes that ultimately affect the cost of the pharmacy benefit they have purchased.

The key concerns are addressed in HB 1332:

- Prescription drug costs continue to rise
- Pharmacy benefit costs continue to escalate, making this option more difficult for employers to provide their employees, and requiring employees to pay more for their prescription drugs
- Pharmacy Benefit Managers (PBMs) contribute to the rising cost of medications in the United States

We'll start with a basic definition of what a pharmacy benefit manager is. If you open the green binder in front of you, the first page has a diagram that describes a business relationship between the pharmacy, the patient, the PBM and the sponsor of the healthcare plan. PBMs originated about 20 years ago to process claims for prescription medications, and they received a fee for those services. Today, claims processing is a small part of what they do. PBMs negotiate "deals" with drug companies who compete to have their products included on the PBM's formularies. As you probably know, being included on these formularies virtually guarantees that your product is prescribed and purchased most of the time, which is a good way to gain market share.

How do we know PBMs contribute to the cost of medications? From the myriad of litigation against pharmacy benefit managers that has permeated the courts in the last two years, bringing to light some questionable business practices directly related to the rebates, discounts and other revenue streams generated from the negotiations between PBMs and drug manufacturers.

Prior to all the lawsuits and investigations, it was very difficult to determine the actual cost of prescription medications because – as you will hear from opponents of this bill – these secret negotiations are the only way to provide savings. PBMs consider their various sources of revenue

including rebates, discounts, marketing fees, education grants, market share rebates, and administrative fees... to name a few... to be confidential trade secrets. They are certain that sharing this proprietary information - even with the employers who are paying the premiums for their employees to receive these pharmacy benefits - would reduce their effectiveness with the drug companies. Yet they insist we should trust them to negotiate in the best interest of their clients, when they carry no risk, have no inventory, and refuse to accept fiduciary responsibility for the millions of lives they represent. Perhaps they truly are talented negotiators but the concern is that they are keeping a lion's share of the savings.

Some State's Attorneys now believe a significant part of the skyrocketing cost of drugs is directly related to savings that are not passed on to the sponsors of the health plans. The public employees of Texas are a good example. Under the administration of the PBM Medco Health Solutions, our nation's largest PBM, they have had 245% increases in the cost of prescription medications. They are demanding to know the details of why this happened, and Medco has filed suit against the Attorney General to avoid disclosure even though the AG ruled several months ago that contracts with public entities were public information.

I'm going to cover more details in the lawsuits in a minute but first I want to dispel the myth that cutting the reimbursement to the pharmacy is an effective way to contain costs. If you look in your Portfolio of exhibitsunder Tab A, page 1 you will see a diagram provided by researchers at the University of Minnesota's Prime Institute. As you can see, this is Medicaid data for which states are able to obtain the best possible prices in the market, because it is a government program. At the least expensive rate available, you can see that 20 years ago you could attribute 63% of prescriptions costs to the cost of the product and 37% to the pharmacy. By contrast, a mere 10% of what we pay for a drug today goes to the pharmacy! And on page 2, you can see that profits as a percent of revenue has declined to an all time low of 3 percent for pharmacies, while drug companies are climbing toward 20 percent...outperforming even the best Fortune 500 companies by nearly 4 to 1.

At the request of the bill's sponsors and the committee chair, I will present some examples that demonstrate our concerns with PBMs - to support our claim that HB 1332 is indeed necessary in North Dakota, and we are not immune from the inappropriate business practices discovered in other parts of the country. Opponents of HB 1332 may say that market competition is what guarantees the best consumer price, but I would argue that the market theory may have worked ten years ago when there were over 125 PBMs competing for business based on price and quality, but today with the three giant PBMs in the country representing 70% of consumers, and a few regional PBMs for everyone else the market doesn't generate the same results. And the ability of PBMs to dictate the parameters of the competition makes it even more difficult to determine if they are offering the best possible options to consumers...unless they tell us, which is what they object to.

As I said, through numerous lawsuits and investigations all over the country in the past two years we have uncovered potential savings that are not being passed on to consumers. Under Tab B, pages 1 through 5 you'll find a long list of these lawsuits, followed by a 3 page announcement from the US Justice Department with details of a settlement for $29 million between Medco and 20 states who alleged unfair trade practices, affecting millions of lives. Medco Health Solutions settled out of court in 2004 to end the investigation that had already uncovered numerous schemes to pocket rebates, disguise discounts, funnel money to other retained fees, and perhaps one of the most flagrant offenses was the drug switching schemes - where drugs were put on formularies based on the highest rebate with no consideration for what would be best for the patient, AND these discounts were not passed on to the plan sponsors. Keep in mind, the PBM agreed to disclosure and fiduciary stipulations in addition to the $29 million penalty, and that settled only the first of five counts in that lawsuit.

In a similar suit, 19 states filed against Caremark, the 2nd largest PBM in the US...alleging the same unethical business practices. And in New York, the state is suing Express Scripts – the 3rd largest PBM. Attorney General Elliot Spitzer said, "rather than being part of a solution to our health care crisis by keeping costs as low as possible, we discovered that Express Scripts has engaged in a series of deceptive schemes... they improperly lined their pockets at the expense of health plans and consumers – driving up the very costs they were suppose to lower."

As listed on page 6 of this section, Medco agreed to stop switching drugs, but they also agreed to disclose to prescribers and patients the actual savings and the financial incentives attached to each medication. Medco also agreed to adopt the code of ethics and principles of practice for pharmaceutical care from the American Pharmacists Association, for employees at their mail order facilities and call centers.

But if you thought Medco learned a lesson in all this, consider the circumstances surrounding their reaction to the settlement on page 8. They simply raised the mandated processing fee paid by each pharmacy by 7 cents thus generating $75 to $100 million annually...more than enough to cover several court settlements. And there isn't a state or federal regulation to stop them from changing these rates whenever they decide to.

Perhaps if the lawsuits have not convinced you that PBMs are using various schemes to generate profits at the expense of consumers, consider the exhibit under Tab C page 1. Here you have a news article based on comments from Tim Dickman, CEO of Prime Therapeutics, the regional PBM based out of Minnesota that is owned by six Blue Cross Blue Shield Organizations including North Dakota. Mr. Dickman admits that PBMs are using schemes to extract revenue from drug manufacturers and keeping too much of the money, and he goes on to add other revenue streams that need adjusting such as selling patient data to drug companies, mail order pricing, and research funds. He calls these revenue streams "pervasive in recent years" and questions the loyalty of PBMs to the point of suggesting the need for an entirely new business model that

- returns to the fee for service structure
- developing an equitable formula to share the rebates with clients
- adopting government regulation that prohibits rebates.

In this article from 2003, Mr. Dickman specifically says PBMs should expect regulation if they fail to take corrective action soon.

Mr. Dickman's prediction was right! That is exactly what is happening all across the country – because PBMs have not taken corrective action many states have begun to develop regulations. We are at Tab D now, pages 1 through 6 which includes an executive summary of the legislation introduced in dozens of states in 2003 and 2004 to address these concerns with PBMs. And in addition 15 or 20 states talking about regulating PBMs, look at the list of other bills introduced to try to get a grip on the rising cost of medications! Bulk purchasing, prices and discounts, state sponsored programs, preferred drug lists, subsidies, mail order, labeling, importation, and the list goes on!

The opponents of HB 1332 may try to tell you that this long list of public policy discussions by your colleagues all over the country is NOT an indication of their interest or concern about these issues. I've heard them say that 15 states introduced PBM legislation and it has died in all but 5, with two on hold while an injunction by the PBMS is resolved. And you are supposed to believe that describes a disinterest by policy makers in the United States. It is clear, when legislative bodies introduced more than 230 bills in 2003 and another 250 in 2004 dealing with the increasing cost of drugs... they are DEFINITELY CONCERNED and will continue to seek remedies. Oh and by the way, of the PBM legislation introduced in 2003 & 2004 that did not actually pass – no action was taken on

26 of those bills by the end of the legislative session, meaning there is the option for consideration later.

On pages 7 through 9 of that same section you will find a listing of the 5 states that have passed PBM legislation, the most recent in South Dakota last summer. HB 1332 is based on the South Dakota legislation which was revised and adjusted to accommodate many of the concerns that arose with previous bills introduced Maine, the District of Columbia, and California. The PBMs filed injunctions in Maine and the District of Columbia to stop the implementation of those laws, but the outcome of those court cases is pending with no way to predict whether the findings will favor either side. It is interesting to note that the PBMs filed an injunction against a second bill in Maine at the same time, but that is now law in Maine, with the courts finding in favor of the state to create its own PBM. But keep in mind, HB 1332 is based on a series of revisions that led to passage of the legislation in South Dakota which we used as our model.

If you move to Tab E, page 1 you find a Wall Street Journal article highlighting Advance PCS - one of many PBMs who use "spreads" as an additional source of profits. What's a "spread?" Essentially, it's another questionable business practice to create more revenue for PBMs. In the article it is described as the difference between a higher cost charged to clients compared to the amount reimbursed to the pharmacy. Under the same Tab E, pages 2, 3 and 4 you have an example of how spreads are occurring in North Dakota. What you see are 15 claims extracted from a dozen pages of actual forms from a pharmacy within 100 miles of Bismarck. You'll notice on the far right, that two columns labeled "Co pay" and "Amount Paid by PBM" are equal to the two columns to the left of the horizontal line, which when added together equal what is paid to the pharmacy for providing the prescription to the patient. If you would please keep in mind the amount at the far right in #1 – the amount paid by the PBM is zero, and then turn to page 4 and compare that to the amount listed under #1 under "Invoice to the Plan" and see that the PBM paid nothing to the pharmacy as part of the reimbursement but turned around and charged the plan sponsor $7.44 for that claim. That is a "spread" and the list of 15 examples is not the complete listing from the 3 months of billing statements that these claims came from.

And I would just like to point out, that on page 4 in the far right column is a 25 cent charge which the pharmacy pays to this PBM to process the claim. It is not a negotiated amount - it is mandated by the PBM, just like the rates that are determined by the PBM to reimburse the pharmacy.

Tim Dickman, CEO of Prime Therapeutics, specifically says in this Wall Street Journal article that using 'spreads" is a common practice with most PBMs but not his. He says Prime's marketing message resonates disclosure of revenue streams which clients appreciate, and he specifically cites the fact that the Blue Cross health plans using Prime Therapeutics as their PBM have equity in the company and are more comfortable with operations because of their ownership position. I'm sure from his position that statement appears to be positive, but there are customers who believe the ownership issue may represent a direct conflict of interest.

For example, an employer and sponsor of a health plan for employees under Blue Cross Blue Shield of MN contacted Prime Therapeutics last month for information about the rebates and discounts associated with HIS plan, only to be told that he could not have the information – it was ONLY provided to the BCBS companies that own Prime. And in the letter he received from BCBS they admitted that the revenue streams originating at Prime through negotiations with drug manufacturers do, indeed, get forwarded to BCBS where they are factored into the rates that determine insurance premiums (Exhibits-Section E). Of course, they keep some undisclosed share for administrative purposes. Think about that for a minute... the insurance premiums to employers

increase by 18% to 20% each year, and that is the reduced rate after factoring in millions of dollars generated through rebates, discounts, fees, and grants.

If you'll turn to Tab F, pages 1 through 5, you'll find the first exhibit in this section that leads consumers and plan sponsors to doubt if in fact Prime Therapeutics is all they claim to be. Here you see two examples of pricing practices that do not represent the best interest of the patient:

1. A patient comes into a pharmacy for Glucophage XR 750 mg., a drug used by diabetics. Prime allows the more expensive brand name drug to be dispensed and paid for but when the pharmacist attempts to give the patient a less expensive generic brand that is therapeutically equivalent the claim is rejected because the generic is not on the formulary. In this instance, the patient is forced to pay 22 cents more for each dose than is necessary.

   Unfortunately, in many compliance studies you find patients with chronic illnesses like diabetes seeking acute care at the ER and hospital because they have not taken the medications prescribed to keep them healthy. The prescriptions were too costly for the patients to buy.

2. The second example is a case where the patient can choose either the brand name drug or the generic to treat high blood pressure. If the patient chooses the generic his co pay rose from $43.96 to $69.24 – a disincentive to the patient of more than $25. Compared to the brand name drug, Plendil, which did not require the patient to pay the additional co pay of $25.28 --- BUT, the charge to the plan sponsor went from $44.24 to $86.88, or $42.64 more!

Use of formulas like this, which pharmacies see every day from all PBMs, leave plenty of doubt about what contributes to the cost of prescription medications.

If you will please turn to Tab G, page 1 you will see a demonstration by a consumer who went to his local pharmacy to have three prescriptions filled, then ordered the exact same three medications through his sponsor's plan with Prime Therapeutics' mail order pharmacy in Texas.

As you can see, the cost to purchase those medications locally was $58.81 and his plan was charged nothing. Prime's mail order charges cost him $79.06, or an extra $20.25....BUT that wasn't the total - his health plan sponsors was charged an additional $15.46 for a total cost of more than $35 compared to simply going downtown to the local pharmacy. It is a common practice for PBMs with mail order facilities to administer plans that offer financial incentives for patients to avoid getting their prescriptions locally. There is NO recourse for the local pharmacy...they are not allowed to counter offer incentives to keep patients. The PBM has control of these processes, including costs and choice. In this instance, the consumer is concerned that his freedom to choose the provider he prefers has been taken away and he wants it back.

These mail order incentives were recently investigated by the Attorney General in Minnesota and deemed to be inappropriate. In private negotiations, Prime Therapeutics agreed to adjust their mail order activities. North Dakota currently has a Patient's Freedom of Choice statute, but these mail order issues were apparently not anticipated, and not addressed when the law was enacted. HB 1332 would support more patient choice.

Are you still wondering if all the concerns about PBMs and the disclosure of information to the employers is actually occurring in North Dakota? Then I offer you one final exhibit – Tab H - an article by Dale Wetzel of the Associated Press highlighting a series of concerns arising from the

introduction of the Medicare-approved Drug Discount Cards last May and June. Among the 42 cards approved for North Dakota Seniors was one from Prime Therapeutics, which was marketed in a way that convinced our elderly that the card was actually from Blue Cross. The insurance commissioner strongly objected to this co-branding technique, calling the tactic a possible violation of antitrust laws. As the Seniors were receiving the promotional materials for this card, six pharmacies in various locations across the state received threatening phone calls from representatives of Prime Therapeutics saying if they did not promote Prime's Medicare-approved discount card they would loose their option to participate in other BCBS programs. Since Blue Cross is the insurance provider for 80 percent or more of North Dakota these pharmacies were very intimated.

I want to be clear - Prime Therapeutics was certainly not the only PBM causing concern when these cards were introduced. Our Senior citizens were overwhelmed with schemes and activities from many PBMs, all trying to get our Medicare recipients to take their card. Why such an extensive effort? Because Medicare represent the largest, single customer in the world! And PBMs want their share of the $500 billion contract to deliver pharmacy benefits to our nation's elderly. The extent of activity in North Dakota created such a stir that the Region 8 office for the Centers for Medicare and Medicaid launched an investigation. As a result of our diligence and advocacy for North Dakota Seniors, CMS granted an additional exception for Seniors to switch cards at any time – if they had been misled by the promotional tactics of a PBM. Keep in mind, that North Dakota has over 100,000 Medicare recipients who will have to deal with the federal drug benefit being launched one year from now.

I'd like to close by sharing the recent experiences of a young couple in Fargo, who agreed that you should hear about this as part of your deliberations. It's important that we don't forget the real focus of what we are trying to accomplish here today... improve patient care - make people healthier - do what we can to lower cost so more people have access to the care they need, when the need it most. Arlin and Megan were expecting twins last summer and to keep this fragile pregnancy in tact for as long as possible Megan had to, religiously, take a daily medication prescribed by her OBGYN. The Fisher's healthcare plan mandates mail order, so Megan and Arlin got a little nervous when her refill hadn't arrived on August 30 and she only had ten days left.

Missing one day meant contractions could start and their twins would be born too soon, so they called the PBM and were promised that the refill would arrive within 8 days. Four days to go and still no medication from the PBM, so Arlin calls again. They are told the "meds are in the mail." Two days to go and they are worried, so they call the doctor who has the local pharmacy fill a five-day supply, expecting the refill from the PBM to arrive soon. Arlin goes to the pharmacy and personally pays for the 5-day refill.

On September 10, the last day of Megan's current supply, a letter arrives from the PBM saying they could not reach her doctor to verify the refilled prescription so it was not sent. Knowing the time-sensitive nature of Megan's condition and the critical need for the medication to keep her pregnancy in tact, the PBM did not follow through to guarantee the refill was sent and received. Arlin and Megan were never notified that the PBM would be communicating with the doctor to gain approval on a refill, they were simply told it had been taken care of. As you can imagine, this created a great deal of stress. Again, they called the doctor who called the PBM himself to arrange for the prescription to be sent, and Arlin went back to the local pharmacy for a few more days supply.

By mid-September the refill had still not arrived as promised, so Arlin AGAIN called the PBM and was told that their doctor had cancelled the refill so the medication had not been sent. They called the doctor who absolutely denied any such conversation, and contacted the local pharmacy for a third time to be sure Arlin could pick up additional doses for Megan and not risk missing one dose.

At this point Arlin contacted the home office of his employer – the sponsor of his family's healthcare plan – and explained what had been going on. Within the hour, the human services department at Microsoft in Seattle had made the necessary calls to the PBM to help Arlin and Megan with their crisis. They were granted an exemption from mail order, so Megan's prescription could be filled locallyl until the babies were born. Two days later a check arrived from the company, to reimburse Arlin for the three weeks of medication he had been forced to purchase out of his own pocket.

Fortunately, the Fishers were able to make it through this crisis and had the finances to pay for Megan's medications. Jerrod and Jacob were born about 2 months ago – just a couple weeks shy of a full term. They are doing very well, thank goodness. Arlin said to be sure you know that they would prefer to use their local pharmacy but their healthcare plan mandates use of mail order. They hope as you deliberate on this issue you will consider more than just money issues, and remember the impact on patients. In this case, the PBM made choices for Arlin and Megan that put lives at risk. The Fishers would prefer to go to the local pharmacy for many reasons, but they don't have the freedom to make that choice.

The question at this point is whether or not you believe, beyond a reasonable doubt, that PBMs operating in North Dakota are ALL making choices about the drugs and services they provide based on what works best for them OR based on the health and welfare of the patients. The ND Supreme Court ruled that the legislature's responsibility is not to find a perfect cure or the best solution, but to take action to diminish a perceived threat in order to protect the public health, safety and welfare. I propose that you will hear more than sufficient evidence today to raise more than a reasonable doubt, and I strongly encourage you to represent the interest of the consumers and support HB 1332.

In closing, I request your support for HB 1332. This bill provides solutions to address the concerns about business practices of ALL pharmacy benefit managers who choose to operate in North Dakota through the following requirements:

- Disclosure of all rebates, discounts, and other revenue streams that are derived from negotiations between the PBM and drug manufacturers who want their products included in health plans administered by the PBM.
- Limit the ability of PBMs to switch drugs by providing the guidelines and conditions under which this would be authorized.
- Provide oversight through the ND Insurance Department, including licensing, certification, and administrative rules as necessary.
- PBMs to exercise good faith and fair dealing toward the plan sponsors.

Thank you for your support.

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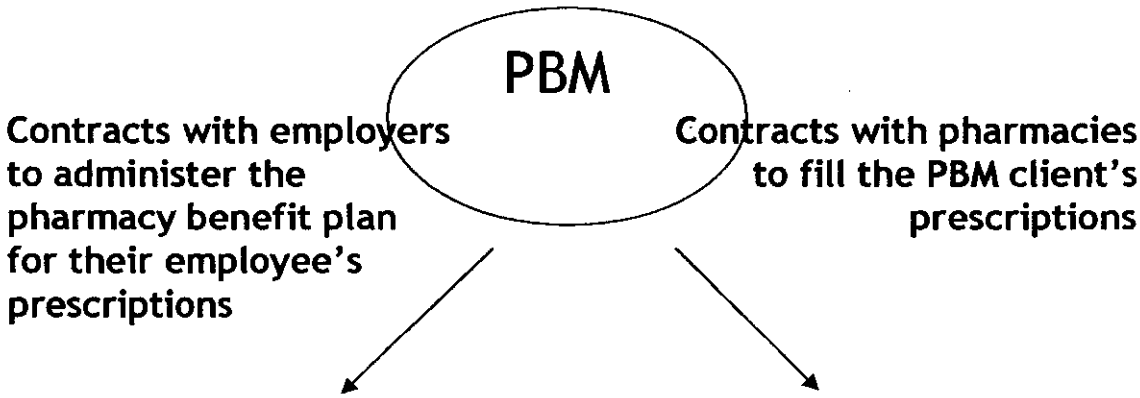
Pharmacy Benefit Managers (def) - third party administrators for prescription drug benefits



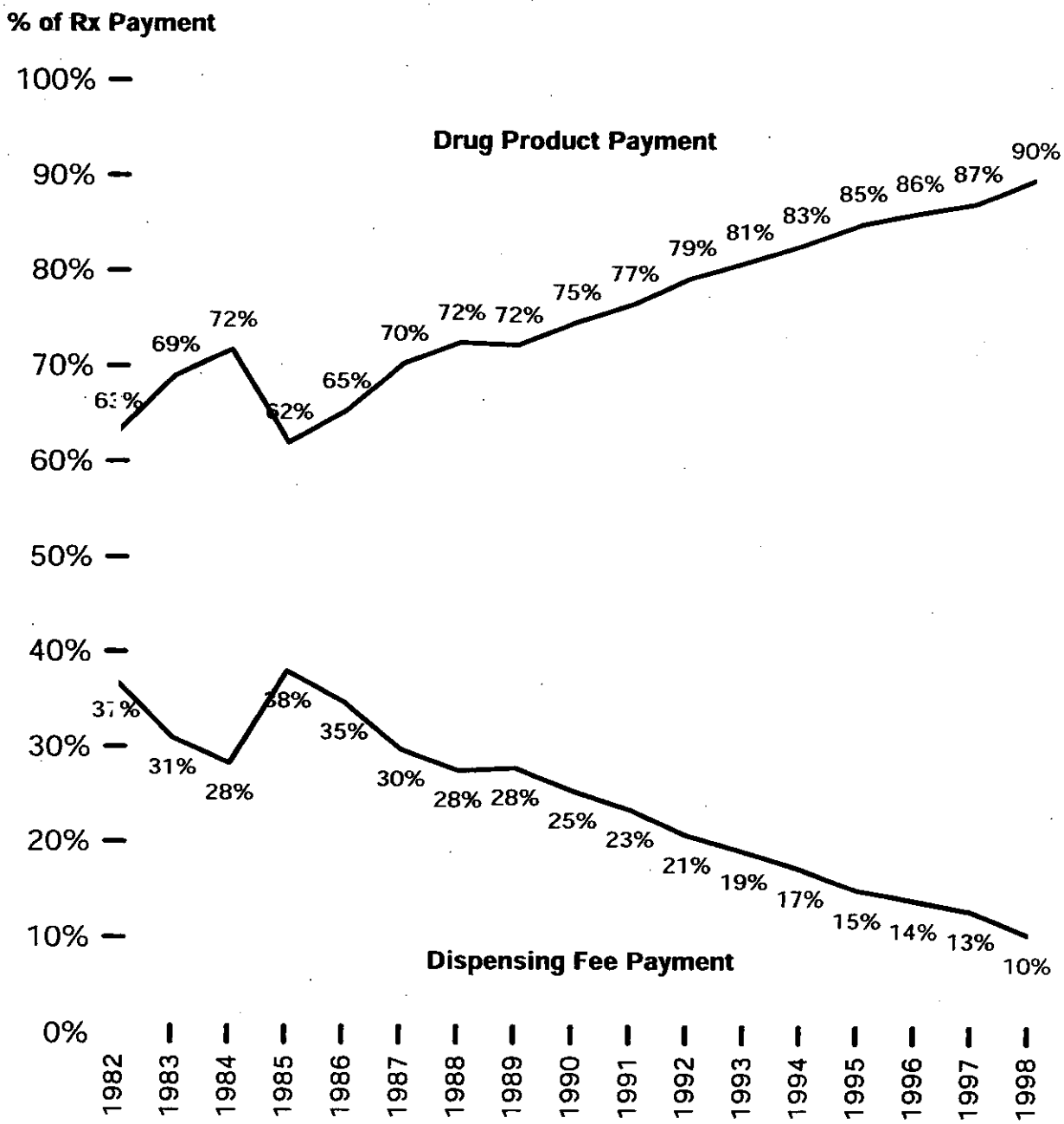
Employer - Plan Sponsor

PBM bills the employer for each employee's prescription (filled at the pharmacy)

Pharmacy

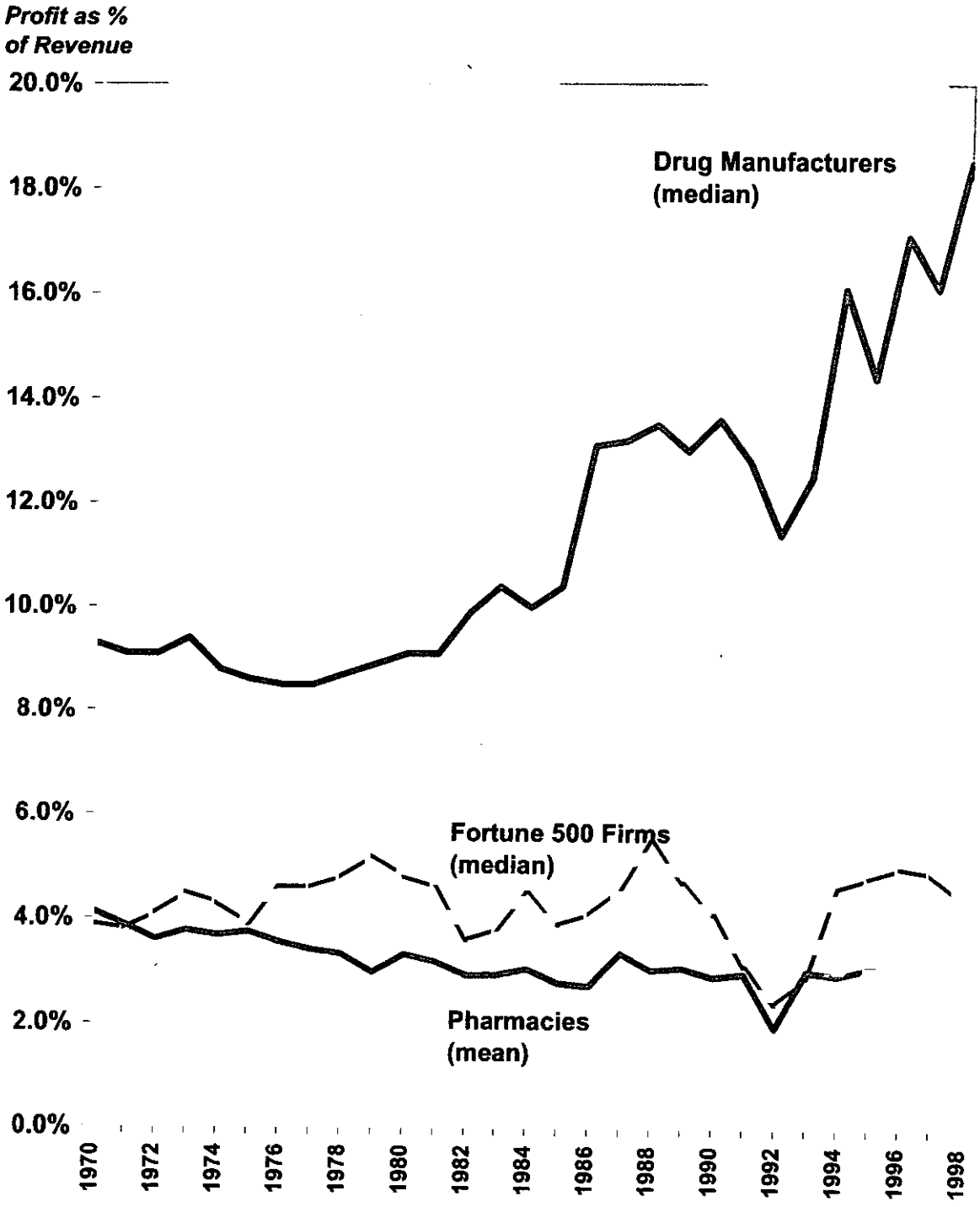
PBM pays the pharmacy for each employee prescription they fill

Minnesota Medicaid Drug Product & Dispensing Fee Payments as % of Rx Payments: 1982 to 1998



SOURCE: Compiled by Stephen W. Schondelmeyer, PRIME Institute, University of Minnesota from data found in Pharmaceutical Benefits Under State Medical Assistance Programs, National Pharmaceutical Council, 1984 to 1998. Data for 1998 are estimates from various sources including HCFA Form 64 and and HCFA Medicaid Drug Rebate public use files.

Profit as % of Revenue for Drug Manufacturers, Pharmacies, and All Fortune 500 Firms: 1970 to 1998



SOURCE: Compiled by PRIME Institute, University of Minnesota based on pharmaceutical firm net profit (after tax) reported in Fortune [Fortune 500 Issue] 1958 to 1999. Service firms were included with industrial firms in the Fortune 500 for the first time in 1994. Pharmacy net profits (before tax) from NCPA-Searle Digest (formerly Lilly Digest), annual reports from 1970 to 1998.

Nationwide Scrutiny of PBMs Prompts Lawsuits & Investigations

Pharmacy Benefit Managers (PBMs) face legal challenges from coast to coast, notably a massive federal prosecution in Philadelphia that has resulted in a $29 million settlement on one of five counts in the lawsuit that includes 20 states. The following list documents the various lawsuits, and investigations across the country.

United States of America v. Medco (2003)

The US Justice Dept accused Medco Health Solutions, Inc, the nation's largest PBM, of "a systematic pattern of conduct" to defraud the federal government and its employees or retirees who received mail order prescriptions from the PBM under a contract with the Blue Cross and Blue Shield Association. Medco is also accused of paying over $87 million in cash kickbacks to health plan to secure Medicare contracts.

United States of America v. Medco (2004)

In US District Court in Philadelphia, the US Justice Dept alledges that the PBM Medco offered a kickback of more than $200 million to a major health insurer in exchange for its business.

20 State Attorney Generals v. Medco

In April 2004 a settlement was reached on alleged unfair trade practices by Medco Health Solutions. Medco paid about $29 million to settle the first of five counts in the lawsuit. In addition Medco agreed to

- disclose to prescribers and patients the minimum or actual cost savings for health plans and the difference in co-payments made by patients;
- disclose to prescribers and patient Medico's financial incentives for certain drug switching
- adopt a code of ethics and professional standards

19 State Attorney Generals Launch Investigation of Caremark

In July 2004 Caremark acknowledged a ongoing probe by 19 states into their business practices, as well as their newly acquired AdvancePCS. Caremark noted that the investigation is looking at similar issues to the Medco investigation by 20 states. Increasing concern over rising costs has led to queries about questionable business practices related to rebates, discounts, drug switching, and other transactions between the PBM and drug manufacturers. These savings are allegedly retained by the PBM rather than passed on to the health plan sponsors.

Two pharmacy groups file suit against Medco and AdvancePCS

The merger of Caremark Rx (number 4 PBM in the country) with Advance PCS (number 2) in the summer of 2004, secured 20% of market share for the new partners, and prompted law suits alleging anti-trust violations. With 140 million members in America the suit says the lack of competition in the field gives overreaching pricing potential in the drug market. The suit also alleges that the PBMs set articially low payments to retail pharmacies and prevented them from fairly competing with the PBM mail order plans. The suit was filed by The Pharmacy Freedom Fund and the National Community Pharmacists Association on behalf of all retail pharmacy owners.

FTC Conducting PBM Conflict of Interest Study

The Federal Trade Commission is conducting a "conflict of interest study" that examines whether the cost to group health plans of using mail order pharmacies integrated with the PBMs is more than using non-integrated mail order pharmacies or over the counter retail pharmacies. Congress asked the Commission to investigate whether PBMs make decisions that increase the PBM's profits while raising the costs to consumers.

Alabama

Two independent pharmacies in October 2003 accused the four biggest PBMs in federal court of using anti-competitive practices against small operators. The plaintiffs claim that Medco, Caremark, AdvancePCS and Express Scripts used their status as middlemen to set price and force "unconscionable" reimbursement rates on community pharmacies.

California

The American Federation of State County and Municipal Employees (AFSCME) sued the four largest PBMs in April 2003 under California's Unfair Competition Act. The union's lawsuit says all four PBMs consistently fail to pass (prescriptions) savings along to health plans and their members...choosing instead to pocket the savings and increase their own profits. In so doing, the four PBMs have willfully contributed to the escalating drug costs and have failed in their fiduciary duty to those client health plans.

Florida

In 2004 a whistleblower lawsuit by two former employees, pharmacists at Caremark's mail order division, said their employer regularly resold medications that had been returned by patients. In an attempt to get around a Florida law prohibiting this practice, the returned drugs were shipped to Illinois and then reused (the pharmacy director for Caremark in Illinois confirmed the practice). The suit also alleges that Caremark not only resold returned drugs, but charge the state twice for the same medications.

August 2003 the state's attorney general's Medicaid Fraud Control Unit subpoenaed records of Medco dealings with several health maintenance organizations to investigate whether citizens were getting the full benefits of the PBM contract and were safe.

December 2002, Medco agreed to pay $42.5 million to settle several lawsuits by employer health plans and beneficiaries. Plaintiffs filed federal cases under the ERISA, accusing Medco of secretly promoting Merck brand drugs to real lucrative rebates (Merck owned Medco until recently). Court documents show Medco kept more than $2.8 BILLION in drug manufacturer rebates from 1995-1999.

Minnesota

September 2001, AARP switched its drug-discount card business from Advance PCS to Express Scripts (3rd largest PBM). According to the AARP law suit filled in US District Court in Minnesota a

sharp drop in the number of prescriptions written for cardholders in the first month of the transition to the new PBM. Court findings indicate Advance PCS kept AARP cardholders on their rolls for four months – processing nearly 3 millions claims – by not deleting the carrier number for AARP participants when the contract should have been discontinued. AdvancePCS claims no responsibility since it owns the codes and has no contractual obligation to change them.

December 2004, Minnesota's Attorney General wrapped up an investigation into unfair trade practices by Prime Therapeutics, a PBM based out of Minnesota that is owned by Blue Cross Blue Shield organizations in 6 states. The investigation focused on Prime's use of incentives to entice clients to use their new mail order pharmacy in Texas rather than purchasing prescriptions locally. Prime Therapeutics agreed to offer the local pharmacies participation in a mail order network at rates matching those from their mail order facility.

The contract that was received by the retail pharmacies offered reimbursement rates that are unacceptable (AWP – 25% and no dispensing fee), and reflect the unfair advantage of mail order pharmacies that can legally "re package" drugs and assign new NDC numbers in order to receive greater profits. Local pharmacies are not allowed to repackage, and therefore cannot get inventories at the same (lower) costs as mail order facilities. Some perceive the new contract to violate trade laws in other ways, and the possibility of further investigations and/or lawsuits is pending.

Missouri

December 2003 - The world's largest private coal company sued Merck, alleging that it former PBM subsidiary – Medco Health Solutions – illegally pushed Merck drugs when cheaper medicines were available. The suit alleges fraud of 31,000 employees and retirees, as well as millions of other patients, through rackterring, fraud and embezzlement. The suit asked for $35 million.

Nevada

Two former (pharmacist) employees, at Medco's mail order pharmacy in Las Vegas filed suit and the US Justice Dept joined them, asking for damages for false claims. A New Jersey physician filed a second suit on similar charges. Each false claim can be assessed a $5000 fine and triple damages.

New York

August 2004, the state filed a breach of contract against Express Scripts, the third largest PBM, accusing them of adding millions of dollars of cost to New York's largest employee health plan. NY Attorney General Elliot Spitzer said, "rather than being part of the solution to this (health care cost) crisis by keeping drug costs as low as possible, we discovered that Express Scripts engaged in a series of deceptive schemes. They improperly lined their pockets at the expense of health plans and consumers...driving up the very costs they were suppose to lower."

Ohio

December 2003 – Ohio Attorney General filed suit against Medco for overcharging the Teachers Retirement System up to $50 million over 13 years. The suit contends that since 1988, Medco kept $8.30 per prescription that should have gone into the fund for 113,000 retired teachers, their spouses and children. AG Jim Petro said, "the corporate culture of Medco encourages profit above service. They did not make a good faith effort to obtain the lowest possible drug prices."

Pennsylvania

August 2003 - Medco is accused in a federal lawsuit of artificially low reimbursement rates for retail drug stores. The plaintiff, Brady Enterprises, seeks class action status.

Texas

November 2004 – Medco sued Attorney General Abott to stop disclosure of proprietary information – deemed confidential by Medco – that explains how the PBM manages the drug benefit program for 200,000 state government workers. The suit seeks to overturn an October 2004 ruling that the public has a right to know the prices charged by government contractors.

Concerns arose when state employees spent $158 million under the Medco contract that ended in August – an increase of 245% in the four years of the contract. During the same time, reimbursement paid to community pharmacies steadily declined, and a majority of the pharmacy benefit has been transferred to Medco's own mail order business.

Vermont

June 2003 – State Auditor Elizabeth Ready, formally requested the Attorney General to investigate Express Scripts, the PBM for nearly 20,000 government workers and retirees, for fraudulent business practices. She noted her concern that the state was paying a hidden profit due to the difference between what Express Scripts pays a pharmacy for a prescription and what the company then charges the state of Vermont for that same prescription.

West Virginia

November 2002 – state's Attorney General Darrell McGraw files suit against Medco for allegedly steering 200,000 state employees to higher priced drugs – especially Merck drugs – and keeping the rebates from drug companies that should have been passed on to the state to lower their costs. The suit identifies at least $6 million that Medco kept and should have forwarded to the state. The state's contract with Medco allowed Medco to keep 5% of rebates, but they kept all the money.

Wisconsin

September 2003 - American Medical Security Holdings, a former customer of Medco, sued the PBM for breach of contract terms involving discounted pricing and dispensing fees.

Sources: This summary was compiled from newspaper and wire service reports, industry newsletters and plaintiff attorney's websites. The Coalition for Quality Healthcare is a not-for-profit organization that seeks to protect the rights of patients to fill prescriptions wherever they wish. It strongly supports efforts to reduce healthcare costs for employers and patients. (www.pharmacychoices.org)

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FOR IMMEDIATE RELEASE

April 26, 2004

THE UNITED STATES SETTLES ITS ANTI-FRAUD CLAIMS FOR INJUNCTIVE RELIEF AND 20 STATE ATTORNEYS GENERAL SETTLE UNFAIR TRADE PRACTICES CLAIMS AGAINST MEDCO HEALTH SOLUTIONS

Medco To Provide Price Information To Doctors And Patients And Pay $29 Million Plus To States In Damages, Fees, And Restitution – Federal Damages Case Continues

PHILADELPHIA – United States Attorney Patrick L. Meehan joined 20 state Attorneys General today in announcing the settlement of claims for injunctive relief and state unfair trade practices laws against Medco Health Solutions, Inc. (Medco), the world's largest pharmaceutical benefits management (PBM) company. An investigation by the United States for more than four years led to the development of a cooperative federal-state investigative effort, spearheaded at the state level by the Attorneys General of Pennsylvania, Maine, and Massachusetts. The consent order filed in the federal district court for the Eastern District of Pennsylvania will not dismiss claims for damages, penalties, or restitution under federal statutes and common law. That portion of the federal case will continue. Medco continues to deny the federal allegations.

In December 2003, the United States, through the United States Attorney's Office for the Eastern District of Pennsylvania, filed an amended complaint against Medco in which it alleged, among other things, that Medco encouraged prescribers to switch patients to different prescription drugs but failed to pass on the resulting savings to patients or their health care plans. The drug switches generally benefited Medco despite Medco's claims that they saved money for patients and health plans. Medco did not tell prescribers or patients that the switches would increase rebate payments from drug manufacturers to Medco.

The attorneys general filed complaints in state courts today settling similar allegations. Both the United States and the attorneys general allege that the drug switches resulted in increased costs to health plans and patients, primarily in follow-up doctor visits and tests. For example, Medco switched patients from certain cholesterol lowering medications to Zocor, but that switch usually required patients to receive follow-up blood tests.

"When getting the proper medication in the proper amounts to the consumer as quickly as possible isn't the focus of a pharmacy benefit manager, it's ultimately the patient who suffers," said Meehan. "We want to make sure that profits never come before patients and today marks an important step toward forever changing the way all PBMs do business."

The United States is joined in this landmark settlement by: Arizona, California, Connecticut, Delaware, Florida, Illinois, Iowa, Louisiana, Maine, Maryland, Massachusetts, Nevada, New York, North Carolina, Oregon, Pennsylvania, Texas, Vermont, Virginia, and Washington.

The settlement prohibits Medco from soliciting drug switches when:

- The net drug cost of the proposed drug exceeds the cost of the prescribed drug;
- The prescribed drug has a generic equivalent and the proposed drug does not;
- The switch is made to avoid competition from generic drugs; or
- The switch is made more often than once in two years within a therapeutic class of drugs for any patient.

The settlement requires Medco to:

- Disclose to prescribers and patients the minimum or actual cost savings for health plans and the difference in co-payments made by patients;
- Disclose to prescribers and patients Medco's financial incentives for certain drug switches;
- Disclose to prescribers material differences in side effects between prescribed drugs and proposed drugs;
- Reimburse patients for out-of-pocket costs for drug switch-related health care costs and notify patients and prescribers that such reimbursement is available;
- Obtain express, verifiable authorization from the prescriber for all drug switches;
- Inform patients that they may decline the drug switch and receive the initially prescribed drug;
- Monitor the effects of drug switches on the health of patients; and
- Adopt the American Pharmacists Association code of ethics and principles of practice for pharmaceutical care for employees at its mail order and call center pharmacies.

The federal investigation has been conducted by the Office of Personnel Management and the Office of Inspector General for the Department of Health and Human Services.

A consent order with the United States will be filed in federal district court, and the United States will dismiss only its claim for injunctive relief at Count VI of the amended complaint filed December, 2003, at United States of America v. Merck-Medco Managed Care L.L.C. et al., Civil Action Number 00-737. The damages portion of the federal case will proceed. A separate consent order will be filed by the states to cover the injunctive and monetary claims for which Medco will pay $20 million to the states in damages, $6.6 million to the states in fees and costs, and about $2.5 million in restitution to patients who incurred expenses related to a certain switch between cholesterol controlling drugs. Some states have elected to receive prescription drug cards in lieu of their monetary payment. States receiving a monetary payment must use the funds to benefit low income, disabled, or elderly consumers of prescription medications, to promote lower drug costs for residents of the state, or to fund other programs reasonably targeted to benefit a substantial number of persons affected by the conduct covered in the complaint.

U.S. Attorney Meehan praised the partnership that the Eastern District of Pennsylvania

developed with the states attorneys general. "Establishing a cooperative effort between federal and state law enforcement officials has proven to significantly benefit health care consumers across the nation. This settlement provides a very good example of the great strides that can be made by such joint efforts."

Added Meehan: "Although the settlement of the United States' claims against Medco for injunctive relief does not resolve the remaining counts of the amended complaint filed against the company in December 2003, we believe that the changes in Medco's business practices resulting from this agreement will positively impact health care consumers across the nation."

Medco is the nation's largest PBM, with over 62 million covered people. PBMs contract with health plans to process prescription drug payments to pharmacies for drugs provided to patients enrolled in the health plan. In the thirty years since the first PBMs appeared, their services have evolved to include complex rebate programs, pharmacy networks, and drug utilization reviews.

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COPIES OF NEWS MEMOS AND RELATED DOCUMENTS CAN ALSO BE FOUND AT HTTP://WWW.USDOJ.GOV/USAO/PAE/

Medco admins plans for 190 companies in the Fortune 500 (52 in the Fortune 100), 120 BCBS plans, plus many state & private plans

AFSCME in the public service

PAL Prescription Access Litigation
A Community Catalyst Initiative

FOR IMMEDIATE RELEASE:
Tuesday, March 18, 2003

Contact: Laurie Covens, PAL, 617-275-2805/
Roberta Heine or Tiffany Ricci,
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Pharmacy Benefit Managers Charged with Inflating Prescription Drug Prices

Lawsuit Alleges Secret Deals between PBMs & Pharmaceutical Companies

Los Angeles – The Prescription Access Litigation (PAL) project and the American Federation of State County and Municipal Employees (AFSCME), AFL-CIO, today announced that they have filed suit against the nation's four largest pharmacy benefit managers (PBMs) for inflating prescription drug prices. The four companies, Advance PCS, Express Scripts, MedCo Health Solutions, and Caremark Rx., control more than 80 percent of the PBM market.

PBMs manage prescription drug benefit programs for employers, unions, health plans and other payers. PBMs were created to act as a broker between these payers and the drug companies to help control the cost of drug coverage. The lawsuit filed in California charges that through a pattern of illegal, secret dealings with drug companies the PBMs have forced health plans and health care consumers to pay inflated prescription drug prices.

"The organizations that were created to make prescription drugs more affordable are cutting inside deals with drug companies and driving up costs. It's corporate greed like this that is chipping away at the paychecks of hard working men and women across the country," AFSCME President Gerald W. McEntee said. "Forty-one million Americans are still without health insurance. The PBMs need to give up this racket and get down to the business they were created to do. We need someone looking out for working families instead of their own corporate interests."

The lawsuit alleges that the four drug benefit managers have reaped billions of dollars in illegal profits by steering health insurers and health care consumers into reliance on more costly drugs. The complaint also charges that the four PBMs have negotiated rebates from drug manufacturers and discounts from retail pharmacies – but haven't passed those savings on to health plans and consumers. Instead they've used those savings to secure exploitative profits. In addition, the complaint charges the PBMs developed a pricing system based on the Average Wholesale Price (AWP), widely considered an inflated "sticker" price set by the drug manufacturer.

"In the early 1990s, they told us PBMs were the key to controlling drug costs," noted PAL Director Ahaviah Glaser. "But now it's clear that PBMs have not only have failed to deliver any savings, but they have built all kinds of new profit-shaving into the system. Let's face it. PBMs have become another big prescription drug rip-off."

PBMs process hundreds of millions of pharmaceutical claims per year and manage drug benefit programs for more than 200 million Americans.

"The irresponsible behavior by the PBMs is helping to gut the health care system. In California we're seeing devastating health care plans being written – higher co-pays and

(More)

deductibles, and plan descriptions that eliminate most of the health care we now have covered," AFSCME District Council 57 Director George Popyack said. Council 57 represents 23,000 public service employees in California.

AFSCME negotiates dozens of contracts in California annually. Steve Kreisberg, the union's senior negotiator, says that health care issues are the most difficult to resolve at the bargaining table because of skyrocketing costs. According to Kreisberg, "Prescription drug costs in particular have been rising at an excessive rate – close to 20 percent annually over the past few years. It now appears that the biggest players in the PBM industry, whom we once thought of as allies in our fight to control drug costs, have been working both sides of the street. This lawsuit will hopefully bring more transparency to their business dealings"

"The suit alleges that PBMs are forcing consumers to play a high-stakes game of three-card monty," said attorney Steve Berman, the attorney bringing the suit on behalf of AFSCME. "We intend to prove that PBMs are hiding the real cost of prescription medication using misdirection and deception while raking in huge profits at the expense of consumers."

AFSCME and PAL seek to put an end to these illegal pricing practices and get immediate restitution from the named PBMs.

In conjunction with PAL, Seattle-based law firm Hagens-Berman filed the lawsuit on behalf of AFSCME, the nation's largest public service employees union. PAL was created by Boston-based Community Catalyst and is a nationwide coalition of consumer groups fighting for fair drug prices.

For a fact sheet and copy of the complaint in this case, go to **www.hagens-berman.com.**

American Federation of State, County and Municipal Employees (AFSCME), AFL-CIO, is the nation's largest and fastest growing public service employees union with more than 1.3 million members. AFSCME is committed to organizing workers for justice in the workplace, and promoting social and economic justice through political action and legislative advocacy. www.afscme.org

Prescription Access Litigation (PAL) project (www.prescriptionaccesslitigation.org) has filed 15 sets of lawsuits targeting drug industry practices that illegally push the price of prescription drugs beyond the reach of the American consumer since its launch nearly two years ago. A project of Boston-based Community Catalyst, PAL is on the ground in 34 states and the District of Columbia; the coalition is comprised of 89 state, local, and national senior and consumer health advocacy groups fighting to make prescription drugs affordable

Community Catalyst (www.communitycatalyst.org) is a national health care advocacy organization dedicated to building consumer and community participation in the decisions that shape our health system. Working in partnership with state, local, and grassroots consumer groups in over 30 states, Community Catalyst has helped preserve over $16 billion in community health assets as hospitals and health plans around the country have become for-profit corporations. It works on a range of health care access issues, including today's struggle to preserve Medicaid services and other health programs amid plunging state revenues nationwide.

Tom Sobol is the managing partner of the Boston office of Hagens-Berman LLP where his areas of practice includes pharmaceuticals, financial fraud, antitrust, medical malpractice, intellectual property, tobacco and toxic torts. Sobol served as a special assistant attorney general for the Commonwealth of Massachusetts and the states of New Hampshire, Maine and Rhode Island in the groundbreaking litigation against the tobacco industry, and was lead private counsel for Massachusetts and New Hampshire bringing injunctive relief and to monetary recovery in excess of $10 billion. *The National Law Journal* names Sobol as one of Massachusetts' ten most leading litigators in 2000.

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March 12, 2003 07:31

PBMs Must Disclose Sources of Revenue or Suffer the Consequences of Forced Change: By Tim Dickman, CEO, Prime Therapeutics, Inc.

ST. PAUL, Minn., March 12 /PRNewswire/ -- The landscape surrounding pharmacy benefit managers (PBMs) needs a major renovation. The traditional model may still work effectively for PBMs in allowing them to maintain their margins; however, the model clearly falls short of adequately serving the needs and interests of PBMs' clients.

Today's model is largely focused on extracting revenue from pharmaceutical manufacturers, only some of which is passed on to clients. The proper focus needs to shift to a true value equation that recognizes which drugs in which classes present the best overall value for the plan, payer and their members. While discounts will continue to play a role in this determination, they should become nothing more than a consideration in the total value equation. Today's unrelenting focus on discounts and other manufacturer revenue streams must be aligned with the clients' best interests -- a focus based on total pharmacy benefit value.

Now is the time for PBMs to re-evaluate their sources of revenue and assess whether too great a percentage of their revenue comes from manufacturers through not just rebates, but the sale of data, funding of clinical programs, mail order services, therapeutic switch programs and research grants. While these revenue streams have become pervasive in recent years, they appear counter-intuitive to sound business practices. Such a model comes perilously close to a scenario in which a business is dependent on a single source of revenue -- pharmaceutical manufacturers. Business schools and consultants alike would be quick to advise any CEO to diversify.

It also potentially puts PBMs in the awkward position of questioned loyalty. After all, whom do we really serve -- health plans, payers and members, or drug manufacturers?

How do we begin to clean up our house? Clearly, there are no easy solutions, but that shouldn't deter PBMs from seeking a better model to manage pharmacy costs. Scenarios include:

1. PBMs developing a fee structure that is palatable to their clients by fully disclosing revenues received from manufacturers and implementing an equitable formula for sharing that revenue.

2. Plans taking their pharmacy benefit management back in house.

3. Government regulation of the PBM industry that curtails or prohibits rebates. Certainly not a scenario anyone wants to see, but political fallout is a real possibility if we fail to take corrective action and very soon.

No single PBM can effect such dramatic change. That's why we should agree as a whole that our industry can evolve to a model that better suits today's landscape. Otherwise, we will face serious challenges as our critics continue to exert pressure on legal and regulatory sources until change is forced upon us.

I believe we can work to the mutual benefit of all -- consumers, payers, plans, PBMs and manufacturers -- by working in concert to create a new model founded on providing the most effective pharmaceutical products to the widest segments of our covered populations for the lowest cost.

Prime Therapeutics, Inc. is a pharmacy benefits solutions company, dedicated to providing innovative, clinically based, cost-effective pharmacy solutions for its clients and their members. Providing services nationwide to approximately nine million covered lives, its client base includes several Blue Cross Blue Shield plans, employers, union groups and third party administrators. Headquartered in St. Paul, Prime Therapeutics is collectively owned by various Blue Cross Blue Shield plans or parents, subsidiaries or affiliates of those plans. Learn more at www.primetherapeutics.com .

SOURCE Prime Therapeutics, Inc.

/NOTE TO EDITORS: The above is an editorial opinion in response to recent allegations that the pharmacy benefit management (PBM) industry is contributing to the escalating cost of prescription drugs. Critics charge that PBMs' financial relationships with pharmaceutical manufacturers drive prescription drug utilization to higher-cost, branded drugs and away from equally effective lower-cost alternatives./

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/Web site: http://www.primetherapeutics.com /

PR Newswire
United Business Media

More Info

No other information available

PRESCRIPTION DRUG LEGISLATION 2003

No. of States	Topic
20	Multi-state or agency bulk purchases
16	Clearinghouse information **
35	Price-related policy or discount issue
19	State sponsored discount program (like MaineRx)
20	Marketing & advertising **
34	Medicaid **
22	Regulate Pharmacy Benefit Managers
30	Preferred Drug Lists
31	Subsidy for low income patients

Other: importation, labeling & packaging, 340B programs, waivers

Many states have more than one bill on a single issue. In some states a special session can reconsider bills not passed in a regular session. In about 25 states bills can be carried over, or continued, for consideration the following year.

Pharmacy Benefit Managers Legislation

AL HB 153 SB 77	requires pbm and other entities that pay claims of any type to pay claims within a specified time frame.	No action before end of session
AR S 313	regulates and licenses pbms	Died in committee at end of session
CO SB03-142	establish evidence-based preferred drug list and regulate pbms	Died in committee.
CT HB6606	require insurance commissioner in consult with pharmacy commission to study pbm plans and decide whether further regulation is required and if so recommend what type is needed	Filed, sent to committee with no further action at end of session
FL HB 1599 SB 2536	enact FL PBM Regulation Act – establish standards and criteria to regulate and license pbms	Died in committee
HI SB 775 HB 18	Establish duties and obligations of pbms that administer or manager prescription drug benefits	Filed, sent to committee, no further action at end of session

IL HB 520	Create PBM Regulation Act to establish standards and criteria to regulate and license pbms	Filed, sent to committee, no further action at end of session
IA HF 496	regulate pbms	Filed, sent to committee, no further action at end of session
KS H 2392	requires registration of pbms, $500 application fee, certificate of authority to be renewed annually, and disclosure of financial matters including all incentives etc.	Filed, sent to committee, no further action at end of session
S 268	requires registration of pbms	Filed, sent to committee, no further action at end of session
LA HB 1612	requires regulation and licensure of pbms through dept of insurance	Filed and passed House, no further action at end of session
ME LD 554 SP 194	regulates pbms to ensure full disclosure of contracted activities, etc....also requires the benefits of special drug pricing deals negotiated by pbms be passed through to consumers and not used as pbm profits. Also clarifies violations of of this law fall under Maine Unfair Trade Practices Act and are enforceable by private action or the AG.	Passed. Signed by Governor 3-9-04 temporarily blocked implementation with injunction in District Court
MD HB 410	requires insurance dept to examine any pbm acting as a private review agent, conducting utilization reviews	Passed. Signed by Governor
MS HB 402	establish standards and criteria for regulation and licensing	Died in committee
NJ A 2337	establish PBM Act and require pbms that manage prescription drug benefits be certified by state.	Filed in 2002.Carried over to 2003. Did not pass
NM SB 871	require licensing and regulation of pbms	Filed. Died in committee
OR SB 629 HB 2613	required licensing and regulation of pbms	Filed, no further action by end of session
PA S 23	require the state to administer a single pbm program for all eligible medical assistance recipients with bid process and a 3 year contract	Filed, no further action by end of session

TN HB 263	require pbm licensing and permits inspection of their premises	Filed, sent to committee. No further action by end of session
TX SB 1746 HB 3302/3320	regulate pbms in various areas	Filed, sent to committee. No further action by end of session
VT H 359 S 116	require licensing of pbms with state, and regulations to operate in accordance with standards of conduct established by law	Filed. No further action by end of session
WA HB 2011	requires state agency contracts with pbms to include full disclosure of rebates or other agreements between the pbm and drug manufacturer and any other related entities	Filed. Passed house. Did not pass Senate by end of session
WY HB 208	requires licensure and certification of pbms. Terms for revocation of certificate to operate, including financial or for a pbm that advertises or merchandises its services in untrue, misleading, deceptive or unfair manner	Died at end of session

PRESCRIPTION DRUG LEGISLATION 2004

No. of States	Topic
16	Multi-state or agency bulk purchases
11	Clearinghouse information
28	Price-related policy or discount program
13	Price only
11	Mail order
8	Use of Generics
13	Marketing & advertising
17	Medicaid
24	Medicare Drug Act of 2003
15	Regulate Pharmacy Benefit Managers
11	Preferred Drug Lists
24	Subsidy for low income patients
24	Importation

Other: labeling & packaging, 340B programs, waivers

Many states have more than one bill on a single issue. In some states a special session can reconsider bills not passed in a regular session. In about 25 states bills can be carried over, or continued, for consideration the following year.

CA AB 1960	regulates PBMs, and imposes fiduciary responsibility on pbm	Filed, sent to committee. Passed both houses. Vetoed by Governor
CT SB 8	regulate pbms, requires annual license from insurance commissioner, and license to practice pharmacy. Disclosure of financial statements, approval of contracts, and no discrimination allowed with local pharmacies based on copays or Days of supply	Filed, passed Senate. No further action by end of session
DC B15-569	Enacts Rx Access Act , requires Dept of Health to run the program for low income elderly. Establishes discount prices and requires drug manufacturers to give rebates for products sold in publicly funded programs with public disclosure and Possible prior authorization restrictions for products lacking rebates. Disclosure includes marketing costs by manufact-urers; allows negotiation with other states or jurisdictions for bulk purchasing. Regulates pbms including establishing fiduciary responsibility, transparent business practices, pass through of rebates and discounts from manufacturers.	Passed. Signed by Mayor Dec. 2004 – temporary injunction to stop implementation
FL HB 1347 S 3042	Define role and responsibilities of pbms and allows for dispensing of Canadian medicines if federall approved	Died in committee
IL HB 6871	Establish regulation of pbms – require certificate of authority from Insurance Dept and pharmacy board; filing and state approval of contracts, and financial exam by state	Filed, sent to committee
IA HF 496 SF 2283	Regulate pbms, including licensing, annual reports and disclosure to PBM enrollees	Filed. No further action by end of session
MD HB 397	Require pbms to register with secretary of health; file application, submit documents, pay fee; authorizes secretary to To suspend or revoke license or deny application under specified circumstances	Passed House. Did not pass Senate
MI HB 5435 HB 5438	regulate pbms, including obtain certificate of authority and file annual reports. Requires annual disclosure to state commissioner and to all purchasers of its coverager about financial relationships with drug manufacturers, billing arrangements and prices used to calculate cost to consumer	Filed, sent to committee. No further action at end of
MN HF 2843 SF 1650	Establish wholesale and drug manufacturers price reporting requirements, including volume discounts - prompt payments -chargebacks – short dated product discounts – cash discounts – free goods – rebates and all other price concessions Or incentives that result in ultimate cost to the purchaser	Filed, favorable report. No further action by end of session
MN SF 2601	require certificate of authority for pbms to operate; requires disclosure of financial information and arrangements related to Prescription drug purchasing	Filed. No further action by end of session

MS HB 61	creates pbm Act. Requires pbm to get license from Insurance commission and certificate of authority – requires filing of annual statements, financial exams, and assessments and fees.	Filed and sent to Committee. No further Action
MS SB 2546	creates marketing disclosure law – requires disclosure by drug manufacturers	Filed and sent to Committee. No further Action
NH SB 383	Modify PBM regs; require mental health advisory committee to review mental health drugs, and authorize state to negotiate with drug companies for supplemental rebates or price discounts for Medicaid	Passed. Signed by Governor
NY A 10440 A 10450 S 1229 S 6948	prohibits mandated mail order, and charging different co payments for retail versus mail order purchases regulates pbms; requires license from insurance commission and board of pharmacy; disclosure of agreements for Rebates and discounts from drug manufacturers, and annual financial statements filed with the state. Prohibits discrimination between pharmacies based on co payments or days of supply	Filed, sent to committee Filed, sent to committee
OK HB 2111 SB 1615	create Oklahoma Prescription Drug Fair Pricing Board – authorized to establish "maximum prices for drugs"	Filed. No action by end of session
SD HB 1311	regulates pbms and requires full disclosure of rebates, discounts and other arrangements that affect price to the covered; entities. Requires licensing; exercise good faith and fair dealing with covered entities; allows for audits.	Passed. Signed by Governor
VT H 617	regulate pbms to protect against unfair prescription drug practices	Filed, sent to committee. No further action by end of Session
H 713	creates healthcare cost containment council; requires disclosure of prescription drug prices, and pbms must disclose financial quotes which identify sources of revenue	Filed, sent to committee No further action by end of session
H768	requires disclosure of prescription drug prices to consumers; pbms and health insurers required to permit retail pharmacies To use same prices and quantities as mail order pharmacies; State dept to use evidence-based research to support Generic utilization; study the expansion of 340B programs.	Passed. Signed by Governor
S 288	require pbms or health insurers to disclose prescription drug prices to consumers and healthcare providers	Filed, passed Senate. No further action by end of Session

WV HB 4084	creates West Virginia Pharmaceutical Availability and Affordability Act – establishes clearinghouse, state sponsored prescription drug discount card for low income residents using rebates but not a formulary or PDL. Establishes state Council to create pricing schedule. Creates study to explore feasibility of accessing federal supply schedule or Canadian pricing. Requires state to investigate possibility of using Canadian supply. Requires report of drug advertising costs.	Passed, signed by Governor
HB 4062 HB 2773	regulates and requires license of drug marketers and detailers creates Prescription Drug Price Reduction Act	Filed, sent to committee. No further action by end Of session

This information was retrieved from the National Conference of State Legislatures website: www.ncsl.org

PRESCRIPTION DRUG LEGISLATION 2005

California	
Illinois	
Maryland	
New Mexico	
North Carolina	
North Dakota	House Bill 1332
Texas	
Wyoming	

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HB 4062 HB 2773	regulates and requires license of drug marketers and detailers creates Prescription Drug Price Reduction Act	Filed, sent to committee. No further action by end Of session

This information was retrieved from the National Conference of State Legislatures website: www.ncsl.org

PRESCRIPTION DRUG LEGISLATION 2005

California	Los Angeles Daily News, January 4, 2005: (excerpt) Lawmakers submitting another package of bills aimed at lowering cost of prescription drugs...a plan that passed the legislature and was vetoed by Governor Schwarzenegger. Current package includes several new and expanded elements including giving the state more authority...website to help consumers buy from other countries... Other bills would consolidate bulk purchasing through one agency for better discounts/ create toll free number as a hotline for consumers/ REQUIRE FINANCIAL DISCLOSURE BY PBMs whose practices are believed to sometimes steer consumers toward more expensive drugs.
Illinois Maryland	Schwarzenegger cited several reasons to veto last years package including: helping people buy drugs from other countries is illegal, and he is opposed to creating a state consortium to buy drugs because it would undermine existing state programs... HE DOES SUPPORT the goal of lowering the cost of prescription drugs in California.
North Dakota	House Bill 1332
No Carolina New Mexico Texas Wyoming	

STATE LAWS TO REGULATE PHARMACY BENEFIT MANAGERS

DISTRICT OF COLUMBIA[1]
Title 48, Subtitle II, Chapter 8A, Subchapter II.
Transparent Business Practices Among Pharmacy Benefit Managers

- Requires a PBM to act as a fiduciary.
- Requires the PBM to notify the covered entity of any practice that is a conflict of interest.
- Requires any payments/benefits that a PBM receives from a drug manufacturer or labeler based on volume of sales or market share must be paid in full to the covered entity.
- Upon request by the covered entity, the PBM must provide information on all rebates, discounts and other similar payments.
- Upon request by the covered entity, the PBM must disclose all financial terms and arrangements for remuneration of any kind between the PBM and a drug manufacturer or labeler including formulary management, drug substitution programs, educational support claims processing and data sales fees.
- PBM may designate the information provided as confidential.
- Establishes guidelines that a PBM must follow prior to substituting the prescribed medication including obtaining the approval of the prescriber. In addition, the PBM must disclose the costs of both drugs to the covered individual and the covered entity prior to switching. Any benefit or payment received as a result of the substitution must be transferred to the covered entity.
- Violations are subject to a fine of not more than $10,000.

Effective: 05/18/04 (Effective date suspended by Court Interim Injunction.)

GEORGIA
Title 26, Chapter 26-4.110.1

- Requires a PBM to be licensed as a pharmacy, with a few exceptions, if it provides the services of benefits that constitute the practice of pharmacy.
- If the PBM is licensed then the Board can inspect its premises whether they are located within or outside the state.

Effective: 05/22/02

MAINE[2]
Title 22, Chapter 603, Subchapter 4, Section 2699
Prescription drug practices

- Provides that a PBM owes a fiduciary duty to a covered entity and must discharge that duty in accordance with the provisions of state and federal law.

- Requires PBM to perform its duties with care, skill, prudence and diligence in accordance with the standards of conduct applicable to a fiduciary in an enterprise of a like character and with like aims.
- Requires the PBM to notify the covered entity of any practice that is a conflict of interest.
- Upon request by the covered entity, the PBM must provide all financial and utilization information relating to services to that covered entity.
- The PBM may designate any information provided to the covered entity as confidential and the information may not be disclosed without the permission of the PBM except that disclosure may be ordered by a court. Also this provision does not limit the Attorney General's use of its investigative authority.
- Requires the PBM to transfer in full to the covered entity any benefit or payment received as a result of a substitution.
- Requires the PBM to disclose to the covered entity all financial terms and arrangements for remuneration of any kind that apply between the PBM and any drug manufacturer or labeler, including formulary management, drug-switch programs, education al support, claims processing and pharmacy network fees that are charged from retail pharmacies and data sales fees. The PBM may designate the information as confidential. However disclosure may e ordered by a court and this provision does not limit the Attorney Genera's use of its investigative authority.
- Provides that a violation of the Act is an unfair trade practice and subject to a fine of not more than $10,000.
- Applies to contracts executed or renewed on or after September 13, 2003.

Effective: 6/3/03 (Effective date suspended by Court Preliminary Injunction.)

MARYLAND
Title 15, Subtitle 10B, Section 15-10B-20
Private Review Agents

- Requires the Insurance Department to conduct an examination of any PBM registered as a private review agent at least once every three years.
- Requires the Commissioner to issue a report based on the examinations.

Effective: 5/13/03.

SOUTH DAKOTA
Chapter 58-29E
Pharmacy Benefits Management

- Requires PBMs to be licensed as a third party administrator.
- Requires PBM to perform its duties by exercising good faith and fair dealing toward the covered entity.
- Gives the covered entity the option to request information from the PBM on rebate revenues and retrospective utilization discounts.

- Gives the covered entity the option to request information on the nature, type and amount of all other revenue received from a pharmaceutical manufacturer or labeler with respect to programs that the covered entity offers to its enrollees.
- Prohibits a PBM from contacting a covered individual without express written permission of the covered entity.
- Provides that information disclosed to the covered entity shall be confidential and proprietary information; however insurance department may request information but it will be considered confidential and privileged and not open to public inspection or disclosure.
- Provides that the covered entity may audit the PBM's records as they relate to rebates and other information described in this Chapter.
- Prescription may be substituted if it is a lower priced generic or if the substitution is for medical reasons but PBM must obtain prior approval from the prescriber.
- Allows the Division of Insurance to promulgate rules.
- Applies to contracts entered into or renewed after June 30, 2004.

Effective: 03/09/04

[1] The Pharmaceutical Care Management Association ("PCMA") filed an interim injunction seeking to enjoin the enforcement of this law. On 12/21/04, the U.S. District Court for the District of Columbia granted the interim injunction. The District of Columbia plans to appeal the interim injunction.

[2] PCMA filed a lawsuit on 09/03/03 seeking declaratory and injunctive relief from this law. On 03/09/04, the court concluded that PCMA had made a compelling argument to warrant the grant of a short term injunction in the case. Although the Court ruled that PCMA had sustained its burden for the purposes of a preliminary injunction, to demonstrate that the law would require the disclosure of a trade secret, it clearly stated that this should not be interpreted as the last word on this issue.

Dec. 16, 2002

WALL STREET JOURNAL.

CORPORATE FOCUS

AdvancePCS Loses a Client

Health Insurers May Be Rethinking Outsourcing to PBMs

By Barbara Martinez

ADVANCEPCS IS STRUGGLING with the blues.

The pharmacy-benefit manager, or PBM, is losing a major Blue Cross Blue Shield client that makes up more than 5% of the prescriptions that it processes every year. The loss—to a little-known competitor that snatched another of AdvancePCS's big customers in October—could portend trouble ahead. An unusually high number of AdvancePCS contracts are up for bid next year.

Moreover, the client loss could make waves because the company winning the contract says it doesn't engage in some common business practices of mainstream pharmacy-benefit managers that have been cited as raising costs for customers and posing conflicts, such as charging health plans a higher price for a prescription than what they pay the retail pharmacy.

The two recent contract losses could be a further sign that health-insurance firms are rethinking the outsourcing of their pharmacy-benefits operations to publicly traded PBMs. Last year, **Aetna** Inc., a major health insurer, announced it would handle its own mail-order pharmacy benefits in-house, dropping its contract with **Express Scripts** Inc., the nation's No. 3 PBM. More than half of AdvancePCS's business comes from health insurers.

AdvancePCS is one of the companies behind the cards that many Americans present at the drugstore to pick up their prescriptions. The pharmacy-benefit manager processes about 500 million prescriptions a year, and says it offers drug benefits to 75 million plan members. The company, which is in the process of being acquired by **Caremark Rx** Inc., another PBM, for roughly $5 billion in stock and cash, negotiates discounts with retail pharmacists and gets rebates from drug manufacturers to lower its clients' prescription-drug spending.

Yesterday, **Prime Therapeutics** Inc., a closely held firm based in Eagan, Minn., won a contract that AdvancePCS had held to offer pharmacy benefits to about four million patients who are members of **Health Care Service Corp.**, a mutual legal reserve concern that operates three plans: Blue Cross and Blue Shield of Illinois, Blue Cross and Blue Shield of Texas, and Blue Cross and Blue Shield of New Mexico.

"It is critical for us to know that our pharmacy-benefit partner's business goals align with ours," said Raymond F. McCaskey, president and chief executive of Health Care Service in a news release that is expected today. "Prime's business model is clear and simple to understand."

> Unlike other PBMs, Prime doesn't sell data to drug manufacturers.

Chicago-based Health Care Service stressed that it had no concerns about AdvancePCS, but that Prime also offers the ability to integrate data on medical conditions and prescriptions more smoothly.

The Health Care Service members spend about $1.5 billion a year in drug outlays, or about 5% of AdvancePCS's total annual drug expenditure of about $28 billion. In October, Prime also took away the Blue Cross and Blue Shield of Oklahoma contract from AdvancePCS.

A spokesman for AdvancePCS said, "We have enjoyed our solid relationship with HCSC to date and look forward to any opportunities to explore working together in the future."

The reversal comes on the heels of a strong period for AdvancePCS, one of the largest PBMs. Its stock price has more than doubled in the past year and, at $55.25 as of 4 p.m. yesterday in Nasdaq Stock Market trading, the stock is near its 52-week high of $58.65. In September, the company renewed its contract with a major client, Health Net Inc., a California health plan with 5.3 million covered lives.

PBMs such as AdvancePCS, of Irving, Texas, and the other three major ones—**Medco Health Solutions** Inc., Express Scripts and Caremark—have been dogged in recent years by litigation and investigations that question whether the companies save as much money as they could for their clients.

PBMs take money from pharmaceutical firms for, among other things, trying to move patients from one brand-name drug to another. Those monies aren't entirely disclosed to or shared with PBM customers, the people who ultimately pay for the prescription medications.

By contrast, Prime has a different business model, says Tim Dickman, chief executive of the company. Unlike other PBMs, for instance, Prime doesn't sell data to drug manufacturers. He also said Prime doesn't charge its clients a higher price for a prescription than what it pays the retail pharmacy. That's called "spread pricing," a common profit center for most PBMs, including AdvancePCS.

"I think our market message around transparency and around disclosure of revenue streams is beginning to resonate," Mr. Dickman said in an interview. "Many of the PBMs have revenue sources that we haven't taken advantage of."

In addition, the health plans that use Prime also have an equity stake in the company, making those plans feel that they have an "in house" PBM business.

To be sure, many employers who hire big PBMs to handle their pharmacy benefits don't really have many choices. But health-insurance firms, already familiar with processing health claims and negotiating with health-care providers, can bring more easily that business in-house.

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TECHNOLOGY

EMC to Buy VMware for $635 Million

By Charles Forelle
And Don Clark

EMC Corp. agreed to buy VMware spread across a large customer's technology infrastructure. EMC—which made its fortune selling big, expensive pieces of hardware—is putting other vendors Windows and Linux on the same system at the same time. But its star rose as companies deployed scores of larger servers based on Intel microprocessors. Instead of using one server for each appli-

NDPhA
NORTH DAKOTA PHARMACISTS ASSOCIATION

January 27, 2005

Representative George Keiser, Chairman
and Representative Jim Kasper, HB 1332 Subcommittee Chair
59th Legislative Assembly
Industry, Business and Labor Committee
600 E. Boulevard Ave
Bismarck, ND 58505

Dear Chairman Keiser and Representative Kasper,

The IBL Committee had some good questions during the hearing and one issue of particular importance revolves around the legislation that passed in South Dakota last summer. I visited with the attorney – Jeff Bloomberg - who wrote that bill and introduced it to their legislature, and he offers the following relevant details for your consideration:

- the RFP for the state employee's programs was sent following passage of the bill and required compliance with the new law. They had nine PBMs bid for the account, interviewed three and selected Prescriptions Solutions out of California. The RFP with the new PBM, was actually LESS expensive than the previous PBM.
- Mr. Bloomberg noted that the South Dakota bill was specifically written to address the judge's decision in Maine with regard to the "takings clause" (protection of the confidential information on rebates and discounts provided to the employer/plan sponsors) and he is confident their legislation can be defended although a lawsuit is not expected.
- He also said the Maine bill mandated that the rebates and discounts be directly forwarded to the consumer, which the South Dakota and HB 1332 do not require. Both bills identify the "client" as the recipient of additional savings IF they choose to request a different amount having been given the details of what level of savings are available.

Also, you should know that we support the amendment proposed by Cal Rolfson on behalf of Pharma, which avoids a possible conflict with existing statute (NDCC 19-02.1-02 (14) with regard to authorized substitution and confusion about "generic and therapeutic equivalence."

Please find attached the requested documents and comments related to HB 1332 and questions asked by members of the committee during the 1-25-05 hearing, including:

1. The GAO (US General Accounting Office) study requested by US Senator Byron Dorgan in 2003, and Dorgan's media release regarding his disappointment with the study lack of validity based on the simple fact that the GAO did not independently verify the data they used in the research and analysis. By all standards this does not provide legitimate results that can be used to defend a position.

1661 Capitol Way, Ste. 102 | Bismarck, ND 58501-2195 | Ph: 701-258-4968 | Fax: 701-258-9312 | www.nodakpharmacy.net

2. HIPAA document (1st green tab), highlighting the security and confidentiality required for all PHI (protected health information) related to individual patients. In other words, nothing in HB 1332 would allow any disclosure of detailed information that would identify an employee in any situation or relation (there was concern about the employee's personal data on prescriptions filled being assessable to their employer, which would not be legal).

3. Response to Price Waterhouse Coopers report (blue tab), 2004, referenced in the presentation by two PBMs (Express Scripts and Prime Therapeutics), with regard to claims of anticipated increases in costs to consumers in ND (about $300M annually) if HB 1332 passed.

4. ERISA (yellow tab) – Employee Retirement Income Security Act and the required fiduciary and disclosure regulations that are provided to BOTH the plan sponsor and the individual consumers. The information provided highlights the ERISA's goal to provide minimum standards that assure employee benefit plans are maintained in a fair and financially sound manner. You'll note on the second page the requirement to manage ERISA plans:

    - for the exclusive benefit of participants and beneficiaries
    - in prudent manner, refraining from conflict of interests transactions
    - by disclosing and reporting information on operations and financial details

    ERISA also includes a Consumer Bill of Rights, and samples from that document are included to highlight 1) the confidentiality protection afforded by HIPAA to each person, and 2) the extent of disclosure provided to individual employees including the disclosure proposed in HB 1332.

    Also, the Bill of Rights provides rationale for disclosure stating: "Value-based purchasing allows consumers to obtain greater value for their health care dollar by seeking higher quality at the best price. To do this, consumers need accurate, reliable information that allows them to assess differences in quality and cost of health benefit plans, the health care providers, and the facilities."

5. Response to the FTC report (second green tab) referenced in the presentation by BCBS and Prime Therapeutics, regarding the California legislation – AB 1960, and its similarity to North Dakota's HB 1332. There are distinct differences, which make the FTC report an inappropriate source in evaluating HB 1332.

    - California has a law that is perceived to protect patients from drug switching because the physician must provide prior approval. We DO NOT have this in ND law.
    - California's AB 1960 was interpreted to require disclosure of information on any and all possible substitutions, AND provide a quarterly monitoring functions by PBMs. Again, HB 1332 DOES NOT have this.
    - The FTC perceives AB 1960 disclosure requirements to include extensive public access. Again, HB 1332 limits disclosure to the plan sponsor, not even the individual consumer.
    - AB 1960 suggested different disclosure requirements among PBMs with varying services and the FTC says this defeats the purpose of providing information to help consumers make informed choices. We agree, which is why HB 1332 applies to ALL PBMs operating in ND.

6. There was some concern mentioned that HB 1332 was not supported by employers. Not true. The president of the ND Retailers testified in support and represents 325 small and large employers across the state, including 30 individual pharmacies, which are employers and plan sponsors of healthcare for their employees. Some of these employers were among those who testified at the hearing on Tuesday.

I would be pleased to provide any additional information and supporting documents to assist the committee and subcommittee determine the merits of HB 1332. Again, I would request a "Do Pass" for HB 1332.

Thank you.

Sincerely,

Dr. Patricia A. Hill, Executive Vice President
ND Pharmacists Association

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Enclosures

cc IBL Committee Members

Mark Dosch

GAO

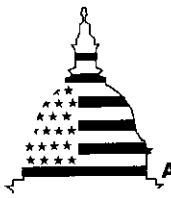
United States General Accounting Office

Report to the Honorable Byron L. Dorgan, U.S. Senate

January 2003

FEDERAL EMPLOYEES' HEALTH BENEFITS

Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies



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GAO-03-196

January 2003

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Highlights

Highlights of GAO-03-196, a report to the Honorable Byron L. Dorgan, U.S. Senate

FEDERAL EMPLOYEES' HEALTH BENEFITS

Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies

Why GAO Did This Study

Rising prescription drug costs have contributed to rising employer health plans premiums in recent years. Most federal employees, retirees, and their dependents participating in the Federal Employees Health Benefits Program (FEHBP), administered by the Office of Personnel Management (OPM), are enrolled in plans that contract with pharmacy benefit managers (PBM) to administer their prescription drug benefits.

GAO was asked to examine how pharmacy benefit managers participating in the federal program affect health plans, enrollees, and pharmacies. GAO examined the use of PBMs by three plans representing about 55 percent of the 8.3 million people covered by FEHBP plans. For example, GAO surveyed 36 retail pharmacies on prices that a customer without third-party coverage would pay for 18 high-volume or high-expenditure drugs and compared these prices to prices paid by the plans and PBMs.

What GAO Found

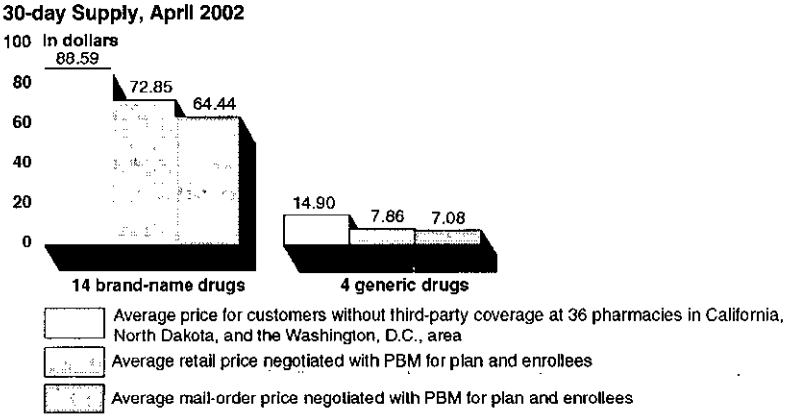
The PBMs reviewed produced savings for health plans participating in FEHBP by obtaining drug price discounts from retail pharmacies and dispensing drugs at lower costs through mail-order pharmacies, passing on certain manufacturer rebates to the plans, and operating drug utilization control programs. For example, the average price PBMs obtained from retail pharmacies for 14 brand name drugs was about 18 percent below the average price paid by customers without third-party coverage.

Enrollees in the plans reviewed had wide access to retail pharmacies, coverage of most drugs, and benefited from cost savings generated by the PBMs. Enrollees typically paid lower out-of-pocket costs for prescriptions filled through mail-order pharmacies and benefited from other savings that reduced plans' costs and therefore helped to lessen rising premiums.

Most retail pharmacies participate in the FEHBP plans' networks in order to obtain business from the large number of enrollees covered. Pharmacy associations report that the PBMs' large market shares leave some retail pharmacies with little leverage in negotiating with PBMs. Retail pharmacies must accept discounted reimbursements from PBMs they contract with and perform additional administrative tasks associated with claims processing.

OPM generally concurred with GAO's findings. The plans and PBMs reviewed provided technical comments, and two independent reviewers stated the report was fair and balanced. One pharmacy association expressed strong concerns, including that the report did not more broadly address economic relationships in the PBM industry. GAO examined relationships between the PBMs and manufacturers and pharmacies specific to their FEHBP business. However, relationships between PBMs and other entities for other plans were beyond the report's scope.

PBM Discounted Prices Compared to Prices for Customers without Third-Party Coverage, 30-day Supply, April 2002



Source: Three plans and PBMs and 36 pharmacies.

www.gao.gov/cgi-bin/getrpt?GAO-03-196.

To view the full report, including the scope and methodology, click on the link above. For more information, contact Kathryn G. Allen at (202) 512-7118.

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Abbreviations

AMP	average manufacturer price
AWP	average wholesale price
BCBS	Blue Cross and Blue Shield
FEHBP	Federal Employees Health Benefits Program
GEHA	Government Employees Hospital Association
HMO	health maintenance organization
IOM	Institute of Medicine
MAC	maximum allowable cost
NACDS	National Association of Chain Drug Stores
NCPA	National Community Pharmacists Association
NDC	National Drug Code
OPM	Office of Personnel Management
PBM	pharmacy benefit managers
SEC	Securities and Exchange Commission
VA	Department of Veterans Affairs
WAC	wholesale acquisition cost

GAO
Accountability * Integrity * Reliability
United States General Accounting Office
Washington, DC 20548

January 10, 2003

The Honorable Byron L. Dorgan
United States Senate

Dear Senator Dorgan:

The increasing cost of prescription drugs has been a key component of rising employer health care costs in recent years. In 2001, total employer health benefit costs rose 11 percent, while prescription drug costs rose 17 percent.[1] Many employer-sponsored health plans and insurers contract with pharmacy benefit managers (PBMs) to help manage their prescription drug benefits. PBMs negotiate drug prices with pharmacies and drug manufacturers on behalf of health plans and, in addition to other administrative, clinical, and cost containment services, process drug claims for the health plans. In 2001, nearly 200 million Americans had their prescription drug benefits managed by a PBM. Most federal employees, retirees, and their dependents participating in the Federal Employees Health Benefits Program (FEHBP), the largest employer-sponsored health insurance program in the United States, are enrolled in plans that contract with PBMs to manage their prescription drug benefits.

Because PBMs play a critical role in managing prescription drug benefits, you asked us to examine PBMs' role within the FEHBP program. In particular, we addressed the following questions:

1. Do PBMs achieve savings, and, if so, how?
2. How do FEHBP plans' use of PBMs affect enrollees, including access to prescription drugs and out-of-pocket spending?
3. How do FEHBP plans' use of PBMs affect retail pharmacies, including pharmacies' reimbursements for drugs dispensed and administrative requirements?
4. How are PBMs compensated for services provided to FEHBP plans?

[1]William M. Mercer Incorporated, *Mercer/Foster Higgins National Survey of Employer-Sponsored Health Plans 2001*, (New York: 2002).

To respond to these questions, we examined the use of PBMs by three FEHBP plans: Blue Cross and Blue Shield (BCBS), Government Employees Hospital Association (GEHA), and PacifiCare of California. Together, these plans accounted for about 55 percent of the 8.3 million people covered by FEHBP as of July 2002 and represented various plan types and PBM contractors.[2] BCBS contracted with the two largest PBMs in the United States for its pharmacy benefit services—Medco Health Solutions, a subsidiary of the pharmaceutical company Merck & Co., Inc., and AdvancePCS. GEHA contracted with Medco Health Solutions and PacifiCare of California contracted with Prescription Solutions, another subsidiary of PacifiCare Health Systems.

We reviewed contracts between the PBMs and plans, financial statements regarding payments made between the plans and PBMs, and retail and mail-order prices for selected drugs from the FEHBP plans we reviewed and the PBMs with which they contracted. We also obtained pricing information from retail pharmacies, interviewed officials at the Office of Personnel Management (OPM),[3] and associations representing PBMs and retail pharmacies, and reviewed studies regarding the use of PBMs and prescription drug payments. Specifically:

- To assess whether PBMs achieve cost savings, we obtained April 2002 prices for 18 drugs that the three FEHBP plans paid to their PBMs for retail and mail order prescriptions.[4] We compared these prices to cash prices[5] that customers would pay at retail pharmacies in California, North Dakota, Washington, D.C., and the Virginia and Maryland suburbs of Washington, D.C., and to Medicaid reimbursement rates in these locations. In addition, we obtained plan and PBM data on drug manufacturers' rebates that PBMs pass on to plans and any estimated savings resulting from certain PBM intervention techniques such as drug utilization reviews and prior authorization.

[2]BCBS and GEHA are fee-for-service plans, while PacifiCare of California is a health maintenance organization (HMO).

[3]OPM has overall administrative responsibility for FEHBP and authority to contract with private plans, including fee-for-service insurers and HMOs, to operate the program. As of July 2002, OPM had contracts with 183 participating plans.

[4]These prices represent the combined enrollee and plan portion paid.

[5]Cash prices refer to the price paid for a prescription without any insurance or other third-party coverage.

- To examine the effect of PBM services on enrollees' access to drugs and out-of-pocket costs, we reviewed plan documents; compared the plans' retail pharmacy networks to the number of licensed retail pharmacies in California, the District of Columbia, Maryland, North Dakota, and Virginia; and compared the number of drugs and therapeutic classes included on the plans' formularies[6] with the National Formulary for the Department of Veterans Affairs (VA).[7]
- To examine the effect of PBMs on retail pharmacies, we interviewed representatives of retail pharmacies and associations and representatives of FEHBP plans and PBMs. We also compared the PBMs' payments to retail pharmacies for selected drugs to industry-reported manufacturer and wholesale prices that estimate pharmacy acquisition costs.
- To examine how PBMs were compensated for services they provided FEHBP plans, we examined the contracts between plans and PBMs and associated annual financial statements and financial information that PBMs filed with the Securities and Exchange Commission (SEC).

While the plans and PBMs provided certain data that they considered proprietary, we do not report such data that can be linked to a specific plan or PBM but instead report aggregated drug price, cost, savings, and compensation data. We did not independently verify information provided by plans, PBMs, or pharmacies. Appendix I provides additional information on our scope and methodology, and a list of our related products is included at the end of this report. Our work was conducted from September 2001 through December 2002 according to generally accepted government auditing standards.

[6]Formularies include lists of prescription drugs, grouped by therapeutic class (groups of drugs that are similar in chemistry, method of action, and purpose of use), that health plans or insurers encourage physicians to prescribe and beneficiaries to use.

[7]We used the VA formulary as a benchmark for comparison because the Institute of Medicine has determined that it is not overly restrictive. The IOM committee also concluded that the VA formulary is in some respects more but in many respects less restrictive than other public or private formularies. See David Blumenthal and Roger Herdman editors, VA Pharmacy Formulary Analysis Committee, Division of Health Care Services, Institute of Medicine, *Description and Analysis of the VA National Formulary* (National Academy Press, Washington, D.C.: 2000).

Results in Brief

The three PBMs we examined achieved savings for FEHBP-participating health plans by using three key approaches: obtaining drug price discounts from retail pharmacies and dispensing drugs at lower costs through their mail-order pharmacies; passing on certain manufacturer rebates to the plans; and using intervention techniques that reduce utilization of certain drugs or substitute other, less costly, drugs. The average price PBMs negotiated for drugs from retail pharmacies was about 18 percent below the average cash price customers would pay at retail pharmacies for 14 selected brand-name drugs and 47 percent below the average cash price for 4 selected generic drugs. These price savings may overstate PBMs' negotiating success because, absent a PBM, plans would likely manage their own drug benefits and also attempt to negotiate discounts with retail pharmacies. PBMs provide plans even greater savings when drugs are dispensed through their mail-order pharmacies. The average mail-order price was about 27 percent and 53 percent below the average cash price customers would pay at a retail pharmacy for the selected brand name and generic drugs, respectively. In addition to discounts, PBMs passed through to plans certain rebates they earned from drug manufacturers. Across the three plans, rebates reduced total annual drug spending by 3 percent to 9 percent from 1998 through 2001. Although difficult to precisely quantify, PBMs also achieved savings through intervention techniques such as prior authorization and drug utilization reviews that identify excess use, duplicative therapies, or the availability of effective, low-cost drug alternatives. For example, plans reported savings in 2001 for various intervention techniques that ranged from less than 1 percent to 9 percent of their total spending on prescription drug benefits.

FEHBP enrollees generally had unrestricted access to retail pharmacies and prescription drugs, savings in out-of-pocket spending, and other safety and customer service benefits. PBMs maintained retail pharmacy networks for the FEHBP plans that included most retail pharmacies—typically 90 percent to nearly 100 percent in five jurisdictions we reviewed. Drug formularies administered by the PBMs were generally not overly restrictive; they included drugs in most major therapeutic categories and mechanisms existed to allow enrollees to obtain nonformulary drugs when prescribed by a physician, although sometimes at a higher out-of-pocket cost. Enrollees also shared in the savings PBMs generated for FEHBP plans. For example, enrollees generally paid less in out-of-pocket costs for drugs from the PBMs' mail-order services than they would at retail pharmacies. Additional PBM savings passed on to plans translated into smaller premium increases for enrollees. Further, each PBM operated a program to review prescriptions at the point of purchase to help prevent

potentially adverse drug interactions, and the PBMs reported that they generally met or exceeded contractual standards on customer service quality.

Pharmacies that participate in retail networks established by FEHBP plans' PBMs must accept discounted prices and undertake additional administrative tasks not required for cash-paying customers' transactions. Although these pharmacies were reimbursed by the PBMs below the level paid by cash-paying customers, we estimate that PBM reimbursements exceeded pharmacies' drug acquisition costs—not including overhead costs or any discounts or rebates some pharmacies may obtain—by an average of approximately 8 percent for brand-name drugs we selected for review. Administrative requirements to process PBM and other third-party prescriptions are greater than for cash transactions. For example, pharmacy staff must file claims electronically, may be required to contact physicians to approve formulary drug substitutions, or counsel patients on plan benefits. Also, retail pharmacies may lose market share to PBM mail-order pharmacies because some PBMs use cost incentives and enrollee health information to promote the use of mail order over retail pharmacies. Nevertheless, most retail pharmacies participate in PBM networks because of the large market share PBMs represent and the prescription and nonprescription sales generated by customers the PBMs help bring into the stores. Pharmacy associations report that retail pharmacies often have little leverage with PBMs, with negotiations only occurring when a large chain will not accept the PBM's contractual terms or an independent pharmacy in a rural area must be included to meet health plans' access requirements.

PBMs received compensation for their FEHBP business from FEHBP plans and payments from pharmaceutical manufacturers through various methods.

- PBMs collected fees from FEHBP plans for various administrative and clinical services including processing claims and conducting drug utilization reviews. These administrative fees, which varied by plan depending on contracted services, accounted for an average of about 1.5 percent of each plan's total drug benefit spending in 2001.
- FEHBP plans we reviewed paid PBMs discounted prices for retail drugs that were virtually the same as prices PBMs paid to reimburse retail pharmacies. However, plans paid lower prices for mail-order drugs supplied by the PBM. While not disclosing their acquisition costs for mail-order drugs, PBM officials said that discounted prices paid by the plans to

PBMs for mail-order drugs were generally higher than prices PBMs paid manufacturers to acquire drugs.

- The PBMs we reviewed varied in the extent to which they retained a share of drug manufacturers' rebates associated with their FEHBP business or passed it all on to the FEHBP plans they contracted with. The PBMs also received other rebates or payments from manufacturers based on their total business with a particular drug manufacturer. While information on the size of these payments was unavailable, PBMs' public financial information suggests that rebates or other payments from drug manufacturers may be a large source of PBM earnings.

In commenting on a draft of this report, OPM generally concurred with our findings. The plans and PBMs we examined reviewed the report for the accuracy of information regarding their arrangements and provided technical comments that we incorporated as appropriate. Two independent experts indicated that the report was fair and balanced and provided technical comments. An official for the National Association of Chain Drug Stores (NACDS) expressed strong concerns in response to our draft report, primarily regarding the scope of our work. An official of the National Community Pharmacists Association (NCPA) separately said he concurred with the NACDS official's comments. A major concern was that the report's focus on FEHBP plans did not adequately address the full scope of economic relationships in the PBM industry, including those between drug manufacturers and PBMs and the extent to which these relationships create incentives for PBMs to encourage the use of certain potentially higher-cost drugs. We examined contracts and relationships between the PBMs and drug manufacturers and pharmacies specific to their FEHBP line of business. However, relationships between PBMs and manufacturers and pharmacies for other plans were beyond the report's scope.

Background

Most FEHBP plans contract with a PBM to help manage their prescription drug benefits, and those that do not contract with a PBM have internal components that employ techniques commonly used by PBMs, according to OPM officials. The three FEHBP plans we reviewed covered more than half of all FEHBP enrollees and paid $3.3 billion for about 65 million prescriptions dispensed to these enrollees in 2001. Table 1 shows plan enrollment and PBMs we reviewed.

Table 1: FEHBP Plans and PBMs Reviewed

	July 2002 Enrollment (percentage of total FEHBP enrollment)	PBMs
BCBS	4,038,671 (48.8)	AdvancePCS (retail) Medco Health Solutions (mail order)
GEHA	441,151 (5.3)	Medco Health Solutions
PacifiCare of California	57,042 (0.7)	Prescription Solutions

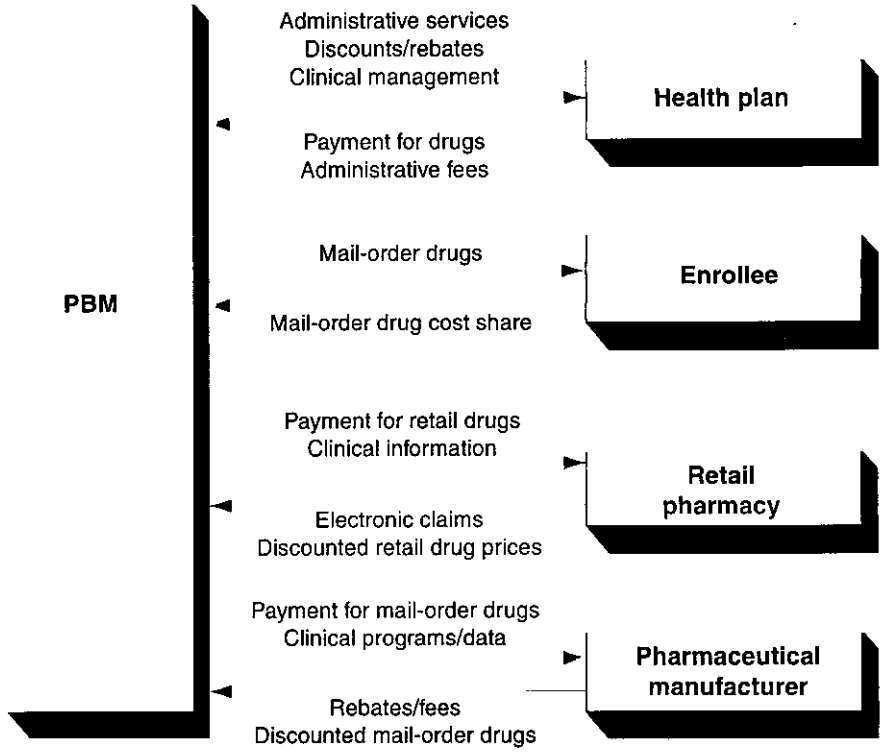
Source: OPM.

Notes: As of July 2002, FEHBP plans covered 8.3 million people.

Some FEHBP plans offer two benefit options, including BCBS (standard and basic options) and GEHA (high and standard options).

PBMs offer health plans a variety of services including negotiating price discounts with retail pharmacies, negotiating rebates with manufacturers, and operating mail-order prescription services and administrative claims processing systems. PBMs also provide health plans with clinical services such as formulary development and management, prior authorization and drug utilization reviews to screen prescriptions for such issues as adverse interactions or therapy duplication, and substitution of generic drugs for therapeutically equivalent brand-name drugs. In order to provide these services, PBMs operate with multiple stakeholders in a complex set of relationships, as shown in figure 1.

Figure 1: PBM Relationships with Market Participants



Source: GAO analysis based on plan and PBM data and literature review.

Note: Other market interactions occur that are not represented in figure 1, including information exchanges among PBMs, manufacturers, wholesalers, physicians, health plans, and enrollees.

Health plans are primarily responsible for overseeing PBM activities and for reporting to OPM any problems that could affect benefits service delivery to enrollees. OPM oversight responsibilities include negotiating plan benefits and changes, monitoring drug benefit service delivery, reviewing customer service reports, conducting on-site visits with pharmacy benefit managers, and handling appeals and complaints from FEHBP enrollees regarding their pharmacy benefits.

PBMs Achieved Savings through Price Discounts, Rebate Payments, and Managing Drug Use

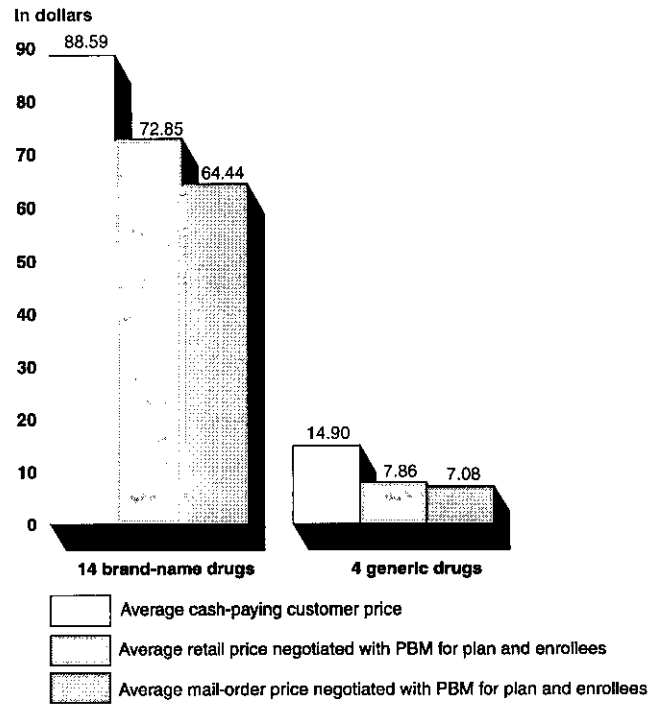
PBMs achieved savings for FEHBP plans primarily by obtaining price discounts for drugs, obtaining rebate payments from manufacturers, and employing various intervention techniques to control drug utilization and cost. In comparison to cash-paying customer prices, PBMs we reviewed obtained significant discounts from retail pharmacies and offered even greater discounts when prescriptions were dispensed through mail-order pharmacies. In addition, PBMs passed on to plans some or all manufacturers' rebates associated with the FEHBP plans' contracts and used intervention techniques that reduced plan spending on drug benefits.

PBMs Obtained Discounted Prices Significantly Below Those Paid by Cash-Paying Customers

In comparison to prices cash-paying customers without third-party coverage would pay at retail pharmacies, the PBMs we examined achieved significant discounts for drugs purchased at retail pharmacies and offered even greater discounts through their mail-order pharmacies. The average price PBMs obtained for drugs from retail pharmacies was about 18 percent below the average price cash-paying customers would pay at retail pharmacies for 14 selected brand-name drugs and 47 percent below the cash price for 4 selected generic drugs. For the same quantity, the average price paid at mail order for the brand and generic drugs was about 27 percent and 53 percent below the average cash-paying customer price, respectively.[8] (See fig. 2.)

[8]In addition to greater discounts, mail-order programs also save money for plans because only one dispensing fee is assessed for a typical 90-day supply of drugs rather than three dispensing fees for each of three 30-day supplies at retail pharmacies. Accounting for the dispensing fee savings for a 90-day supply, effective average discounts from cash-paying customer prices rise slightly from 27.3 to 27.7 percent for the selected brand drugs and from 52.5 to 59.1 percent for the selected generic drugs. Two of the three plans we reviewed limit coverage for prescriptions dispensed at retail pharmacies to a 30-day supply. The third plan limits coverage for retail prescriptions up to an initial 34-day supply but allows up to a 90-day supply for subsequent prescriptions under its lower option; it allows 90-day supplies for all prescriptions under its higher option. We did not survey retail pharmacies for drug prices for a 90-day supply.

Figure 2: PBM Discounted Plan Prices Compared to Cash-Paying Customer Prices for 30-Day Supplies, April 2002



Source: GAO analysis of plan prices from three FEHBP plans and cash-paying customer prices at 36 pharmacies in California, North Dakota, and the Washington, D.C., area.

Note: Most mail-order pharmacies dispense at larger volumes, typically a 90-day supply. Average mail-order discounts from cash-paying customer prices increase slightly if prescriptions are dispensed for a 90-day supply rather than for a 30-day supply.

Moreover, PBMs we reviewed obtained greater discounts from retail pharmacies than did state Medicaid programs, which represent another major purchaser of drugs through retail pharmacies. We estimate that the average reimbursement rate for drugs by 5 Medicaid programs we reviewed was about 11 percent below the average price cash-paying customers would pay at retail pharmacies for the selected brand-name drugs (compared to 18 percent for the FEHBP plans we reviewed) and 23

percent below the average cash price for the selected generic drugs (compared to 47 percent for the FEHBP plans we reviewed).[9]

While PBMs negotiated prices significantly lower than a cash-paying customer would pay, these discounts may overstate the level of savings plans achieve from using PBMs since no benchmark exists to accurately determine what discounts plans would obtain without a PBM. In the absence of a PBM, FEHBP plans could obtain some level of drug price discounts from retail pharmacies and drug manufacturers but would also directly incur the costs associated with undertaking these responsibilities. Also, PBMs can negotiate deeper discounts for plans with smaller networks of retail pharmacies because the pharmacies can anticipate receiving a higher concentration of the plans' enrollees. For example, BCBS introduced its basic option in 2002 that includes a smaller network of retail pharmacies—about 70 percent as many pharmacies as its standard option—and deeper discounts in its retail pharmacy payments compared to its standard option.

PBMs Further Reduced Plans' Drug Expenditures by Passing Through Certain Manufacturer Rebates

PBMs also passed through to the FEHBP plans they contracted with some or all of drug manufacturer rebates associated with their FEHBP business. Over the past 4 years, we estimate that the plans we reviewed received rebate payments that effectively reduced plans' annual spending on prescription drugs by 3 percent to 9 percent. The share of rebates PBMs pass through to plans varies and is subject to contractual agreements negotiated between PBMs and the plans.[10]

Rebates and formularies are interrelated. Drug manufacturers provide PBMs certain rebates depending not only on inclusion of their drugs on a plan's formulary but also on the PBMs' ability to increase a manufacturer's market share for certain drugs. Formulary incentives, such as lower

[9]Medicaid reimbursement and cash-paying customer prices are for California, North Dakota, Washington, D.C., and the Virginia and Maryland suburbs of Washington, D.C.

[10]Under FEHBP, plans may negotiate rebates as part of contractual agreements with PBMs. In contrast, as a condition of Medicaid coverage for outpatient drugs, manufacturers are required to provide state Medicaid programs with certain rebates. For brand name drugs, Medicaid rebates must be a minimum of 15.1 percent of the average manufacturers' price (AMP). For the 14 brand name drugs we reviewed, we estimate that the minimum Medicaid rebate would reduce costs by an average of at least 12 percent. For generic drugs, Medicaid rebates must equal 11 percent of the AMP, which we estimate would reduce costs by an average of about 2 percent for the 4 generic drugs we reviewed. Moreover, states may negotiate additional rebates with manufacturers in order to reduce costs.

enrollee cost sharing for certain drugs compared to competing therapeutically equivalent drugs, encourage the former's use. Manufacturers may pay higher rebates when formularies have stronger incentives to use specific drugs. Therefore, PBMs may be able to provide other health plans with higher rebates if their formularies are more restrictive than those of the FEHBP plans we examined.

PBM Intervention Techniques Contributed to Plans' Savings, but Are Difficult to Quantify

Although PBM intervention techniques help contain plans' cost increases by managing drug utilization and identifying opportunities to dispense less expensive drugs, their full impact on savings is not easily quantifiable. The FEHBP plans and PBMs we reviewed reported savings for individual intervention techniques ranging from less than 1 percent to 9 percent of plans' total drug spending in 2001.[11] Because plans varied in their use of intervention techniques and employed different cost savings methodologies, these estimates may not be comparable across plans. Techniques plans most commonly used included concurrent drug utilization review, prior authorization, therapeutic brand interchange, and brand to generic substitution. The reported cumulative effect of several techniques for one plan amounted to 14 percent of drug spending.

Measuring cost savings from PBM intervention techniques is difficult for various reasons, including:

- Savings methodologies did not reflect the effect intervention techniques may have over time on enrollees' utilization patterns and physicians' prescribing practices. That is, there may be a sentinel effect from PBMs' reviews whereby enrollees and physicians may stop filling or prescribing drugs that do not meet PBMs' utilization review or refill criteria, but the extent to which these behavior changes occur is beyond the scope of PBMs' data systems.
- Plans and PBMs we reviewed did not consistently measure the number or costs of drugs not dispensed as a result of PBM interventions that result in drug substitutions, denials for adverse drug interaction, or other interventions, making it difficult to estimate savings from certain intervention techniques.
- Plans did not systematically measure savings when the primary goal of the intervention technique was patient safety and compliance with drugs' clinical guidelines.

[11]Plans did not have estimates for all of their intervention techniques.

Among various intervention techniques, concurrent drug utilization and prior authorization provided some plans the largest quantifiable savings. The following are examples of intervention savings estimates reported by plans we reviewed.

- *Drug utilization review* includes the PBM examining prescriptions concurrently at the time of purchase to assess safety considerations, such as potential adverse interactions, and compliance with clinical guidelines, including quantity and dose. These reviews can also occur retrospectively to analyze enrollees' drug utilization and physicians' prescribing patterns. Two plans estimated savings from drug utilization review ranging from 6 percent to 9 percent, with about 60 percent to 80 percent of the savings from concurrent reviews, including claim denials from the PBM to prevent early drug refills and safety advisories to caution pharmacists about potential adverse interactions or therapy duplications.[12] The remaining estimated savings are from retrospective reviews.
- *Prior authorization* requires enrollees to receive approval from the plan or PBM before dispensing certain drugs that treat conditions or illnesses not otherwise covered by plans, have high costs, have a high potential for abuse, or are ordered in unusual quantities. Some plans may also require prior authorization for nonformulary drugs. Each of the plans we reviewed required prior authorization for certain drugs such as growth hormones and a drug used to treat Alzheimer's disease. Two plans reported savings from prior authorization ranging from 1 percent to 6 percent of plan spending for drugs that either were not dispensed or were substituted for with less costly alternatives.
- *Therapeutic interchange* encourages the substitution of less expensive formulary brand-name medications considered safe and effective for more expensive nonformulary drugs within the same drug class. Two plans reported savings ranging from 1 percent to 4.5 percent from therapeutic

[12]Savings from concurrent utilization review may be reduced if an enrollee subsequently obtains a prescription or refill. One PBM estimated savings for claims denied for early refills only if a refill had not been obtained within 14 days.

interchange. These estimates are in addition to savings associated with rebates plans earned for drugs in the formulary.[13]

- *Generic substitution* involves dispensing less expensive, chemically-equivalent generic drugs in place of brand name drugs. Where a PBM specifically intervened by contacting the physician to change a prescription from requiring a brand name to allowing a generic drug, one plan reported savings of less than 1 percent of the plan's total drug spending. The other two plans said they do not have readily available data to measure savings from PBM interventions for generic drugs. All three plans reported more general information on their generic drug use, but the extent to which generic drugs are used cannot solely be attributed to PBMs because plan benefit design and physician prescribing patterns also influence generic drug use. On average, the plans we reviewed reported that generic drugs were dispensed more often by retail pharmacies (about 45 percent of all drugs dispensed) than by mail-order pharmacies (about 34 percent). The difference in use of generic drugs may in part reflect differences in the types of drugs that are typically dispensed through retail and mail-order pharmacies. For drugs where a generic version was available, the retail and mail-order pharmacies dispensed generic drugs at more similar rates—on average 89 percent of the time for retail pharmacies and 87 percent of the time for mail-order pharmacies.

[13]While plans reported savings from therapeutic interchange, concerns have been raised that in some cases PBMs' relationships with manufacturers and retail pharmacies influence PBM interventions, such as substituting higher-cost drugs when lower-cost therapeutic equivalent drugs are available. Medco Health Solutions and Advance PCS filings with the SEC indicate that the Department of Justice is undertaking an industrywide investigation to examine PBM relationships with pharmaceutical manufacturers and retail pharmacies and PBMs' programs related to drug formulary compliance, which includes rebates and other payments made by manufacturers to PBMs. The SEC filings show that the Department of Justice is also investigating payments made by PBMs to retail pharmacies or others in connection with PBM interventions.

PBMs Provided FEHBP Enrollees Generally Unrestricted Access to Prescription Drugs, Cost Savings, and Other Benefits

PBMs we reviewed generally provided enrollees with access to a nearby pharmacy, maintained formularies for plan enrollees that included drugs in most major therapeutic categories, and provided access to nonformulary drugs when medically necessary. The FEHBP plans passed on savings generated by the PBMs to enrollees in the form of lower out-of-pocket costs for prescription drugs in certain instances, such as through lower cost sharing for drugs obtained through mail-order pharmacies, and a smaller increase in premiums for all enrollees than might occur absent the PBM savings. Enrollees also benefited from PBM intervention programs to prevent potentially dangerous drug interactions and customer service that generally met or exceeded quality standards established in contracts negotiated with the FEHBP plans.

PBMs Provided Enrollees Access to Broad Retail Pharmacy Networks and Generally Nonrestrictive Drug Formularies

Nearly all FEHBP enrollees had a retail pharmacy participating in their plan within a few miles of their residence. Two of the plans required the PBM to assure that at least 90 percent of enrollees had at least one pharmacy located within 5 miles of their residences. The PBMs for these plans reported to us they exceeded plans' access standards and that close to 100 percent of enrollees live within 5 miles of a network pharmacy. The third plan did not have a specific contractual access standard, but plan officials said they have verified that well over 90 percent of enrollees live within 5 miles of a network pharmacy. We also compared the PBMs' networks statewide in five states to the total of licensed retail pharmacies and found high levels of pharmacy participation. In most instances, we estimate that more than 90 percent to nearly 100 percent of licensed retail pharmacies participated in the PBM networks.[14]

Enrollees also had few restrictions on which drugs they could obtain. While the plans' formularies varied with respect to the number of drugs covered, they included prescription drugs in most major therapeutic

[14]The states are California, the District of Columbia, Maryland, North Dakota, and Virginia. Estimates of pharmacy participation rates are approximate because of ongoing changes in the number of pharmacies licensed in each state and included in each PBM network and because PBM retail pharmacy networks may include a small number of nonretail pharmacies, such as hospital pharmacies. In 2002, BCBS began offering a basic option to FEHBP enrollees that includes about 70 percent as many pharmacies nationwide as the BCBS standard option but still meets contractual standards for a retail pharmacy to be located within a few miles of nearly all basic option enrollees. More than 200,000 people are in BCBS's basic option compared to about 3.8 million people in the standard option.

categories.[15] To provide a benchmark for comparing the breadth and depth of the FEHBP formularies, we compared the three formularies to the outpatient prescription drugs included in the Department of Veterans Affairs (VA) National Formulary, considered by the Institute of Medicine to be not overly restrictive.[16] Each plan included over 90 percent of the drugs listed on the VA formulary or a therapeutically equivalent alternative, and included at least one drug in 93 percent to 98 percent of the therapeutic classes covered by VA.[17] (See table 2.)

[15]Formularies may be developed by the plan with suggestions for changes from a PBM, or entirely by a PBM and used by the plan. BCBS and PacifiCare designed their own formularies, while GEHA used a formulary developed by Medco Health Solutions. Decisions on inclusion of drugs in a formulary are typically made by a pharmacy and therapeutics committee composed of physicians and pharmacists. Plan officials and documents described such committees as being designed to evaluate the safety, efficacy, and cost of drugs in all therapeutic categories before recommending drugs for inclusion on the formulary. Plans we reviewed had no or few committee members affiliated with the plan or PBM.

[16]See Blumenthal and Herdman, *Description and Analysis of the VA National Formulary.*

[17]BCBS excluded from its formulary 7 percent of the VA therapeutic classes, which contain drugs to treat insect stings, itching, psoriasis and other skin disorders, erectile dysfunction, certain types of rheumatoid arthritis, fungal eye infections, lung diseases where mucous complicates the condition, constipation, and a topical anesthetic and water inhaler. GEHA excluded from its formulary 2 percent of the VA therapeutic classes, which contain drugs to treat opiate (e.g., heroin, morphine) dependence, constipation, and a topical anesthetic. PacifiCare of California excluded from its formulary 5 percent of the VA therapeutic classes, which contain drugs to treat various infections, opiate (e.g., heroin, morphine) dependence, psoriasis and other skin disorders, erectile dysfunction, and inflamed gingiva. PacifiCare of California's formulary also did not include several injectable drugs that are covered separately under the plan's medical benefit.

Table 2: FEHBP Plans' Formularies Compared to VA National Formulary

Plan	Percent of VA formulary drugs included in plan formulary	Percent of VA formulary drugs not in plan formulary but having a therapeutic equivalent in plan formulary	Percent of VA formulary's therapeutic classes covered by plan formulary[a]
BCBS	80	16	93
GEHA	97	2	98
PacifiCare of California	79	15	95

Source: GAO analysis of 2002 BCBS, GEHA, and PacifiCare of California formularies and the VA National Formulary.

[a]A VA therapeutic class was considered included if the plan formulary listed one or more VA drugs or a therapeutically equivalent alternate within the VA therapeutic class.

Each plan provided enrollees access to nonformulary drugs, although sometimes with higher cost sharing requirements.[18] GEHA provided coverage to all nonformulary drugs at no additional cost to enrollees. BCBS had additional cost sharing requirements for nonformulary and certain formulary drugs under its basic option plan. Enrollees must pay a flat $25 copayment for formulary brand drugs but must pay the greater of a $35 copayment or 50 percent of the plan's cost for nonformulary brand drugs (known as coinsurance). BCBS required the enrollees to pay the same 25 percent coinsurance for formulary and nonformulary drugs under its standard option plan. PacifiCare of California did not impose additional cost sharing for nonformulary drugs but generally required enrollees (or their physicians) to demonstrate the medical necessity and lack of effective alternative formulary drugs prior to approving coverage of a nonformulary drug.

PBM Savings Helped Reduce Enrollees' Costs for Out-of-Pocket Prescription Drug Spending and Premiums

FEHBP enrollees benefited from cost savings generated from PBM services through lower costs for mail-order prescriptions, lower cost sharing linked to PBMs' discounts obtained from retail pharmacies, and a lower increase in premiums overall. PBM mail-order pharmacy programs often provided for lower out-of-pocket costs for 90-day supplies of drugs than an enrollee would pay for the same prescriptions filled at a retail

[18]OPM indicates that, in conducting annual negotiations with plans, it seeks to ensure enrollee access to nonformulary drugs although such access may involve higher cost sharing requirements.

pharmacy. The GEHA high option plan and PacifiCare of California imposed lower cost-sharing requirements for mail order while the BCBS standard option plan imposed a flat copayment for mail order but required enrollees to pay 25-percent coinsurance at retail. The flat copayments provided an incentive for enrollees to use mail order for more expensive brand drugs. Only the GEHA standard plan included the same cost sharing requirements for both retail and mail order. (See table 3.)

Table 3: Comparison of Enrollee Cost-Sharing for a 90-day Supply of Retail and Mail-Order Prescription Drugs, 2002

Plan	Option	Enrollee's cost share at retail pharmacy	Enrollee's cost share at mail-order pharmacy
BCBS	Standard	25% coinsurance	$10 copayment generic $35 copayment brand
	Basic[a]	$30 generic $75 brand Greater of 50% coinsurance or $105 copayment for nonformulary brand	Mail-order not available
GEHA[b]	High	$15 generic $45 single-source brand[c] $90 multisource brand[d] Second and subsequent refills are greater of 50% coinsurance or applicable copayment	$10 generic $35 single-source brand[c] $50 multisource brand[d]
	Standard	$15 copayment generic 50% coinsurance brand	$15 copayment generic 50% coinsurance brand
PacifiCare of California[b]	HMO	$15 copayment generic $45 copayment brand	$10 copayment generic $30 copayment brand

Source: GAO analysis of BCBS, GEHA, and PacifiCare of California prescription drug benefits literature.

[a]BCBS basic option limits initial prescription to a 34-day supply with a $10 copayment for generic drugs, $25 copayment for brand-name drugs, and the greater of 50 percent coinsurance or $35 for nonformulary brand-name drugs. Continuing prescriptions and refills can be for up to a 90-day supply with the enrollee paying the higher cost share amount.

[b]GEHA and PacifiCare of California limit the quantity of drugs dispensed through retail pharmacies to a 30-day supply; therefore, we tripled the copayments required for a 30-day supply.

[c]Brand-name drugs available from only one manufacturer, no generic equivalent available.

[d]Brand-name drugs available from more than one manufacturer and have a generic equivalent available.

The interaction between a plan's benefit design and PBM cost savings can also affect the amount of enrollees' out-of-pocket costs for prescription drugs.[19] For example, in instances where a plan required enrollees to pay a coinsurance rate representing a portion of the actual drug cost, enrollees shared directly in price discounts PBMs obtained from pharmacies. To illustrate, for a hypothetical drug with an undiscounted cash price of $64, and a PBM-obtained discount price of $52, an enrollee in a plan with a 25-percent coinsurance requirement would pay $13 rather than $16. In contrast, where a plan's benefit design provides for a fixed copayment, such as $15 per prescription, enrollees would pay the same regardless of the discount that PBMs obtained.

PBM savings were also passed on to enrollees in the form of premiums that were less than they otherwise would be. Fee-for-service FEHBP plan premiums are based on past years' claims data for FEHBP enrollees.[20] Consequently, PBM reductions in plan claims costs for prescription drugs translate into lower premiums for enrollees in later years. For example, we estimate that PBM savings in the form of rebates passed on to the two fee-for-service FEHBP plans we examined between 1998 and 2000 translate into about a 1-percent decrease from what the plans' future premiums would have been. In contrast to savings through cost sharing and other benefit design features that accrue only to those enrollees who use the prescription drug benefit, PBM savings in the form of premium savings accrue to all enrollees, regardless of whether they use prescription drugs.

Enrollees Also Benefit from PBM Drug Utilization Review Programs and Customer Service

Each FEHBP plan's PBM provided a drug utilization review program to screen prescription drug therapies for such problems as adverse interactions, incorrect dosages, or improper duration of treatment. PBMs maintained a centralized database on each enrollee's drug history and shared this information electronically with pharmacies at the time the

[19]A plan's pharmacy benefit design includes the drugs a plan will cover through its formulary, the quantities in which drugs will be dispensed, the sources from which drugs may be obtained, and enrollee's cost-sharing requirements, such as copayments.

[20]For most HMOs, the premium rate is based on rates charged to the two employer groups closest in size to the plan's FEHBP enrollment. Because these premiums are based on the HMO's overall premium setting strategies and not just the FEHBP claims experience, the extent to which rebates and other PBM savings for the plan's FEHBP business would yield lower premiums depends on the HMO's current market strategies for setting competitive premiums and passing on lower costs in the form of lower premiums to FEHBP and similarly sized groups. About 30 percent of FEHBP enrollees are covered under an HMO plan.

prescription was filled. PBMs are often the only entity with complete information on a patient's medications—particularly when enrollees are prescribed medication by more than one physician or fill prescriptions at different pharmacies. We have previously reported that automated drug utilization systems linked to a centralized database provide a more thorough prospective review and more benefits than reviews based on manual or local systems.[21]

PBMs provide customer service when they interact directly with FEHBP enrollees, such as when enrollees contact the PBMs to seek information about their prescriptions, resolve problems with having their prescription drugs filled, or obtain drugs through the mail-order pharmacy. Customer service quality is measured against customer service standards negotiated between each FEHBP plan and PBM. These standards included such measures as phone call answer time, mail-order prescription turn-around time and accuracy rates, and customer satisfaction as measured through enrollee surveys. Data provided by the PBMs indicate that they generally met or exceeded these standards, although we did not independently verify these data.[22]

Pharmacies Included in PBM Retail Networks Must Accept Discounted Prices and Perform Various Administrative Tasks

Retail pharmacies that participate in the PBM networks used by FEHBP plans are affected by PBM policies and practices. For example, PBMs reimbursed pharmacies at levels below cash-paying customers, but above the pharmacies' estimated drug acquisition costs. Processing PBM or other third-party prescriptions involves additional administrative requirements compared to cash transactions, and some PBMs may draw business away from retail pharmacies by providing savings and other incentives to encourage pharmacy customers to use PBMs' mail-order pharmacies. Nevertheless, participation in the PBM retail networks is important for pharmacies because the PBMs serving the FEHBP plans we reviewed also

[21]U.S. General Accounting Office, *Prescription Drugs: Automated Prospective Review Systems Offer Potential Benefits for Medicaid*, GAO/AIMD-94-130 (Washington, D.C.: Aug. 5, 1994).

[22]Contracts called for the PBMs to regularly report to the plans their actual performance in relation to the standards and usually provided plans with the right to audit these performance reports and impose penalties or terminate the contract if PBM performance fell below the standards. In a few recent instances, financial penalties were imposed when performance temporarily fell short of a standard. For example, one PBM paid a penalty of $40,000 for failing to meet the plan standard concerning call answer time during 2 months of 2001, but the PBM met the standard during the remainder of the year.

contract with other clients that cumulatively represent a large share of the national population that purchase prescription and other nonprescription items from retail pharmacies.

PBMs Reimbursed Retail Pharmacies Less than Cash-Paying Customers but Above Estimated Costs

PBMs for the three FEHBP plans we reviewed reimbursed retail pharmacies at rates below what a cash-paying customer would pay but still above the pharmacies' estimated acquisition costs. The average price paid for a typical 30-day supply was nearly 18 percent below the cash-paying customer price for 14 selected brand-name drugs and 47 percent below the average case price for 4 selected generic drugs. As a result, the gross margin earned by retail pharmacies on the PBM transactions is lower on average than for cash-paying customers.[23]

We estimate that these PBM discounted prices are higher on average than the pharmacies' cost to acquire these drugs. Retail pharmacies typically purchase drugs from intermediary wholesale distributors and, to a lesser extent, from drug manufacturers directly. Because no data source exists to identify pharmacies' actual acquisition costs for drugs, we used the wholesale acquisition cost (WAC) and added a mark-up of 3 percent to estimate pharmacy acquisition costs for drugs purchased from wholesalers.[24] Accordingly, for the three FEHBP plans we reviewed, we estimate that the prices that the PBMs paid to retail pharmacies provided an average margin of about 8 percent above the pharmacies' average

[23]In 2001, about 16 percent of all prescriptions were purchased by customers who paid the entire cost without any third-party coverage, and the remainder were paid by customers with third-party payers, including Medicaid, according to the National Association of Chain Drug Stores.

[24]WAC is a published, industry-reported measure of the average price manufacturers charge wholesalers. According to retail pharmacy representatives, wholesalers sell drugs to retail pharmacists for about 1 to 3 percent above WAC on average. WAC does not include rebates or discounts manufacturers may offer to wholesalers.

acquisition costs for 10 brand drugs we reviewed.[25,26] These estimated margins on the drugs do not reflect a drug store's profit on drug sales because store overhead and dispensing costs are not deducted.[27] They also do not reflect the costs of drugs when purchased directly from manufacturers rather than wholesalers nor any rebates or discounts that pharmacies may receive from suppliers or manufacturers. Moreover, because WAC is an average of prices charged by manufacturers to multiple purchasers, it may not accurately reflect the acquisition costs for any individual retail pharmacy.

PBM Transactions Require Additional Administrative Tasks and Incur Higher Processing Costs for Retail Pharmacies

PBM and other third-party transactions require pharmacy staff to undertake tasks not associated with cash-paying customer transactions, such as submitting claims electronically, responding to prior authorization requests, contacting physicians to approve formulary drug substitutions, and responding to patients' questions about their health plan benefits. Pharmacists and pharmacy association representatives we interviewed indicated that the administrative requirements imposed by FEHBP-participating PBMs are generally similar to those imposed by PBMs

[25]Margins on drugs represent the portion of PBM drug reimbursements (including dispensing fees) and enrollees' share of costs that exceed the pharmacy's acquisition costs for the selected drugs. Retail plan prices represent 10 of the 14 brand-name drugs we examined because the wholesale acquisition cost was not available for the other 4 brand-name drugs. The PBM negotiated prices were also higher than the estimated acquisition costs for all four generic drugs we reviewed.

[26]The U.S. Department of Health and Human Services Office of Inspector General recently released estimates of pharmacy acquisition costs for drugs reimbursed by state Medicaid programs. Using its approach to estimate the acquisition costs for the drugs we reviewed would result in prices that PBMs paid retail pharmacies providing an average margin of about 6 percent above the pharmacies' average acquisition costs for the 10 brand drugs and about 14 percent above for the 4 generic drugs. See Department of Health and Human Services, Office of Inspector General, *Medicaid Pharmacy – Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products*, (Washington, D.C.: September 2002).

[27]While it was not possible to identify the pharmacies' overhead costs for the 18 drugs we reviewed, recent studies done for the California and Texas Medicaid programs estimate that the median dispensing costs for pharmacies participating in these states' Medicaid programs were about $6.95 and $5.95 per prescription, respectively. See Myers and Stauffer LC, "Study of Medi-Cal Pharmacy Reimbursement,"(Missouri: June 2002) and "Determination of the Cost of Dispensing Pharmaceutical Prescriptions for the Texas Vendor Drug Program," (Missouri: August 2002). The National Association of Chain Drug Stores (NACDS) estimates that retail pharmacies' dispensing costs were on average $7.26 per prescription in 2001. See NACDS, *The Chain Pharmacy Industry Profile 2002* (Alexandria, Virginia: 2002).

associated with other health plans. Several studies have found that pharmacy staff spent significant time addressing third-party payment issues. For example, based on surveys of 201 retail pharmacies, one consultant found that 20 percent of pharmacy staff time was spent on activities directly related to third-party issues.[28] A synthesis of multiple studies concluded that third-party prescriptions cost from $0.36 to $1.55 more than cash transactions to process.[29]

Compared to larger chain pharmacies, independent pharmacies may find PBM processing tasks particularly burdensome or costly. For example, independent pharmacies may be more likely to use pharmacists to process third-party transactions because they tend to have fewer other staff available, such as pharmacy technicians and clerks, according to a retail pharmacy association official. One study found that the average labor cost to process third-party prescriptions that required pharmacy staff intervention (such as responding to an initial claim denial) was 44 percent higher for an independent than a chain pharmacy. This study attributes the higher costs to the independent pharmacy's greater reliance on pharmacists for performing certain third-party processing tasks.[30]

PBMs Use Financial and Other Incentives to Steer Retail Pharmacy Customers to Mail-Order Programs

PBMs may also attempt to steer some enrollees away from retail pharmacies to their mail-order pharmacies. Two of the PBMs we reviewed send letters to some enrollees who purchase medications at a retail pharmacy informing them that their costs under the mail-service pharmacy program would be lower. These letters may include forms to facilitate the transfer of the prescription from the retail to the mail-order pharmacy. In 2001, the three FEHBP plans we reviewed dispensed 21 percent of all prescriptions through mail order, a higher share than the industry average. Nationally, a growing but still small share of prescription drugs is .

[28]Arthur Andersen LLP, *Pharmacy Activity Cost and Productivity Study*, November 1999.

[29]Richard N. Herrier et al., "Case Study Using Descriptive Analysis to Estimate Hidden Costs In Processing Third Party Prescriptions," *Journal of the American Pharmaceutical Association*, 40, no. 5 (September/October 2000). In addition to synthesizing other studies, this study also conducted time and motion measurement of retail pharmacies and based on this new research estimated that third-party prescriptions cost an average of $0.44 to $0.61 more than cash transactions to process.

[30]Richard N. Herrier, et al.

dispensed through mail-order pharmacies—about 5 percent of prescriptions and 17 percent of prescription sales in 2001.[31]

Most Pharmacies Participate in PBMs' Retail Networks

Most licensed pharmacies participate in the FEHBP PBMs' retail pharmacy networks, in part because PBMs represent such a substantial market share–nearly 200 million Americans in 2001.[32] Plan and PBM representatives noted that access to these enrollees benefits retail pharmacies by increasing traffic in the stores and thus sales of prescriptions and nonprescription items. According to NACDS, nonprescription sales nationally accounted for 5 percent of total sales for independent pharmacies and 39 percent of total sales for chain pharmacies in 2001.[33] However, pharmacy association representatives report that PBMs' large market shares leave many retail pharmacies with little leverage in negotiating with PBMs. These officials indicate that retail pharmacies may have to "take or leave" a PBMs' proposed contract with actual negotiations only occurring in instances when a large chain will not accept the contractual terms or an independent pharmacy without nearby competitors in a rural area must be included to meet health plans' access requirements. While it is difficult to assess how frequently these situations occur, chain pharmacies constituted 37 percent of all retail pharmacies and the top four chain drugs stores accounted for 30 percent of all pharmacy sales in 2000, according to NACDS.[34]

[31]National Association of Chain Drug Stores, *The Chain Pharmacy Industry Profile, 2002* (Alexandria, VA: 2002).

[32]Independent pharmacies were somewhat less likely to participate in FEHBP PBM retail networks than chain pharmacies. For example, we found that all but one of the pharmacies not participating in two PBM retail networks in the District of Columbia were independent. Similarly, a 2001 survey of pharmacies in Connecticut, New Jersey, New York, and Pennsylvania by the Pharmaceutical Care Management Association found independent drug stores somewhat less likely to participate in PBM retail networks (96.5 percent) than chain drug stores (99.9 percent). According to a pharmacy industry representative, independent pharmacies may have fewer staff available to manage third-party transactions and contracting functions. In addition, certain PBM contract requirements can pose a challenge, such as requiring the use of computer systems or software that may be unaffordable to some small, independent pharmacies, according to another pharmacy industry representative.

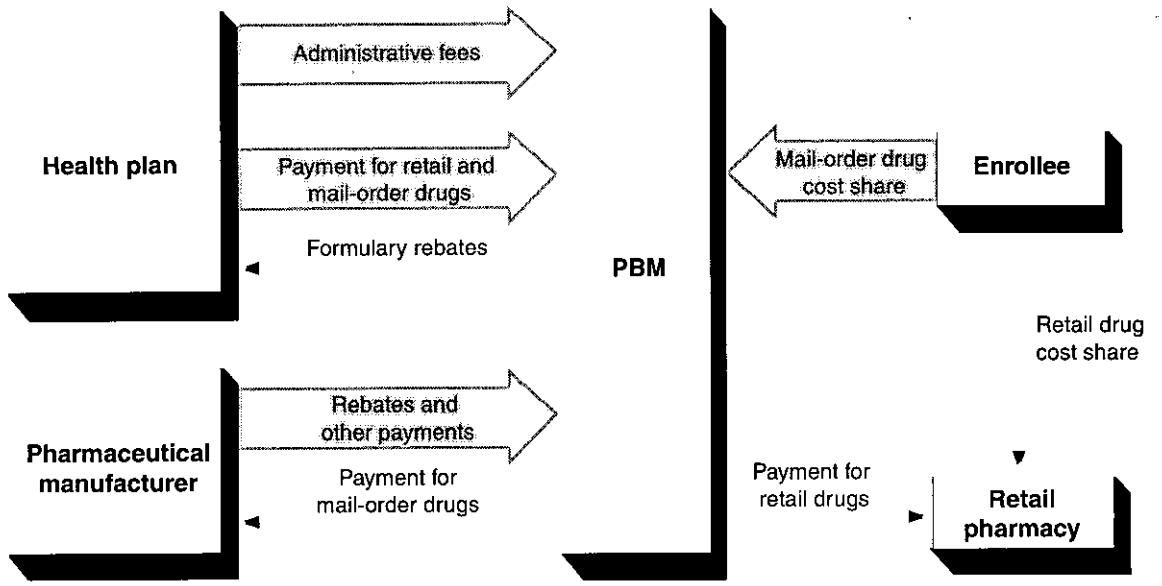
[33]National Association of Chain Drug Stores, *The Chain Pharmacy Industry Profile, 2002* (Alexandria, VA: 2002).

[34]National Association of Chain Drug Stores, *The Chain Pharmacy Industry Profile, 2002* (Alexandria, VA: 2002) and Booz Allen Hamilton, *Medicare-endorsed Prescription Drug Card Assistance Initiative*, (McLean, VA: 2002).

PBMs Received Compensation from Plans and Payments from Manufacturers for Their FEHBP Business

PBMs received compensation directly from FEHBP plans for administrative services and drug costs as well as payments from pharmaceutical manufacturers. (See fig. 3.) PBM earnings from administrative fees and payments for mail-order drugs paid by the plans we reviewed varied depending on contractual arrangements. In addition, the PBMs we reviewed varied as to whether they retained a portion of drug manufacturer rebates associated with the FEHBP contracts, and all the PBMs received other rebates or payments from drug manufacturers.

Figure 3: Overview of PBMs' Compensation and Payment Sources



Source: GAO analysis of plans and PBMs reviewed.

Note: The extent to which a PBM receives compensation and payments from any one of these sources varies based on its contractual arrangements with plans and manufacturers. For example, some PBMs may contract with a separate entity to provide mail-order services.

Specifically, the PBMs we reviewed received administrative fees, payments for drugs, and manufacturer rebates for their FEHBP business. They also received other rebates or payments from drug manufacturers based on their entire line of business with a particular manufacturer.

Administrative fees. PBMs charged plans fees for a broad range of clinical and administrative services, including utilization reviews, prior authorization, formulary development and compliance, claims processing, and reporting. Administrative fees for plans we reviewed varied but on average accounted for about 1.5 percent of total plan drug spending in 2001.

Payments for Retail and Mail-Order Drugs. PBMs we reviewed retained little or no revenue from plan payments for retail drug costs and dispensing fees because they were largely passed through to retail

pharmacies.[35] While not disclosing their acquisition costs for mail-order drugs, PBM officials said that plan payments were somewhat higher than their payments to pharmaceutical manufacturers for mail-order drugs. Using the average manufacturer price (AMP) as a proxy for PBMs' mail-order acquisition costs,[36] we estimate that the discounted price for mail-order drugs that plans and enrollees paid were on average higher than the estimated mail-order acquisition cost for some (but not all) brand-name drugs and all generic drugs that we reviewed. On average, the AMP was about 2 percent below the plan prices for 7 of the 14 brand-name drugs we reviewed but about 3 percent higher than the plan prices for the other 7 brand-name drugs. The AMP was below plan prices for all four generic drugs we reviewed.

Rebates. PBMs shared with the FEHBP plans certain rebates that a drug manufacturer provides a PBM associated with their FEHBP business, although the extent to which the PBMs retained a portion of these rebates varied, depending on the contracts negotiated between the plans and PBMs. We estimate the rebates retained by the PBMs we reviewed represented less than half of one percent of total plan drug spending. The plans we reviewed varied as to whether they reimbursed PBMs separately for administrative services in exchange for a larger share of contractual rebates or they received less of the contractual rebates and were charged low or no fees for administrative services.

PBMs also received other manufacturer rebates or payments for services based on their total volume of a particular manufacturer's drugs sold through FEHBP plans and other plans. For example, one PBM we reviewed earned additional manufacturer rebates for its efforts to increase drug manufacturers' share of certain products. The PBMs also received fees from manufacturers for various services, such as encouraging physicians to change prescribing patterns, educational services to enrollees regarding compliance with certain drug regimens, and data reporting services. These rebates and other payments were a large portion

[35]The plan and enrollees share the cost of retail drugs, with the enrollee share paid directly to the retail pharmacy.

[36]The AMP is the average price paid to a drug manufacturer by wholesalers for prescription drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts. AMP was created by the Omnibus Budget Reconciliation Act of 1990 (Pub. L. No. 101-508, § 4401, 104 Stat. 1388, 1388-156) for determining Medicaid rebates and is not publicly available. It is calculated by the manufacturer and submitted to the Centers for Medicare & Medicaid Services, the federal agency that determines Medicaid rebates.

of PBMs' earnings, according to PBM officials and industry experts, but the actual amounts were undisclosed because they are proprietary. Public financial information suggests that manufacturer payments are important sources of earnings. For example, in financial reports submitted to the SEC, two of the PBMs we reviewed stated that manufacturer rebates and fees were key to their profitability.[37]

Concluding Observations

PBMs are central to most FEHBP plan efforts to manage their prescription drug benefits, and PBMs have helped the FEHBP plans we reviewed reduce what they would likely otherwise pay in prescription drug expenditures while generally maintaining wide access to most retail pharmacies and drugs. As the cost of prescription drugs continues to increase, FEHBP plans are likely to encourage PBMs to continue to leverage their purchasing power with drug manufacturers and retail pharmacies and pass on the savings to the plans and their enrollees. However, attempts to achieve additional cost savings can involve trade-offs for plan enrollees. For example, additional savings through formulary management can accrue if more restrictive formularies are used, but enrollees would likely have unrestricted access to fewer drugs. Similarly, retail pharmacies may be willing to provide deeper discounts as part of smaller, more selective retail pharmacy networks. Smaller networks have the potential to draw more enrollees into participating stores but offer enrollees access to fewer retail pharmacies. OPM, FEHBP plans, and PBMs must balance these trade-offs in designing affordable and accessible prescription drug benefits for federal employees.

Agency and Other Comments and Our Evaluation

We provided a draft of this report to OPM, the three plans and three PBMs we reviewed, two pharmacy associations (NACDS and NCPA), and two independent expert reviewers.

In written comments, OPM generally concurred with our findings. OPM highlighted the advantages and trade-offs associated with FEHBP plans'

[37]See AdvancePCS, 10-K Form filed with SEC on June 28, 2002 and Medco Health Solutions Form S-1, filed with SEC on April 17, 2002. A 10-K Form is an annual report that many for-profit corporations must file with SEC within 90 days of the close of their fiscal year and a S-1 Form is a basic registration form that may be used to register a proposed public offering with SEC. These publicly available documents contain audited financial statements and other information on a corporation's financial condition.

use of PBMs in providing affordable drug benefits and providing enrollees with access to prescription drugs. Appendix II contains OPM's comments.

The plans and PBMs reviewed the report for the accuracy of information regarding their arrangements and provided technical comments regarding information we reported about them, which we incorporated as appropriate. Two independent external experts on pharmaceutical drug pricing who were not affiliated with PBMs, pharmacies, or drug manufacturers indicated that the draft was fair and balanced. They also provided technical comments that we incorporated as appropriate.

In oral comments, NACDS' Vice President for Policy and Programs expressed strong concerns, particularly focusing on the scope of our work, and NCPA's Senior Vice President for Government Affairs and General Counsel separately informed us that he generally concurred with NACDS' comments. NACDS' concerns included the following:

- Our draft did not adequately address the overall PBM industry and how it operates, including special economic relationships that may exist between some drug manufacturers and PBMs. The NACDS representative stated that these relationships create incentives for PBMs to encourage use of certain manufacturers' drugs even if they are more costly to the plan or enrollees. As we noted in the draft, we were asked to examine the role of PBMs specifically for FEHBP-participating plans and enrollees, not the PBM industry in general. While the savings we report through discounts, rebates, and certain interventions do not reflect whether PBMs encourage higher-cost drugs, the FEHBP plans we reviewed informed us they believed they saved money from using PBMs. Relationships between PBMs and manufacturers and pharmacies for other plans were beyond the scope of this report. In response to the concern about PBMs' influence on drug switching, we added information based on two PBMs' filings with the SEC regarding an ongoing Department of Justice investigation of certain PBMs' relationships with pharmaceutical manufacturers and retail pharmacies.
- The draft report did not include information about all three plans' use of generic drugs, which is one means to reduce the overall cost of the drug benefit. In the draft report, we addressed savings PBMs achieve through direct interventions to switch from a prescribed brand drug to a generic, as opposed to overall generic use rates, which are affected by other factors such as plans' benefit designs. To clarify our findings, we added information on the relative use of generic drugs among the retail and mail order pharmacy services for the plans we reviewed.
- Our finding that the PBMs we reviewed retained little or no compensation from the payments they receive from plans for retail drugs because they pass these payments on in total to the retail pharmacies seemed

inconsistent with NACDS' experience. While PBMs' contractual arrangements with other plans may differ, the contractual arrangements with the FEHBP-participating plans we reviewed resulted in the PBMs passing through to the retail pharmacies the entire payment that they receive from the plans.

- Our estimate that retail pharmacies' drug acquisition costs are on average about 8 percent below the payments they receive from the FEHBP plans we reviewed implies this is a profit and does not adequately acknowledge overhead costs. Our draft report stated that this estimated margin does not reflect a retail drug store's profit because it does not include overhead costs nor certain other savings that may be available to some drug stores. We revised the report to better clarify this point and added information regarding NACDS' and other recent studies' estimates of overhead costs for retail pharmacies on a per prescription basis.

We are sending copies of this report to the Director of the Office of Personnel Management, appropriate congressional committees, and other interested parties. We will also make copies available to others upon request. This report is also available at no charge on GAO's Web site at http://www.gao.gov.

If you or your staff have any questions, please call me at (202) 512-7118. Another contact and key contributors to this assignment are listed in appendix III.

Sincerely yours,

Kathryn G. Allen

Kathryn G. Allen
Director, Health Care—Medicaid
and Private Health Insurance Issues

Appendix I: Scope and Methodology

We examined the use of pharmacy benefit managers (PBM) by three Federal Employees Health Benefits Program (FEHBP) plans: Blue Cross and Blue Shield (BCBS), Government Employees Hospital Association (GEHA), and PacifiCare of California. Together, these plans accounted for about 55 percent of the 8.3 million people covered through FEHBP plans as of July 2002 and represented various plan types and PBM contractors.[1] BCBS contracted with the two largest PBMs in the United States, Medco Health Solutions and AdvancePCS, for its pharmacy benefit services. GEHA contracted with Medco Health Solutions and PacifiCare of California contracted with Prescription Solutions, another subsidiary of PacifiCare Health Systems.

We reviewed contracts between the PBMs and plans, financial statements regarding payments made between the plans and PBMs, and retail and mail-order prices for selected drugs from the FEHBP plans we reviewed and the PBMs with which they contracted. We also obtained pricing information from retail pharmacies, interviewed officials at the Office of Personnel Management (OPM), the federal agency responsible for administering FEHBP, and associations representing PBMs and retail pharmacies, and reviewed studies regarding the use of PBMs and prescription drug payments.

Specifically, to assess the drug discount savings PBMs achieved, we selected 18 drugs that were among the drugs with the highest expenditures or number of prescriptions dispensed based on data reported by the plans. Combined, these 18 high-volume/high-expenditure drugs represented 12 percent of all prescriptions dispensed to enrollees of the selected FEHBP plans and 16 percent of total plans' drug expenditures in 2001. In selecting these drugs, we also sought to ensure a distribution of generic and brand drugs for a range of treatment conditions sold by different drug manufacturers. Table 4 lists the drugs included in our price comparisons.

[1]BCBS and GEHA are fee-for-service plans, while PacifiCare of California is a health maintenance organization (HMO).

Table 4: Selected High-Volume or High-Expenditure Drugs for 3 FEHBP Plans

Drug name (strength) and dosage form	Condition for which drug is used[a]
Brand	
Aciphex (20 mg), tablets	Ulcers
Allegra (180 mg), tablets	Allergies
Celebrex (200 mg), capsules	Arthritis
Celexa (20 mg), tablets	Depression
Claritin (10 mg), tablets	Allergies
Fosamax (70 mg), tablets	Osteoporosis
Lipitor (10 mg), tablets	Cholesterol
Lotensin (20 mg), tablets	High blood pressure
Norvasc (5 mg), tablets	High blood pressure
Paxil (20 mg), tablets	Depression
Premarin (0.625 mg), tablets	Osteoporosis
Prevacid (30 mg), capsules	Ulcers
Prilosec (20 mg), capsules	Ulcers
Zocor (20 mg), tablets	Cholesterol
Generic	
Albuterol (90 mcg), aerosol	Asthma
Atenolol (50 mg), tablets	High blood pressure
Furosemide (40 mg), tablets	High blood pressure
Hydrocodone with Acetaminophen (5-500 mg), tablets	Pain

Source: Rx List at http://www.rxlist.com/.

[a]These drugs may also be used be used to treat conditions other than those listed in the table.

At our request, the plans provided prices paid as of April 2002 for the most common strength, dosage form, and quantity dispensed for these drugs at retail pharmacies (typically, a 30-day supply) and at mail-order pharmacies (typically, a 90-day supply).[2] Prices represent the plan and enrollees' share of the drug ingredient cost—expressed as a discount from an industry standard price such as the average wholesale price (AWP)[3] or maximum

[2]We were unable to obtain the retail and mail-order price for one drug from one plan because the drug was not available on the plan's formulary at the specified strength.

[3]Drug manufacturers suggest a list price that wholesalers charge pharmacies. The average of the list prices, collected for many wholesalers, is called a drug's AWP.

allowable cost (MAC)[4]—plus a dispensing fee. We did not independently verify the accuracy of these plan-reported prices.

To compare prices negotiated with PBMs for retail and mail-order prescriptions to cash prices a customer without third-party coverage would pay at retail pharmacies, we surveyed 36 pharmacies in California, North Dakota, Washington, D.C., and the Virginia and Maryland suburbs of Washington, D.C., from April 18 through April 30, 2002. We selected the locations to be geographically diverse, specifically including California because it is the only state in which PacifiCare of California operates, North Dakota to include a state with a low population density, and the Washington, D.C., metropolitan area because it includes a large number of FEHBP enrollees. We randomly selected 12 pharmacies in each of these areas, including both large chain pharmacies and independent or small chain pharmacies. We determined that each of the pharmacies surveyed participated in the retail networks for each of our selected FEHBP plans serving that area. From each pharmacy, we obtained prices for a 30-day supply of the 18 selected drugs. These prices are applicable only to the pharmacies surveyed and at the time they were obtained.

We also compared prices plans paid to retail and mail-order pharmacies to the pharmacies' estimated acquisition costs. Retail pharmacies typically purchase drugs from intermediary wholesale distributors and—to a lesser extent—drug manufacturers, while PBM-owned mail-order pharmacies more typically purchase drugs from manufacturers. Since no data source exists to identify pharmacy acquisition costs, we estimated retail pharmacies' acquisition costs for drugs purchased from wholesalers using the wholesale acquisition prices (WAC) reported in Red Book, a compilation of drug pricing data published by Medical Economics Company, Inc., as of April 2002.[5] We added 3 percent to WAC to estimate the wholesalers' margin, based on information provided by retail pharmacy officials. To estimate mail-order pharmacies' acquisition costs for drugs purchased directly from drug manufacturers, we used industry-reported and confidential average manufacturers' price information (AMP) obtained from the Centers for Medicare & Medicaid Services. We selected WAC and AMP prices for our 18 selected drugs using the most common national drug code reported by the plans for reimbursing retail and mail-

[4]MACs represent upper limit prices that an insurer or health plan will reimburse for generically available or multiple source medications.

[5]Red Book CD-ROM, vol. 24 (April 2002).

order prescription claims.[6] The acquisition costs we have estimated cannot be generalized beyond the drugs we reviewed. Also, the acquisition costs we reported are based on averages for the drugs we reviewed, and individual pharmacies or mail-order operations may have higher or lower acquisition costs.

To assess enrollee access to prescription drugs, we compared the number of retail pharmacies in the plans' retail pharmacy networks to the total number of licensed retail pharmacies in California, the District of Columbia, Maryland, North Dakota, and Virginia. To examine the breadth and depth of each plan's formulary, we compared each plan's formulary to the National Formulary developed by the Department of Veterans Affairs (VA). Although the VA formulary was designed for the veteran-specific population, it is considered by the Institute of Medicine as not overly restrictive based on its comparison with other formularies and clinical literature.[7] We obtained the National Formulary from the VA's Pharmacy Benefits Management Strategic Healthcare Group. The VA formulary contains approximately 1,200 items, including generic, brand name, and over-the-counter drugs, devices, and supplies. We requested that VA officials remove devices, supplies, and drugs that are usually prescribed on an in-patient basis or are available over-the-counter because the FEHBP plans we reviewed cover inpatient drugs as part of the hospital benefit and do not cover drugs available over-the-counter. The resulting list included 513 outpatient prescription drugs representing 162 therapeutic classes. To examine the breadth and depth of each plan's formulary relative to these outpatient prescription drugs from the VA formulary, we determined whether each of the drugs and therapeutic classes included on the list of drugs drawn from the VA formulary was also included on each of the plan formularies. Each plan also provided us with examples of therapeutically equivalent drugs included on the plan's formulary for drugs that did not have an exact match on the VA formulary

[6]National Drug Codes (NDCs) are the universal product identifiers for drugs for human use and are unique for each chemical entity, dosage form, manufacturer, strength, and package size.

[7]See *IOM, Description and Analysis of the VA National Formulary*. The IOM used several criteria to assess the restrictiveness of the VA formulary, including how the VA formulary compares to formularies used in other public and private health care systems, and how it compares to reasonableness standards in the literature. The IOM committee also concluded that the VA formulary is in some respects more but in many respects less restrictive that other public or private formularies. The VA formulary does not contain specific types of drugs, such as pediatric drugs, that typically would be covered by the FEHBP plans we reviewed.

list. We considered a VA therapeutic class to be included on a plan formulary if at least one of the VA drugs in that class or a therapeutically equivalent drug was listed in the plan formulary. For VA therapeutic classes not included on a plan formulary, we used National Institutes of Health and Medco Health Solutions on-line databases to analyze the types of medical conditions treated by the excluded drugs within these classes.

Appendix II: Comments from the Office of Personnel Management

OFFICE OF THE DIRECTOR

UNITED STATES
OFFICE OF PERSONNEL MANAGEMENT
WASHINGTON, DC 20415-1000

NOV 2 2 2002

Ms. Kathryn G. Allen
Director, Health Care -- Medicaid
and Private Health Insurance Issues
U.S. General Accounting Office
Washington, D.C. 20548

Dear Ms. Allen:

Thank you for the opportunity to comment on draft report *FEDERAL EMPLOYEES' HEALTH BENEFITS: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies* (GAO-03-196).

We have always believed our health plans' private sector Pharmacy Benefit Management (PBM) partners help our health plans provide affordable drug benefits that meet our enrollees' needs and help keep costs down. I was pleased to see you determined that PBMs do help keep costs down while offering excellent access to prescriptions for our consumers. We understand and agree that PBMs add administrative costs, but that they are not excessive.

The President's health care agenda is based on patient-centered health care, preservation of choice and excellent quality. The Federal Employees Health Benefits (FEHB) Program is a competitive model and health plans offer the benefits that they believe their current enrollees want and that would also be attractive to prospective enrollees. Our consumers are also price sensitive, so health plans make efforts to offer their benefit packages at affordable prices. FEHB is market-driven - aspects of the insurance industry that work in the private sector are also reflected in the FEHB Program. Many private sector employers take advantage of the opportunities offered through the use of PBMs.

Your review of PBMs in the FEHB Program rightly points out the advantages of PBMs as well as the trade-offs. Our Federal consumers have come to expect convenient and easy-to-use pharmacy benefits programs that offer a broad range of affordable prescription drugs. The role of the Office of Personnel Management (OPM) as a purchaser is to balance our consumers' expectations for comprehensive benefits against cost implications and marketplace realities. We believe our traditional private-sector partnerships have allowed us to deliver the goods and services our consumers want and to help keep the FEHB Program on the cutting-edge of employer-sponsored benefit programs.

It should be pointed out that OPM's reliance on the private sector is fundamental. The private sector PBMs must generate income above actual costs in order to stay in business, as is the case in any market. That is why, for example, net pharmacy acquisition costs are incorporated into the negotiated price health plans pay for the services offered by PBMs. The fundamentals of the

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September 2001

market place also contribute to the reasons why some pharmacies devote more resources to managing their PBM business than others do. Likewise, the customer service component of each type of vendor plays a big role in building customer business and retention.

We have also provided comments on several technical issues related to the draft report in the enclosure.

Thank you, again, for the opportunity to comment.

Sincerely,

Kay Coles James
Director

Enclosure

Federal Employees' Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies

U.S. General Accounting Office, January 2003

FINDINGS EXCERPTED DIRECTLY FROM GAO REPORT:

PBMs achieved savings through price discounts, rebate payments, and managing drug use.

PBMs obtained discounted prices significantly below those paid by cash-paying customers.

- The average price PBMs negotiated for drugs from retail pharmacies was about 18 percent below the average cash price customers would pay at retail pharmacies for 14 selected brand-name drugs and 47 percent below the average cash price for 4 selected generic drugs.

- PBMs provide plans even greater savings when drugs are dispensed through their mail-order pharmacies. The average mail-order price was about 27 percent and 53 percent below the average cash price customers would pay at a retail pharmacy for the selected brand name and generic drugs, respectively.

PBMs obtained greater discounts from retail pharmacies than did state Medicaid programs.

In addition to discounts, PBMs passed through to plans certain rebates they earned from drug manufacturers.

- Across the three plans, rebates reduced total annual drug spending by 3 percent to 9 percent from 1998 through 2001.

- Estimated rebates retained by the PBMs GAO reviewed represented less than half of one percent of total plan drug spending.

PBMs achieved savings through intervention techniques such as prior authorization and drug utilization reviews that identify excess use, duplicative therapies, or the availability of effective, low-cost drug alternatives.

- Two plans reported savings from prior authorization ranging from 1 percent to 6 percent of plan spending for drugs that either were not dispensed or were substituted for with less costly alternatives.
- Two plans estimated savings from drug utilization review ranging from 6 percent to 9 percent.

- Two plans reported savings ranging from 1 percent to 4.5 percent from therapeutic interchange.

PBMs collected fees from FEHBP plans for various administrative and clinical services including processing claims and conducting drug utilization reviews.

- Administrative fees, which varied by plan depending on contracted services, accounted for an average of about 1.5 percent of each plan's total drug benefit spending in 2001.

Enrollees in the plans reviewed had wide access to retail pharmacies, coverage of most drugs, and benefited from cost savings generated by the PBMs.

- PBMs maintained retail pharmacy networks for the FEHBP plans that included most retail pharmacies—typically 90 percent to nearly 100 percent in five jurisdictions GAO reviewed.
- Drug formularies administered by the PBMs were generally not overly restrictive; they included drugs in most major therapeutic categories and mechanisms existed to allow enrollees to obtain non-formulary drugs when prescribed by a physician, although sometimes at a higher out-of-pocket cost.
- Enrollees typically paid lower out-of-pocket costs for prescriptions filled through mail-order pharmacies and benefited from other savings that reduced plans' costs and therefore helped to lessen rising premiums.

Decisions on inclusion of drugs in a formulary are typically made by a pharmacy and therapeutics committee composed of physicians and pharmacists.

- Plans GAO reviewed had no or few committee members affiliated with the plan or PBM.
- Formularies may be developed by the plan with suggestions for changes from a PBM, or entirely by a PBM and used by the plan.

Each PBM operated a program to review prescriptions at the point of purchase to help prevent potentially adverse drug interactions.

- PBMs maintained a centralized database on each enrollee's drug history and shared this information electronically with pharmacies at the time the prescription was filled.

- PBMs are often the only entity with complete information on a patient's medications—particularly when enrollees are prescribed medication by more than one physician or fill prescriptions at different pharmacies.

Most retail pharmacies participate in PBM networks because of the large market share PBMs represent and the prescription and nonprescription sales generated by customers the PBMs help bring into the stores.

- More than 90 percent to nearly 100 percent of licensed retail pharmacies participated in the PBM networks.
- PBM reimbursements exceeded pharmacies' drug acquisition costs—not including overhead costs or any discounts or rebates some pharmacies may obtain—by an average of approximately 8 percent for brand-name drugs we selected for review.

PBM reductions in plan claims costs for prescription drugs translate into lower premiums for enrollees in later years.

- PBM savings in the form of rebates passed on to the two fee-for-service FEHBP plans GAO examined between 1998 and 2000 translate into about a 1-percent decrease from what the plans' future premiums would have been.
- PBM savings in the form of premium savings accrue to all enrollees, regardless of whether they use prescription drugs.

PHARMACY Benefi

PBMs Catch a Break from the Feds: GAO Report Favorable

Drug Cost Management Report, February 2003

After months of widespread media attention to the topic of PBMs, the General Accounti (GAO) on Jan. 10, 2003, published a report to Congress on the impact of PBMs. The G asked to examine how PBMs participating in the Federal Employees Health Benefits Pr (FEHBP) affect health plans, enrollees and pharmacies. Approximately 8.3 million peop covered by FEHBP health plans, and the GAO examined three health plans that cover population.

The plans examined by the GAO were:

- Blue Cross and Blue Shield fee-for-service plan, with more than 4 million enrolle representing almost half of all FEHBP enrollees. BCBS-contracted PBMs were A for retail and Medco Health Solutions for mail order.
- Government Employees Hospital Association fee-for-service plan, with 441,151 representing 5.3% of FEHBP enrollees. GEHA contracts with Medco Health Solu PBM services.
- PacifiCare of California HMO, with 57,042 enrollees. PacifiCare has its own PBM Prescription Solutions.

The GAO found that PBMs save health plans and enrollees an average of 18% on bran prescription drugs filled at retail, compared to the cost of these products without third-p coverage. The savings average 47% on generic drugs. For mail-order fulfillment, PBMs an average of 27% on brand-name medications and 53% on generics, compared to the price.

The GAO attributed the savings to several specific techniques employed by PBMs:

Obtaining drug price discounts from retail pharmacies;

- Dispensing drugs at lower cost via mail-order pharmacies;
- Passing on drug manufacturer rebates to health plans;
- Using intervention techniques that guide utilization toward lowest-cost, most app

medications.

The actual out-of-pocket cost for members would vary based on their copay structure. M BCBS members in this study were operating under a 25% cost-sharing structure. The G that PBMs save out-of-pocket costs for FEHBP plan members in two ways:

1. by obtaining discounts that result in savings per Rx for members with a percenta copay, and

2. by reducing premiums, which are based on past years' claims data for FEHBP e

Overall, the findings of the GAO report were extremely favorable toward PBMs. This is break for the PBM industry after years of operating under a cloud of suspicion exacerba government investigations. As a result, the Pharmaceutical Care Management Associat has launched an advertising campaign to showcase the contributions of PBMs. In addit FEHBP, the campaign names several major employers such as AT&T, the U.S. Chamb Commerce, and Bethlehem Steel as "satisfied customers."

However, the National Association of Chain Drug Stores (NACDS) was disappointed th didn't delve into the impact of PBMs on retail pharmacies. The NACDS issued a scathir release questioning the validity of the report. In the opinion of NACDS, "It is baffling hov arrive at this conclusion when PBMs contracted by the FEHBP plans refused to disclos of drug manufacturer rebate dollars they keep and do not pass back to the FEHBP plan enrollees." In particular, the NACDS is concerned with the profits PBMs are gaining fror of mail-order pharmacies.

The report acknowledges that PBMs' large market share leaves retail pharmacies little l negotiating with PBMs, and that the administrative burdens placed by PBMs increase c pharmacies. It also acknowledges that PBMs owe a significant portion of their profits to from the pharmaceutical manufacturing industry, but it does not divulge specific dollar fi

Whatever amount of drug industry revenue the PBMs are keeping for themselves, the G determined that they are sharing enough to make it worthwhile for their clients. Across t plans studied, manufacturer rebates reduced health plan drug expenditures by 3% to 9 to 2001. Savings from intervention techniques amounted to 1% to 9% of total spending. techniques all result in health plan savings that, in turn, slow the escalation of premium for payers, including the federal government.

In addition, the report found that the efforts of PBMs do not unduly inhibit access to me patients. Formularies were not deemed too restrictive, and the majority of retail pharma found to participate in the plans.

One of the most interesting findings of the report was that PBMs are obtaining greater r discounts than are state Medicaid programs. The GAO estimated that Medicaid prograr saving an average of only 11%, compared to the 18% achieved by the FEHBP program more good news for PBMs, since many PBMs plan to aggressively pursue new Medica in the coming year.

The GAO Report, "Federal Employees' Health Benefits: Effects of Using Pharmacy Ber Managers on Health Plans, Enrollees and Pharmacies," (GAO-03-196) can be viewed at www.gao.gov . For more information contact: Crystal Wright, NACDS, (703) 837-424 Voles, PCMA, (202) 973-5829.

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EMPLOYMENT RETIREMENT INCOME SECURITY ACT OF 1974 (ERISA)

#2 and #4

29 USC 1001 et seq., 29 CFR 2509 et seq.
The Employee Retirement Income Security Act (ERISA) regulates certain activities of employers who have pension or welfare benefit plans. This statute preempts many state laws in this area and is administered by DOL's Pension and Welfare Benefits Administration (PWBA). The statute also provides an insurance mechanism to protect retirement benefits through a requirement that employers pay annual pension benefit insurance premiums to the Pension Benefits Guarantee Corporation (PBGC), which is associated with the Department.

Under ERISA, Pension Plans must meet a wide range of fiduciary and reporting and disclosure requirements, with regulations defining such concepts as the value of plan assets, what is adequate consideration for the sale of assets, the effects of participants having control over the assets in their plans, etc.

Welfare Benefit Plans also must meet a wide range of fiduciary, reporting, and disclosure requirements. In addition, PWBA administers the disclosure and notification requirements for the continuation of health care provisions that were enacted as part of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA). These provisions cover group health plans of employers with 20 or more employees on a typical business day in the previous calendar year. COBRA gives separated participants and beneficiaries an election to maintain, at their own expense, coverage under the employer's health plan for a limited period of time.
NOTE: Generally, employers are not required to provide benefits; however, if they do provide them, they are required to follow ERISA's rules.

WHO IS COVERED
The provisions of Title I of ERISA cover most private sector employee benefit plans. Employee benefit plans are voluntarily established and maintained by an employer, an employee organization, or jointly by one or more such employers and an employee organization. Employee benefit plans which are pension plans are established and maintained to provide retirement income or to defer income to termination of covered employment or beyond. Employee benefit plans which are welfare plans are established and maintained to provide health benefits, disability benefits, death benefits, prepaid legal services, vacation benefits, day care centers, scholarship funds, apprenticeship and training benefits, or other similar benefits.
In general, **ERISA does not cover plans established or maintained by governmental entities or churches for their employees, or plans which are maintained solely to comply with applicable workers compensation, unemployment or disability laws**. ERISA also does not cover plans maintained outside the United States primarily for the benefit of nonresident aliens or unfunded excess benefit plans.

BASIC PROVISIONS/REQUIREMENTS
ERISA sets uniform minimum standards to assure that employee benefit plans are established and maintained in a fair and financially sound manner. In addition, employers have an

obligation to provide promised benefits and satisfy ERISA's requirements on managing and administering private pension and welfare plans. The Department's Pension and Welfare Benefits Administration (PWBA), together with the Internal Revenue Service (IRS), carries out its statutory and regulatory authority to assure that workers receive the promised benefits. The Department has principal jurisdiction over **Title I of ERISA, which requires persons and entities who manage and control plan funds to:**

¥ Manage plans for the exclusive benefit of participants and beneficiaries;
¥ Carry out their duties in a prudent manner and refrain from conflict-of-interest transactions expressly prohibited by law;
¥ Comply with limitations on certain plans' investments in employer securities and properties;
¥ Fund benefits in accordance with the law and plan rules;
¥ Report and disclose information on the operations and financial condition of plans to the government and participants;
¥ Provide documents required in the conduct of investigations to assure compliance with the law.

The IRS administers Title II of ERISA, which includes vesting, participation, nondiscrimination and funding standards.

REPORTING AND DISCLOSURE

Part 1 of Title I requires the administrator of an employee benefit plan to furnish participants and beneficiaries with a summary plan description (SPD), describing in understandable terms, their rights, benefits and responsibilities under the plan. Plan administrators are also required to furnish participants with a summary of any material changes to the plan or changes to the information contained in the summary plan description.

Generally, copies of these documents must be filed with the Department.

In addition, the administrator must file an annual report (Form 5500 Series) each year containing financial and other information concerning the operation of the plan. Plans with 100 or more participants must file the Form 5500. Plans with fewer than 100 participants must file the Form 5500-C at least every third year and may file a Form 5500-R, an abbreviated report, in the two intervening years. The forms are filed with the Internal Revenue Service, which furnishes the information to the Department of Labor. Welfare benefit plans with fewer than 100 participants that are fully insured or unfunded (i.e., benefits are provided exclusively through insurance contracts where the premiums are paid directly from the general assets of the employer or the benefits are paid from the general assets of the employer) are not required to file an annual report under regulations issued by the Department. Plan administrators must furnish participants and beneficiaries with a summary of the information in the annual report.

The Department's regulations governing reporting and disclosure requirements are set forth at 29 CFR 2520.101-1 et seq.

Rebuttal on the Price Waterhouse Coopers Report commissioned by the trade organization for PBMs called PCMA (July 2004)

1. The report claims that transparency will cause higher prices, yet South Dakota has not experience higher prices and they passed legislation in 2004. (the template for HB 1332)

2. PBM transparency means charges to the plan sponsor would be made known to the plan sponsor.... Leaving PBMs to compete on price. The current PBM model can be explained in a grocery store context:

   The non-transparent PBM model is like buying a shopping cart full of groceries and the checkout person NOT GIVING THE BUYER AN ITEMIZED CASH REGISTER RECEIPT. Instead, the shopper is simply told the total amount to pay. Transparency by PBMs would allow the "shopper" to get an itemized cash register receipt for their payment.

   In addition, rebates can be thought of as grocery store coupons. In the current non-transparent PBM environment the shopper is NOT allowed to know the exact value of the coupon, nor does the shopper know the exact price of the grocery item on the shelf. Yet the shopper is told by the grocer that "we are saving you money." How could the shopper possibly know?

3. The report suggests that transparency will increase prices, yet prices have been escalating out of control for years within the current non-transparent PBM model. There is no evidence to suggest that transparency will be higher, especially considering that those PBMs practicing transparency and pass through of up to 97% of rebates to the plan sponsors are a more expensive alternative.

4. The report estimates that over the next 10 years ND would incur $300M in lost savings if HB 1332 passed.

   This is based on the false assumption that all the tools for managing the pharmacy benefit (eg, formulary development, mail order, substitution, etc) would cease to exist if PBMs were transparent. For example, this incorrect theory would mean everyone involved in delivering the pharmacy benefit would forget that substituting Prilosec OTC for Nexium would save the sponsor more than $50 per prescription. Obviously, that is not true. Other transparent healthcare organizations (PBMs, hospitals, managed care organizations) do this routinely and would continue to do so.

5. The report argues that PBMs should not be required to abide by the rules of therapeutic interchange (drug switching) such as:
   - the switch must benefit the patient
   - the switch must benefit the sponsor
   - the patient's physician must approve the switch

- the PBM must tell the patient and plan the costs of the two drugs and the cash flow to the PBM because of the switch

Most consumers would say these rules are fair.

6. The report strongly opposes PBMs being required to have fiduciary responsibilities, including activities such as:
   - acting in good faith and in the best interest of the plan and beneficiary
   - reporting to the sponsor on financial transactions affecting the sponsor
   - notifying the sponsor of potential conflict of interest

   Plans regulated under ERISA already benefit from these requirements, in addition to disclosure of information to the sponsor and the beneficiary.

Shouldn't all healthcare plans and sponsors have the same protection whether it is under state or federal guidelines?

And what about plans and consumers protected under ERISA that are victims of unfair business practices by PBMs anyway, like Northwest Airlines....

The class action suit by Northwest Airline's prescription plan and all other similar plans versus Merck-Medco highlights typical PBM practices: "Medco secretly exercises its discretion to create pricing "spreads" through which Medco enriches itself at the expense of the plans.... Medco determines the terms of the plan contracts, including terms that require manufacturers to pay Medco kickbacks in the form of rebates, discounts and to other "soft dollar" payments that Medco secretly and subversively diverts and converts to Medco's own use and benefit...Medco often decides to favor higher-cost drugs over lower-cost therapeutic equivalents in exchange for the receipt of manufacturer kickbacks that Medco retains for itself. The plans not only are deprived of assets that Medco should have passed through to them, but they incur increased costs from Medco's favoring of higher-cost products.... Medco's favoritism results in increased incremental revenue for Merck, but simultaneously increases the plans' costs... conspires secretly with drug manufacturers to subvert and circumvent the best pricing rules set forth in the 1990 OBRA."

(OBRA is part of the ERISA, as well as HIPAA regulations – all designed to provide consumer protections)

preemption does not arise because the UPDPA has "no real bearing on the intricate web of relationships among the principal players in the ERISA scenario" and because "PCMA's member PBMs are not ERISA fiduciaries." (Docket No. 88 at 15.) I agree with the Attorney General that the UPDPA does not impermissibly intrude upon the remedial scheme Congress devised to govern the relationships among ERISA entities. Although ERISA prescribes the duties that are owed by ERISA entities to one another, and prescribes remedies for their breach, it is not designed to regulate or afford remedies against entities that provide services to plans. Furthermore, PCMA has failed to present any set of circumstances in which enforcement of the UPDPA's "required practices" against a PBM would undercut ERISA's civil enforcement scheme. Finally, it seems to me that there is no logical basis to infer that Congress intended for ERISA to foreclose state regulation of third-party pharmacy benefits management services engaged in by non-ERISA fiduciaries or to preclude ERISA plans from employing state-created remedies against PBMs on an equal footing with other consumers of such services.

ERISA

II. FEHBA Preemption

PCMA maintains that the UPDPA is preempted by the Federal Employee Health Benefits Act (FEHBA). (Docket No. 85 at 14-15.) The Attorney General argues that it is not. (Docket No. 88 at 16-18.) Both agree that whether the FEHBA preempts the UPDPA depends on essentially the same analysis as the question of whether ERISA preempts the UPDPA. (Docket No. 85 at 15; Docket No. 88 at 18.) Based on the parties' concessions that the analysis would be redundant, I conclude that the FEHBA does not preempt the UPDPA for the same reasons I set forth with regard to ERISA preemption.

PCMA contends that the constitutional finding it seeks is plainly required by Ruckelshaus v. Monsanto and Philip Morris and that the court only needs to determine that PCMA's members have at least some reasonable investment-backed expectation that their trade secrets will remain secret, to conclude, categorically, that disclosure to PBM's provider customers works a taking. (Docket No. 88 at 17-18.) I disagree because the record does not compel a finding that confidential disclosure to these customers will destroy or extinguish the PBMs' alleged trade secrets. The point is that viewing the record in the light most favorable to the Attorney General, and drawing all reasonable inference in his favor, the court cannot conclude that the confidential disclosures the UPDPA requires will destroy the PBMs' trade secrets or their reasonable investment-backed expectations.

Disclose Trade Secrets

In Ruckelshaus v. Monsanto, the Supreme Court considered whether trade secret data Monsanto submitted to the Environmental Protection Agency under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), could be disclosed publicly by the EPA without effecting a regulatory taking. The Court's answer was that it depended upon which of three evolving statutory schemes applied at the time the data were submitted. Ruckelshaus v. Monsanto, 467 U.S. at 990-97 (describing FIFRA's original purpose and its evolution through two amendments), 998-99 (describing the nature of Monsanto's claims), & 1004-14 (discussing the merits based on which statutory scheme the data were submitted under). The question of whether the data deserved trade secret protection was not before the Court. The EPA stipulated that Monsanto had property rights in the data, and the Court merely paused to consider whether "the intangible nature of a trade secret" deserved protection under the Fifth Amendment. Id. at 1001-1004. The Court concluded that trade secrets are protected by the Takings Clause. Id. at 1003-1004. Turning to the ultimate takings question, the Court observed that the ad hoc,

HIPAA Compliance

The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") initially impacted the healthcare industry by mandating the "portability" of health insurance for employees changing jobs, prohibiting discrimination based on health and easing pre-existing condition restrictions imposed by health plans. However, HIPAA also required that certain "administrative simplification" rules, if not passed by Congress on or before August 21, 1999, be promulgated by the Department of Health and Human Services ("HHS"). These rules were intended to: (1) standardize data formats and use identifiers in order to improve the interchange of health information; (2) safeguard the privacy of health information; (3) enhance security for the systems used to maintain or store patients' health information; and (4) allow electronic signatures to be used in the healthcare industry. Because Congress failed to enact any such regulations by the August 21, 1999, cutoff date, HHS issued a comprehensive set of regulations addressing the confidentiality of privacy information (the "Privacy Rule" or the "Rule"), which was published in final form in the Federal Register on August 14, 2002.

The Privacy Rule governs the use and disclosure of "protected health information" ("PHI") in any form, including electronic, written and oral, created by (1) health plans; (2) health plan clearinghouses; or (3) healthcare providers which transmit health information in electronic form (collectively, "Covered Entities"). Subject to certain exceptions, use or disclosure of such PHI by Covered Entities for purposes other than healthcare treatment, payment or operations, is prohibited, absent the consent or authorization of the individual to whom the information pertains

Consumer Bill of Rights and Responsibilities

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Consumer Bill of Rights and Responsibilities
Executive Summary

The Advisory Commission on Consumer Protection and Quality in the Health Care Industry was appointed by the President on March 26, 1997, to "advise the President on changes occurring in the health care system and recommend measures as may be necessary to promote and assure health care quality and value, and protect consumers and workers in the health care system." As part of its work, the President asked the Commission to draft a "consumer bill of rights."

The Commission included 34 members and was co-chaired by the Secretary of Labor and the Secretary of Health and Human Services. Its members included individuals from a wide variety of backgrounds including consumers, business, labor, health care providers, health plans, State and local governments, and health care quality experts.

Following is a summary of the eight areas of consumer rights and responsibilities adopted by the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry:

I. Information Disclosure **Consumers have the right to receive accurate, easily**

VI. Confidentiality of Health Information **Consumers have the right to communicate with health care providers in confidence and to have the confidentiality of their individually identifiable health care information protected. Consumers also have the right to review and copy their own medical records and request amendments to their records.**

In order to ensure this right:

- With very few exceptions, individually identifiable health care information can be used without written consent for health purposes only, including the provision of health care, payment for services, peer review, health promotion, disease management, and quality assurance.
- In addition, disclosure of individually identifiable health care information without written consent should be permitted in very limited circumstances where there is a clear legal basis for doing so. Such reasons include: medical or health care research for which a institutional review board has determined anonymous records will not suffice, investigation of health care fraud, and public health reporting.
- To the maximum feasible extent in all situations, nonidentifiable health care information should be used unless the individual has consented to the disclosure of individually identifiable information. When disclosure is required, no greater amount of information should be disclosed than is necessary to achieve the specific purpose of the disclosure.

VII. Complaints and Appeals **All consumers have the right to a fair and efficient process for resolving differences with their health plans, health care providers, and the institutions that serve them, including a rigorous system of internal review and an independent system of external review.**

Internal appeals systems should include:

- Timely written notification of a decision to deny, reduce, or terminate services or deny payment for services. Such notification should include an explanation of the reasons for the decisions and the procedures available for appealing them.
- Resolution of all appeals in a timely manner with expedited consideration for decisions involving emergency or urgent care consistent with time frames consistent with those required by Medicare (i.e., 72 hours).
- A claim review process conducted by health care professionals who are appropriately credentialed with respect to the treatment involved. Reviews should be conducted by individuals who were not involved in the initial decision.
- Written notification of the final determination by the plan of an internal appeal that includes information on the reason for the determination and how a consumer can appeal that decision to an external entity.
- Reasonable processes for resolving consumer complaints about such issues as waiting times, operating hours, the demeanor of health care personnel, and the adequacy of facilities.

External appeals systems should:

The Commission does not, in this report, speak to the issues of implementation or enforcement of the Consumer Bill of Rights and Responsibilities. The rights enumerated in this report can be achieved in several ways including voluntary actions by health plans, purchasers, facilities, and providers; the effects of market forces; accreditation processes; as well as State or Federal legislation or regulation. In its final report to the President, the Commission intends to speak to the optimal methods for implementing and enforcing these rights through one or more of these approaches.

Finally, the Commission believes that the American people should have access to health care that is of high quality, evidence-based, safe, free of errors, and is available to all Americans regardless of ability to pay. Progress, over time, will require changes that must be made prudently, realistically, and with due regard to the needs of all stakeholders in the system. This Consumer Bill of Rights and Responsibilities specifies improvements that we believe are achievable now and in the next several years. It acquires even more meaning in the context of a broader overarching commitment to ensure that full access to high-quality health care will eventually be available to all Americans.

Consumer Bill of Rights and Responsibilities
Chapter One
Information Disclosure

Statement of the Right **Consumers have the right to receive accurate, easily understood information and some require assistance in making informed health care decisions about their health plans, professionals and facilities.**

This information should include:

- **Health plans:**[4] Covered benefits, cost-sharing, and procedures for resolving complaints; licensure, certification, and accreditation status; comparable measures of quality and consumer satisfaction; provider network composition; the procedures that govern access to specialists and emergency services; and care management information.
- **Health professionals:** Education and board certification and recertification; years of practice; experience performing certain procedures; and comparable measures of quality and consumer satisfaction.
- **Health care facilities:** Experience in performing certain procedures and services; accreditation status; comparable measures of quality and worker and consumer satisfaction; procedures for resolving complaints; and community benefits provided.

Consumer assistance programs must be carefully structured to promote consumer confidence and to work cooperatively with health plans, providers, payers, and regulators. Sponsorship that assures accountability to the interests of consumers and stable, adequate funding are desirable characteristics of such programs.

Rationale

Value-based purchasing allows consumers to obtain greater value for their health care

dollar by seeking higher quality care at the best price. To do this, consumers need accurate, reliable information that will allow them to assess differences in the quality and cost of health benefits plans, the health care providers who treat them, and the facilities and institutions that house them. Active and informed decisionmaking by consumers will improve the performance of the health care system, as providers seek to enhance their quality and reduce their costs in order to be more attractive to value-seeking consumers.

A more basic reason for providing consumers with information is an ethical one. Health plans, facilities, and professionals have an ethical obligation to inform consumers about how their actions can affect the consumer's life and health. Medical ethicists ground this obligation in the principle of respect for individual autonomy and individuals' right to make choices about how they receive medical care (Beauchamp and Childress, 1994).

This chapter provides a description of the types of information on health plans, health professionals, and health care facilities that should be made available to consumers either routinely or upon request. The Commission recognizes that much work remains to be done if all this information is to be readily available and understandable to consumers, specifically:

- **Detailed explanation is needed for certain types of information.** Some types of information are straightforward and require no further definition (e.g., the names, board certification status, and geographic location of primary care providers in a plan's network). Other types of information would benefit from the development of more detailed explanation, such as the care management information on clinical protocols, practice guidelines, and preauthorization and utilization review standards and procedures.
- **Standardized measures are needed for comparative purposes.** For the information intended to support consumer decisions regarding the choice of a health benefits plan, or choice of an individual provider or facility, standardized definitions will be needed to allow for "apples to apples" comparisons.
- **Ongoing development and promulgation of standardized measurement sets and instruments are needed for assessing satisfaction and quality.** The Commission believes that some of the most important types of information a consumer has a right to receive fall into the categories of consumer satisfaction ratings and clinical quality performance measures for health plans, health care professionals, and facilities. For all consumers to exercise this right, processes must be put in place to create standardized performance measures. In its final report, the Commission intends to address how such a process might be established so as to build on existing efforts, encourage ongoing innovation in quality measurement, and provide the best possible information to consumers at any given time to encourage quality improvement through market-based decisions.
- **Useful and appropriate reporting formats and processes are needed for consumers.** Although the Commission believes that consumers should have access to pertinent information, it recognizes that caution must be taken to provide information to consumers in useful formats (e.g., summary and detailed reports, printed copy, and Internet), at appropriate times (i.e., decision points), with assistance for vulnerable groups (i.e., those who are hearing impaired or non-English speaking). These issues also will be addressed in the Commission's final report.

Consumers should be able to obtain other information upon request as outlined below. Plans, providers, and facilities should inform consumers that such information is available and describe how it can be obtained.

Health Plan Information

Many consumers face a choice of health plans such as an indemnity plan, an HMO, a point-of-service plan, or a preferred provider organization. Consumers' choice of a health plan has a significant impact on consumers' ability to make other choices about facilities, health professionals, and treatment options. Even in cases where consumers do not have a choice of plans, they require information on the plan in which they are enrolled to use the available services effectively.

To the extent that a right to information creates disclosure requirements for health plans, these requirements should apply equally to all types of plans (including indemnity, HMO, PPO, and POS) regardless of sponsor (e.g., such government programs as CHAMPUS, VA, FEHBP, Medicare, and Medicaid and private plans including fully funded, partially self-funded, or fully self-funded plans). If the specific information required for disclosure does not exist, or is unavailable, the consumer should be informed.

The primary responsibility of providing consumers with health plan information falls upon the plans themselves. In the case of self-insured plans, this responsibility will rest with the plan sponsor unless it is delegated or contracted to a third-party administrator.

Within the category of health plan information, one can discern four principal subcategories of information: (1) benefits, cost-sharing, and dispute resolution; (2) health plan characteristics and performance information; (3) network characteristics; and (4) care management information.

A. **Benefits, Cost-Sharing, and Dispute Resolution.** Consumers should receive the following information about a health benefits plan:
   - A general summary of all covered benefits, including:
     - General limits on coverage, including any annual or lifetime limits, as well as limits for specific conditions.
     - Whether preventative services are covered.
     - Whether a drug formulary is used and, if so, how decisions are made pertaining to inclusion of drugs, particularly new drugs (including a process to consider exceptions).
     - How drugs, devices, and procedures are deemed experimental.
   - Enrollee cost-sharing, including employee or beneficiary premium contributions, deductibles, copayments, and coinsurance.
   - Type and extent of dispute resolution procedures available in the event of a dispute.

B. **Health Plan Characteristics and Performance Information.** Consumers joining or considering whether or not to join a health plan should receive information about:
   - State licensure status, Federal certification, and private accreditation status (including publicly available reports).
   - Consumer satisfaction measures.
   - Clinical quality performance measures.

- Service performance measures (e.g., waiting time to obtain an appointment with primary care providers and specialists).
- Disenrollment rates (adjusted for involuntary disenrollment and other relevant factors).

Additional information that should be made available *upon request* includes:

- Number of years in existence.
- Corporate form of the plan (i.e., public or private; gateway.html or for-profit ownership and management).
- Whether the plan meets requirements (State and Federal) for fiscal solvency.
- Whether the plan meets standards (State, Federal, and private accreditation) that assure confidentiality of medical records and orderly transfer to caregivers.

C. **Network Characteristics.** It is important to provide consumers with information about the characteristics of the network and the procedures that govern its use. Consumers should receive:

- Aggregate information on the numbers, types, board certification status, and geographic distribution of primary care providers and specialists.
- Detailed list of names, board certification status, and geographic location of all contracting primary care providers; whether they are accepting new patients; language(s) spoken and availability of interpreter services; and whether facilities are accessible to people with disabilities.
- Provider compensation methods, including base payment (e.g., capitation, salary, fee schedule) and additional financial incentives (e.g., bonus, withholds, etc.).
- Rules regarding coverage of out-of-network services, and applicable rates of cost-sharing.
- Information about circumstances under which primary care referral is required to access specialty care.
- Information about what options exist for 24-hour coverage and whether enrollees have access to urgent care centers.

Additional information that should be made available *upon request* includes:

- Detailed list of names, board certification status, and geographic location of all contracting specialists and specialty care centers; whether they are accepting new patients; language(s) spoken and availability of interpreter services; and whether facilities are accessible to people with disabilities.
- Detailed list of names, accreditation status, and geographic location of hospitals, home health agencies, rehabilitation and long-term care facilities; whether they are accepting new patients; language(s) spoken and availability of interpreter services; and whether they are accessible to people with disabilities.

D. **Care Management Information.** Information in this category that should be available *upon request* includes:

- Preauthorization and utilization review procedures followed.
- Use of clinical protocols, practice guidelines, and utilization review standards pertinent to a patient's clinical circumstances.
- Whether the plan has special disease management programs or programs for

persons with disabilities. (This information should indicate whether these programs are voluntary or mandatory or if a significant benefit differential results.)
  - Whether a specific prescription drug is included in a formulary and procedures for considering requests for patient-specific waivers.
  - Qualifications of reviewers at the primary and appeals levels.

Health Professional Information

All consumers should receive information on:

- Whether the health professional's ownership or affiliation arrangement with a provider group or institution would make it more likely that a consumer would be referred to particular specialists or facility or receive a particular service.
- How the provider is compensated, including base payment method (e.g., capitation, salary, fee schedule) and types of additional financial incentives (e.g., bonus, withholds).

Consumers should receive *upon request* the following information on health professionals:

- Education, board certification, and recertification status.
- Names of hospitals where physicians have admitting privileges.
- Years of practice as a physician and as a specialist if so identified.
- Experience with performing certain medical or surgical procedures (e.g., volume of care/services delivered), adjusted for case mix and severity.
- Consumer satisfaction measures.
- Clinical quality performance measures.
- Service performance measures.
- Accreditation status (if applicable).
- Corporate form of the practice (i.e., public or private, gateway.html or for-profit, ownership and management, sole proprietorship or group practice).
- The availability of translation or interpretation services for non-English speakers and people with communication disabilities.
- Any cancellation, suspension, or exclusion from participation in Federal programs or sanctions from Federal agencies; any suspension or revocation of medical licensure, Federal controlled substance license, or hospital privileges.

Health Care Facility Information

Consumers should receive the following information from a health care facility:

- Corporate form of the facility (i.e., public or private; gateway.html or for-profit; ownership and management; affiliation with other corporate entities).
- Accreditation status.
- Whether specialty programs meet guidelines established by specialty societies or other appropriate bodies (e.g., whether a cancer treatment center has been approved by the American College of Surgeons, the Association of Community Cancer Centers, or the National Cancer Institute).
- The volume of certain procedures performed at each facility.

- Consumer satisfaction measures.
- Clinical quality performance measures.
- Service performance measures.
- Procedures for registering a complaint and achieving resolution of that complaint.
- The availability of translation or interpretation services for non-English speakers and people with communication disabilities.
- Numbers and credentials of providers of direct patient care (e.g., registered nurses, other licensed providers, and other caregivers).
- Whether the facility's affiliation with a provider network would make it more likely that a consumer would be referred to health professionals or other organizations in that network.
- Whether the facility has been excluded from any Federal health programs (i.e., Medicare or Medicaid).

Consumer Assistance Programs

Initial results indicate that consumer assistance programs support consumer needs for information on health plans, providers, and facilities. A loose patchwork of consumer assistance services currently exists in the public and private sectors. In the public sector, 14 State or locally based Medicaid programs now have established ombudsmen programs to assist beneficiaries with information needs. Some Medicare beneficiaries and people with chronic health problems have access to consumer assistance services through Information, Counseling, and Assistance (ICA) programs, long-term care ombudsmen programs, and protection and advocacy programs.

In the private sector, health plans often provide consumers with assistance services through customer and member service departments (Oxford Health Plans, 1997; Harvard Pilgrim Health Plan, 1997). Large group purchasers and labor unions often provide their employees with consumer assistance by organizing information on plans, educating employees about their rights, and intervening when employees have complaints about their plans (Darling, 1997).

While there are a number of sources that provide assistance to consumers, most programs target specific subpopulations and have limited funds, and hence provide a limited range of services. There are reasons to believe that consumers and other stakeholders would benefit from greater availability of consumer assistance programs that:

- **Inspire confidence.** Consumers want to know that they will be treated fairly.
- **Provide a safety valve.** Even in the best of systems, there will be individuals who fall through the cracks. Assistance programs provide a resource that can help such individuals resolve problems quickly and efficiently, often bridging communication failures between the consumer and the provider or health plan.
- **Foster collaboration.** Assistance programs should work with the array of available resources to best meet the needs of consumers.

The challenge to crafting assistance programs for health care consumers is to ensure that such programs are not duplicative, but rather that they supplement and complement existing resources.

With regard to consumer assistance, the Commission has not addressed issues of

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Testimony on HB 1332
House Industry, Business and Labor Committee
January 25, 2005

Mister Chairman and Committee Members, for the record I am David Lassen, Senior Director of Care Management of Prime Therapeutics. Prime is a pharmacy benefits manager or PBM which is jointly owned by nine Blue Cross Blue Shield companies including Blue Cross Blue Shield of North Dakota. I appear before your committee to voice our opposition to this bill.

This bill should be defeated for several reasons.

As previously stated by Mr. St. Aubyn, the proposed legislation would interfere with the ability of two private companies to contract. Prime and Blue Cross Blue Shield of North Dakota have a unique relationship where Prime is the PBM and Blue Cross Blue Shield is the Client as well as partial owner. Our current agreement provides for sharing of revenue information, as well as the ability of Blue Cross to audit Prime's records. Transparency is a fundamental principle at Prime and Prime believes it accomplishes this goal through its agreements and practices. The proposed legislation seems unnecessary and places inappropriate and unreasonable demands on Prime and Blue Cross Blue Shield.

As Mr. St. Aubyn indicated, there has been similar legislation passed in South Dakota and Washington, DC. The legislation in DC was recently challenged by the Pharmaceutical Care Management Association (PCMA). It was successful in having this legislation blocked by a temporary injunction. The court ruled PCMA had a good chance of succeeding at trial with a permanent injunction on the issue of the Takings Clause (involving forced disclosure). In Primes' situation, it currently shares revenue information with its clients, such as Blue Cross Blue Shield of North Dakota, and legislation is not required.

The court also recognized PCMA's argument regarding fiduciary duties imposed by the legislation in DC. While the court did not rule on this issue specifically, the temporary injunction blocked the imposition of fiduciary status on PBMs. In March 2004, the U.S. District Court in Maine found the imposition of fiduciary duties on PBMs in conflict with the federal Employee Retirement Income Security Act (ERISA). This argument is still under review by the courts.

We think it would be more beneficial to strike the entire legislation and allow the parties to continue their open sharing of information on a contract basis versus defending potential trade association lawsuits regarding such legislation.

If the legislation is passed as written, we are concerned of the potential increased costs to the entire health care industry. PriceWaterhouseCoopers released a study in July of 2004 regarding the value of PBMs and the national cost impact of proposed PBM legislation. This report can be found at:

http://www.pwc.com/extweb/pwcpublications.nsf/docid/D5E8B5900A6E17C880256EFB003773AA.

The report reviewed the various legislative proposals that were under consideration and stated such legislation would "translate into a [cost] range of $97 billion to $328 billion over the 2005 to 2014 period." The increases would be a result of additional costs to the PBM to comply with legislative requirements. These costs would unfortunately be passed on to the consumer in higher premiums.

In July 2004, the U.S. Federal Trade Commission and the Antitrust Division of the US Department of Justice released a report concluding "in general, vigorous competition in the marketplace for PBMs is more likely to arrive at an optimal level of transparency than regulation of those terms." The report also recognized the PriceWaterhouseCoopers report and potential for increased costs.

In reviewing the specific proposed legislation, there are a few additional issues. First, in Section 2, it requires a PBM to be licensed as an administrator under North Dakota Century Code 26.1-27. There are requirements regarding the contract between an administrator and insurer. It specifically mentions the "Trust agreement" between the parties. In Prime's case, there is no "trust" agreement between Prime and the client because Prime does not hold any assets in trust. Prime does not collect premiums or create the formulary. It merely acts at the direction of the client health plan.

Second, subsection 1-06 prohibits a PBM from requesting a substitution of one prescription drug for another. Prime does not make the substitution – it administers a formulary set by the client, which may provide for therapeutically equivalent or generic substitutions. The language is this subsection confuses the issue.

Subsection 1-06 also includes language regarding "any willing provider"-type language for pharmacies. This language has already been passed and is included in the North Dakota Century Code at 26.1-36-12.1(c). Further, there is language regarding discrimination on the basis of co-payments or days of supply. Again, this language is covered in the Code at 26.1-36.12.1(b).

For those entities that value transparency, there are options available in the marketplace. Prime offers these types of services to its clients and Prime's level of disclosure is meeting the needs of its customers. There is no need to regulate. I would urge you to defeat the bill and allow the parties to continue to contract in an open manner in this highly competitive field. I would be willing to answer your questions.

EXPRES[redacted]SCRIPTS – Pharmacy Reimbursement form

	DATE	NDC NUMBER/NAME	DAYS SUPPLY	PAID TO PHARMACY INGREDIENT COST PAID	PAID TO PHARMACY DISPENSING FEE	COPAY	AMT PAID BY PBM
1.	1-04	59772002503 Estradiol .5mg	30	12.50	2.50	15.00	.00
2.	1-04	00378214605 Sprionolactone 25 mg	30	13.08	2.50	15.00	.58
3.	1-04	00378201201 Lisinopril-HCTZ	30	12.50	2.50	15.00	.00
4.	1-04	59930156001 Albuteral 90mcg	30	23.75	2.50	15.00	11.25
5.	1-04	00047008430 Gemfibrozil 600mg	30	18.04	2.50	15.00	5.54
6.	2-04	00378050301 Bisoproplol/HCTZ	30	6.36	2.50	5.00	3.86
7.	2-04	00378116591 Buspirone HCL 15 mg	14	12.50	2.50	15.00	.00
8.	3-04	00093977405 Hydroxychloroquine	30	12.96	2.50	15.00	.46
9.	3-04	00093226805 Amoxicillin 250 mg	10	12.50	2.50	15.00	.00
10.	3-04	00172439018 Albuterol	10	15.83	2.50	15.00	3.33
11.	3-04	00378116591 Buspirone HCL 15 mg	30	25.49	2.50	15.00	12.99
12.	3-04	00185440051 Tizanidine HCL 4mg	12	43.33	2.50	15.00	30.83

13.	[redacted]	00054422125 Diclofenac SOD 50 mg	30	[redacted]	22.59	2.50	15.00	10.[redacted]
14.	3-04	00172443560 Metformin HCL	30		66.31	2.50	5.00	63.81
15.	3-04	00406036105 Hydrocodone	22		11.53	2.50	10.00	4.03

EXPRES[redacted]CRIPTS CLAIM FOR PLAN SPONSOR TO PAY T[redacted]BM FOR EACH PRESCRIPTION FILLED

	DATE OF SERVICE	CONTRACT NO.	CLAIM NO.	DRUG NAME	INVOICE TO PLAN	PROCESS FEE (PD BY PHARMACY)
1.	1-04	#######	#####	Estradiol .5mg	$ 7.44	.25
2.	1-04	#######	#####	Sprionolactone	$ 8.10	.25
3.	1-04	#######	#####	Lisinopril-HCTZ	$ 5.18	.25
4.	1-04	#######	#####	Albuteral 90mcg	$27.77	.25
5.	1-04	#######	#####	Gemfibrozil 600mg	$13.21	.25
6.	2-04	#######	#####	Bisoproplol/HCTZ	$11.43	.25
7.	2-04	#######	#####	Buspirone HCL 15 mg	$ 8.06	.25
8.	3-04	########	########	Hydroxychloroquine	$14.37	.25
9.	3-04	########	########	Amoxicillin	$ 1.90	.25
10.	3-04	########	########	Albuterol 90mcg	$14.30	.25
11.	3-04	########	########	Buspirone HCL 15 mg	$34.20	.25
12.	3-04	########	########	Tizanidine HCL 4mg	$59.87	.25
13.	3-04	########	########	Diclofenac SOD 50 mg	$34.45	.25
14.	3-04	########	########	Metformin HCL	$70.79	.25
15.	3-04	########	########	Hydrocodone	$14.63	.25

IBL Subcommittee Hearing on HB 1332
Rep. James Kasper, Chair
February 2, 2005

Testimony in support of HB 1332

Chairman Kasper and members of the subcommittee, my name is Patricia Hill and I serve as the Executive Vice President of the North Dakota Pharmacists Association. Thank you for another opportunity to visit about HB 1332.

To continue from where Dave left off, please turn to page 18. We heard some members of the committee voice concern about PBMs filing injunctions in Maine, and I can understand concern about a similar situation in North Dakota. But you will be relieved to know that I spoke to the attorney in South Dakota who wrote their PBM disclosure legislation and he assures me that he went over the details of the Judge's decision in Maine and addressed all the issues related to the "takings clause." Because the South Dakota bill was designed to specifically address the trade secrets and confidentiality concerns, Mr. Bloomberg is confident the legislation is not going to be challenged.

Even though South Dakota is also in the middle of a legislative session, Mr. Bloomberg said he is willing to accept calls from members of the committee to provide further details or answer questions and his contact information is on page 18.

He confirmed that the PBMs in South Dakota did, indeed, threaten to leave the state if the legislation passed and predicted that the state would loose access to PBM services; but that has not happened. In fact, after the legislation passed the state employees group sent out RFPs and received 9 bids from PBMs more than willing to abide by the new regulations. The state interviewed 3 and chose one (Prescription Solutions, out of California). And they are currently spending LESS than all previous contracts.

Page 19 addresses another comment heard from the opponents of HB 1332... where were all the employers at the first hearing if this bill is for them? Well as I am sure you recall, that marathon hearing lasted close to 3 ½ hours at which point I can only imagine that members of the IBL committee were more than a little overwhelmed with the depth and breadth of information presented. It is not surprising that the committee may have missed the presentation by the President of the ND Retailers Association endorsing HB 1332 on behalf of their 325 members all across the state.

I've received many phone calls of support of HB 1332 but sharing those with you may be considered hearsay, so I won't. But you do have letters received from employers since last week's hearing in support of HB 1332. And perhaps the most important comments from those letters focus on a concern among these plan sponsors about how little they truly know with regard to drug prices and the complexity of their plans. This is not unusual...you now realize just how complex this entire process really is, so it is not hard to see why this is such a challenge to these employers.

And for those of you who haven't heard from Mr. Poolman personally - because he assures me that he has had conversations with most of the committee members - he has been a strong supporter of HB 1332 from the start and has been part of the entire planning process to bring this bill to you for consideration.

I received phone calls from a couple drug companies prior to the first hearing, letting us know they were not opposing HB 1332, but we did not know until the Pharma lobbyist spoke that ALL drug companies shared this position. That raises the question, why? Since the drug companies are intimately involved in this process of negotiations and rebates and discounts, they certainly have an inside track on what is actually going on. Perhaps they have come to realize that there is a bottom line – there is an actual cost of product that must be paid somehow. In order to offer rebates on some products and be included on the PBM's formularies, is seems the drug companies must then turn around and compensate by charging higher prices on other products. And I am speculating, but what if they are tired of this vicious cycle and simply want to stop and that is the motivation for not opposing legislation like HB 1332 in North Dakota or other states?

One final issue to share on behalf of your colleagues in Human Services, who are sponsors of this bill and requested your support of HB 1332 - the potential impact on Medicaid. I'm sure you are all aware that state Medicaid programs receive rebates and that these are set at the Federal level. Based on use of each product, the state receives payment from drug manufacturers.

What you may find interesting is another side of the Medicaid story. Page 20 is a brief synopsis of a 2001 report to the US Dept of Health & Human Services from the Office of the Inspector General, describing tremendous concerns faced by many states trying to work with PBMs through their Medicaid programs.

The purpose of this OIG report titled - Medicaid Recovery of Pharmacy Payments from Liable Third Parties - was to quantify the Medicaid dollars at risk of being lost when Medicaid pays prescription claims for recipients and other insurance coverage is involved. Millions of beneficiaries have other coverage – which is considered primary and Medicaid secondary in terms of who is liable to pay the claim. Next year when Medicaid recipients are combined into the Medicare Part D drug program this could become a bigger issue.

Highlights of the report include:

- Results include all entities involved in payment of claims included in report (includes PBMs)
- Estimates 70% of all claims are handled by PBMs – means Medicaid must often recover payment of claims from PBMs
- 58% of states recover less than 40% of the money they pursue
- PBMs are cited as creating the most obstacles for payment recovery
- PBMs not processing Medicaid claims, not willing to identify insurance companies, nor employers they contract with
- Claims denied for missing data are resubmitted with new information. One PBM does not point out ALL the data elements that are missing. Following each

additional resubmission this PBM simply identified yet another data error forcing the state to continually find data and resubmit. One PBM denies claims not submitted in a certain sequence, and some reimburse at lower rates as a penalty for submitting out of sequence or in the wrong format. This process is extremely expensive for state Medicaid programs.

On page 21 you see a chart of the data duplicated from page 10 of the OIG report...stating that 32 states had more problems dealing with PBMs than with the combined total of ALL OTHER 3rd parties.

Appendixes A and B include financial data from these 32 states, as well as all 50 states. Between 40 and 99 percent of claims are not recovered from 3rd party administrators by state Medicaid programs. This OIG report is included in your handout materials. Pages 23 and 24 are more reports of serious concern with the business practices of PBMs, but our time is limited today so I will stop here...again, ask for your support of HB 1332 and accept any questions you have.

Testimony to the
House Industry, Business and Labor
Subcommittee for HB 1332
Rep. James Kasper, Chair

February 8, 2005

Support for HB 1332

Chairman Kasper and members of the subcommittee, my name is Patricia Hill, Executive Vice President for the North Dakota Pharmacists Association. I am here on behalf of the association's 695 members in support of HB 1332.

- The ultimate goal of HB 1332 is to address the rising cost of prescription medications. The disclosure mandate is intended to reduce cost by giving plan sponsors the opportunity to receive a greater portion of the rebates and discounts than they currently receive. Right now, they cannot know what additional savings are possible because the information is not available.

As discussions about HB 1332 continue formally and informally there appear to be some issues that deserve highlighting:

1. In South Dakota, where the template for this bill originated, PBM's are required to disclose information to covered entities with a minimum requirement to share the information with the employers. Simply sharing information between the PBM and an insurance company – and excluding the plan sponsors - does NOT meet the intent of HB 1332. If that were not clear in HB 1332 we would propose to edit the bill and make it clear.

2. While it may have been preferred to mandate that the savings from rebates and discounts be delivered to the consumer at the point of sale, it is the employer who is paying the premiums and who is told by the insurance companies and PBMs that their premium costs are directly impacted by these rebates and discounts. Under these circumstances, it seems appropriate to allow the employer to determine how those savings are applied to the healthcare plan, and if they choose to provide the savings at point of sale to their employees that would be their choice.

3. Based on testimony at the previous hearings, it appears employers in North Dakota are not prepared, nor do they have resources to build an expertise, to act in their own best interest even after receiving the information on rebates and discounts from PBMs. With that in mind, there is growing interest in having the Insurance Department assume more oversight and provide the needed expertise on behalf of consumers and employers. We support language that would incorporate this expanded role and necessary resources for the Insurance Department to meet legislative intent.

In closing, I offer you two new developments in support of HB 1332. Attached is a New York Times article from February 3rd - where Medco has agreed to provide ONLY the claims processing for four major companies who will handle their own negotiations with drug companies. The companies project at least a $50 million (6%) savings the first year. A Medco Senior Executive is quoted to say, "when you have nothing to hide, transparency is no problem."

And the second attachment is dated February 4 and announces that a US magistrate issued a decision to lift the injunction in Maine and allow the state to enforce the PBM law. While this doesn't end the legal wrangling in Maine, it certainly alleviates the threat of a lawsuit that was implied in previous testimony. And I remind you that the South Dakota bill -which is our guide- was written to specifically respond to the judge's concerns about confidentiality and the takings clause.

Thank you. I would be happy to respond to questions, Mr. Chair.

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February 3, 2005

Employers Unite in Effort to Curb Prescription Costs

By MILT FREUDENHEIM

In a new strategy to rein in prescription drug costs, a group of 30 large employers has banded together to monitor the business practices of the middlemen drug buyers that most employers use to get discounts from pharmaceutical companies.

The new group, called Rx Collaborative, to be announced today, is part of a stepped-up effort by employers across the country to cope with drug costs that have been rising 11 percent or more annually. National spending on drugs rose to an estimated total of $199 billion last year.

The companies in the group - including Eastman Chemical, Mattel, Unocal and ING Americas - are using Medco Health Solutions, the largest of a small group of pharmacy benefit managers, or P.B.M.'s, that control 75 percent of drug purchasing by employers' health plans and insurers.

Medco has agreed to allow the group to monitor its revenues and to provide it with important, rarely disclosed information like payments made by the drug makers for information on product purchases by doctors and consumers. Under the agreement, an independent auditing firm will do the actual monitoring.

The companies in the group expect to save at least 6 percent, or $50 million a year initially, from total spending of $800 million, by collecting 100 percent of all discounts and manufacturers' rebates and by increasing their control over prices and products. They said the projected savings would grow as more companies join the group in the next few weeks.

"Our pharmacy benefit costs were about $14 million in 2004," said Kim Shattuck, head of employee benefits for 9,000 workers at ING Americas, the Dutch-owned financial services company. "We estimate our expenditures will be $2.9 million less over the next four years," she said, because of the group's negotiating power.

Pharmacy benefit managers like Medco have been important players in the managed care arena since the 1980's because they are able to make bulk purchases of drugs by buying for millions of consumers. Their purchasing power makes it possible for them to wrest an array of discounts, rebates and fees from drug manufacturers.

Drug makers typically pay P.B.M.'s with rebates on drugs that are placed on preferred lists, or formularies, and further rebates for reaching market share targets. They also pay them administrative fees and other fees for running disease management programs that feature certain drugs.

But critics have noted that it is often unclear whether the benefit managers pass along all the rebates to the health plans or how much they may be keeping for themselves.

Employers, the ultimate payers, often have a hard time figuring out where the money is going.

Industry specialists said that as managed care health plans squeezed the drug managers for better deals by threatening to go to another drug benefit manager, some drug benefit managers have reported increased revenues from the manufacturers' side.

For its part, Medco said it welcomed the monitoring proposal.

Tim Wentworth, a senior Medco executive, noted that "transparency in drug purchasing was becoming a buzzword."

Medco agreed in a settlement with 20 state attorneys general and the Justice Department last April to tell its customers about payments it gets from manufacturers for persuading doctors to switch prescriptions to particular drugs.

"When you have nothing to hide, transparency is no problem," Mr. Wentworth said.

The Rx group, organized by Towers Perrin, a benefits consulting firm, also hopes to use its access to Medco data to help steer employees toward drugs deemed appropriate and cost-effective. The companies will pay Medco a flat monthly fee for each employee in the program plus a dispensing fee for mail-order drugs, instead of letting Medco share in discounts and rebates. Information about drug prices, adjusted to reflect discounts, rebates and fees, is increasingly important as many employers ask their workers to take a larger share in selecting and paying for medicines and other health needs.

Indeed, ING employees will immediately feel the pain if prices keep rising and they will benefit if the rate of increases slow down. Like a growing number of health plan members, they currently pay a percentage of the cost of brand-name drugs, rather than a flat $10 or $20 co-payment.

"We are trying to move toward a more consumer-based approach to purchasing," said Jeffrey C. McGuiness, president of the H. R. Policy Association, a group of large companies that also plans to announce a new drug-purchasing organization later this year. "If you don't know the true price of the drug, you can't get there," he said.

Last year, the association asked some of the large pharmaceutical companies to agree to deal with them directly, bypassing pharmacy benefit managers, but the drug makers were not responsive, apparently preferring their relationships with the P.B.M.'s, according to several industry executives.

"Price transparency is an emerging issue and employers are paying attention to it," said Debbie Martin, head of pharmacy consulting at Mercer Human Resources Consulting, a benefits firm that is working with seven employers' buying groups that spend a total of $1.2 billion annually on drugs.

But Ms. Martin said most employers "don't have the time and energy to take a day-by-day active role in managing their drug plans." Most smaller businesses "opted to stick with guaranteed pricing" based on discounts, she said.

Some of the largest companies have developed their own cost-monitoring strategies. Verizon Communications, for example, looks closely at sales patterns like inappropriate prescriptions of 30 sleeping pills, which typically should be limited to use for only 7 to 10 days, said Patricia Wilson, a pharmaceuticals consultant who advises Verizon.

AON, an insurance brokerage, is working with six large companies including DuPont and AT&T "to open the door wide around full disclosure" of drug manufacturers' payments, said Randy Vogenberg, a senior vice president for AON.

Pharmacy benefit managers will also have a prime role in the $40 billion-a-year Medicare drug benefit, starting in 2006, and their business practices will be crucial to its success.

Under the new Medicare program, the inspector general of the Health and Human Services Department "will be able to investigate whether any misrepresentation of overall rebates and costs has been reported to us," said Mark B. McClellan, head of the Centers for Medicare and Medicaid Services. According to the agency's recently published regulations, health plans have to disclose "price concessions obtained from pharmaceutical manufacturers," and can expect "periodic audits" their financial statements and records by the agency and the inspector general.

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IN THE STATES

Maine law regulating PBMs... one small step closer to implementation

The Pharmaceutical Care Management Association (PCMA), the trade association representing PBMs, and the State of Maine, have been locked in a legal battle over the state's efforts to regulate PBMs since mid-2003 when PCMA filed a lawsuit to halt the state's law. In March 2004, PCMA won a victory with a court decision imposing a preliminary injunction on the state's PBM law ... but the state has been fighting back ever since.

➔ *This week, a U.S. magistrate issued a recommended decision to lift the injunction and permit the State to enforce the law. That's good news for consumers interested in transparency for prescription drug prices. However, there's likely a long way to go before the legal battle is over.*

Next steps: the district court judge in charge of the case must issue a decision . . . But there's no set deadline for a decision... could be weeks, months, or longer and no way to know if the judge will adopt the Magistrate's recommendation in whole, in part or go in another direction. Additionally, if and when the judge issues a decision, there is a strong likelihood that the losing party will challenge the decision and ultimately appeal to the Federal Circuit Court and after that, the U.S. Supreme Court. In short, the magistrate's decision this week was one of many needed to complete the case... but it's positive a step in the right direction for PBM transparency.

ELSEWHERE IN THE STATES

Alabama. Legislation was introduced to put products containing 60 mg of pseudoephedrine behind the counter and require consumers to sign a log book. Law enforcement will then use the logs to determine when the sales of pseudoephedrine products were abused.

Arkansas. Senator/pharmacist Percy Malone's bill modeled after the Oklahoma Schedule V law... moving certain products containing pseudoephedrine behind the counter to help curb misuses leading to illegal methamphetamine production... unanimously passed the Senate Committee on 2/2/05 (S 109). Governor Mike Huckabee (R) has pledged to sign the bill, which would take effect 30 days later.

Testimony on Proposed Amendments to HB 1332
February 14, 2005
Afternoon hearing – revisions to amendments offered at the morning
Subcommittee Hearing by the Insurance Commission

Mr. Chairman and members of the committee I am Patricia Hill, Executive Vice President for the North Dakota Pharmacists Association. Thank you for one more opportunity to discuss HB 1332. I asked Mr. Keiser if the committee needed to hear rebuttals to the long list of concerns from the PBMs, because numerous issues presented in the past two hearings had been addressed on previous occasions, and he assured me you were well versed on the issues and it was not necessary. But I am willing to respond to questions you may have at the close of these comments.

I've had these changes for about one hour, and I think Mr. Johnson is doing a good job based on his time restraints. We believe the subcommittee has gone to great lengths to find the truth, and a middle ground from which to move forward. With that in mind and in support of moving forward, I am not going to give you a long list of objections, but instead go on record with regard to only one of the many revisions made since this morning's hearing.

Section 26.1-27.1-04. Prohibited practices.

Number 3 has been deleted, in response to concerns that this issue is strictly a contractual arrangement between the pharmacy and the PBM, and therefore not appropriate for inclusion in transparency legislation. We see it differently.

Number 3 prohibits PBMs from discriminating based on co-insurance, co-payments, deductibles, or days of supply. This section was designed to support current statute – Chapter 26.1-36-12.2, Consumer Freedom of Choice for Pharmacy Services - and protect consumers from financial disincentives that drive them away from the local pharmacy based on claims of less expensive medications through mail order pharmacies owned by the PBMs.

We have visited with you about this issue in past hearings, demonstrated how these incentives are used to entice consumers to purchase medications through the mail – even when they are often more expensive, either to the consumer or the plan sponsor. We have more supportive information to share with you but in hopes this bill will be passed on for further consideration I will only continue with that additional information if you request it.

The fact is North Dakotans will not have freedom of choice if public policy does not include this section in HB 1332. It is definitely related to this particular piece of legislation because it addresses another financing scheme used to generate new revenue streams through the mail order facilities owned by PBMs. And the ONLY way to disclose the impact of these activities is to INCLUDE this section in this bill and require transparency of this aspect of pharmacy services as well as the others identified in HB 1332.

We have forfeited several sections of the original bill, in a spirit of negotiation and compromise. We hope these latest revisions will provide the opportunity for the committee to move forward and allow your colleagues in the Senate a chance to participate in these deliberations.

Thank you.

Senate IBL Committee
Senator Duane Mutch, Chair
March 7, 2005

Testimony in Support of HB 1332

Chairman Mutch and members of the committee, my name is Patricia Hill. I serve as the Executive Vice President for the North Dakota Pharmacists Association. Thank you for this opportunity to visit with you this morning.

We are here this morning - following many weeks of extensive scrutiny by the House and overwhelming support from the committee and on the floor – to talk about HB 1332. Rather than inundate you with reams of information and documents that were reviewed in the House, we will provide the highlights of those deliberations. If you are interested in having a complete set of the documents prepared and presented in the House I would be happy to provide those and arrange to meet with you to cover the materials and answer questions. For now we will proceed with the main points:

1. **Lower prescription drug costs**
   The purpose of HB 1332 is to significantly lower the cost of prescription drugs for thousands of North Dakotans. This is possible by regulating pharmacy benefit managers (PBMs) and requiring them to pass on greater savings to North Dakota employers who pay for a drug benefit as part of their employee's healthcare coverage.

   Lower cost achieved with increased savings from rebates and discounts
   HB 1332 requires the PBM to be "transparent" – to disclose the actual revenues that are generated in private negotiations between the PBM and drug companies AND to make those savings available to the employer to reduce their cost.

2. **Lawsuits (all over the country) have uncovered savings being kept by PBMs, substantially adding to consumer cost** [*1]

   PBMs will tell you they provide savings to employers and that there are reports to prove this claim. The two reports cited most often are the GAO report which was rejected because the data used in the analysis was never verified, and the FTC report on PBM legislation in California which cannot be applied to HB 1332 because the two bills are very different. [*2]

   It is true that PBMs are suppose to lower drug costs, and some do, but it was growing concern over skyrocketing increases in drug costs that led 20 states to investigate PBMs. And only through these investigations was it uncovered that those confidential negotiations – deemed to be proprietary information - were indeed creating huge savings but those were NOT being passed on to the plan sponsors. Large portions were hidden or disguised and kept by the PBMs as profits.

1. Partial listing of lawsuits against PBMs in the United States
2. GAO report rejected by Senator Dorgan, and FTC comparison report

The New York Attorney General gave the most concise comment on what had been discovered from these numerous lawsuits –

"The PBMs lined their pockets at the expense of health plans and consumers, driving up the very costs they were suppose to lower." New York AG Elliott Spitzer

3. Legislation to regulate PBMs not unique to North Dakota

The escalating cost of drugs is a national problem, and dozens of state legislatures have introduced legislation similar to HB 1332. The opponents will tell you that it has been introduced in about 20 states [*3] but only passed in a few and that is suppose to suggest that it is not a good idea. Nothing could be further from the truth. In fact, there are eight states that have introduced PBM regulation bills this year, and six are repeats from last year! It looks more like a continuing effort by states to get to the bottom of this.

4. Lawsuits less threatening with Maine decision of February 3, 2005

The opponents may also try to suggest that any state passing a bill like this should expect litigation, because the PBMs filed an injunction to stop the implementation of the law in Maine – which was the first state to pass a PBM regulation law.

If this causes concern, you will be relieved to know that on February 3rd a U.S. Magistrate judge in Maine ruled in favor of the state ON ALL COUNTS – thus moving that legislation one step closer to implementation. The major findings were:

- Requiring PBMs to disclose the negotiations with drug companies, said to be trade secrets, does NOT violate the federal "takings clause" nor other commerce considerations
- The transparency requirements of the law do NOT violate the PBMs due process rights or freedom of speech
- The law does NOT preempt federal law under ERISA

One note on ERISA. The opponents testified earlier that the state law was unnecessary because it would not apply to self funded plans that are covered under ERISA, and about half of the plans administered by BCBS fall under ERISA. The Judge in Maine disagreed with this view and ruled:

*"Although ERISA prescribes the duties that are owed by ERISA entities to one another, and prescribes remedies for their breach, it is not designed to regulate or afford remedies against entities that provide service to plans. (The PBMs) have failed to present any set of circumstances in which enforcement of the (law's) "required practices" against a PBM would undercut ERISA's civil enforcement.....there is no logical basis to infer that Congress intended for ERISA to foreclose state regulation of third-party pharmacy benefit management services engaged in by non-ERISA fiduciaries or to preclude ERISA plans from employing state-created remedies against PBMs on an equal footing with other consumers of such services." *4*

3. States introducing PBM legislation and other related public policy to reduce drug costs
4. Ruling by US Magistrate Judge in Maine, - February 2005

5. Potential savings from HB 1332.

HB 1332 was drafted using a bill that is now law in South Dakota and their experience provides evidence of the potential for significant savings in North Dakota.

The Human Resources Director for the state employees plan sent out RFPs last summer, requiring compliance with the new PBM transparency law. Thirteen PBMs responded. Of those, three were interviewed and one selected to provide the claims processing services for the state employee's drug benefit. This is a PBM that did not operate in SD before.

Initial savings to the state employees of South Dakota was $800,000 and total estimated savings for the biennium will exceed $2 million. [*5] Compared to North Dakota's public employees plan, the South Dakota plan includes about 24,000 covered lives and ours is about 52,000. That suggests the savings yet to be realized in North Dakota would be substantially higher than $2 million.

South Dakota chooses to retain all the savings from rebates and discounts, and pays the PBM a fee for service. In addition, the state does not allow incentives to be used for mail order so patients are given the freedom to choose the provider they prefer.

6. Benefit to employers and consumers

As Representative Johnson noted in her introduction, HB 1332 is a direct benefit to employers who are paying the premiums for their employees to receive a drug benefit as part of their healthcare plan. And while it is true, that over 300 business members of the state's retail association are on record in support, AARP is on record in support, and you have copies of letters from a few large employers who support the bill [*6] - there is not a long line of other employers testifying at these hearings.

The opponents to HB 1332 suggested that this was a reason to not support the bill, but during ongoing testimony in the House it became abundantly clear that the contracts and negotiations, as well as the reporting processes on healthcare plans require an expertise that you will not find at small businesses across North Dakota. Nor do business owners have the kind of financial resources necessary to hire consultants to help them with these issues – and that creates a huge disadvantage for employers. It is for that reason, that amendments to HB 1332 specifically give the employers an "advocate" in the ND Insurance Department – to look out for their best interests.

In closing, I request your support of HB 1332 which is before you as a compromise between both sides.

Also offering support for HB 1332 and its intended outcomes are senior executives of PBMs operating nationally, as well as regionally and in North Dakota, who said (and I quote): [*7]

5. Data from SD Human Resources Director
6. Support for HB 1332
7. Articles with quotes from PBM senior executives, supporting transparency and disclosure

"If you have nothing to hide, transparency is not a problem,"

Medco Health Solutions ($29M fine in 2005 for unfair business practices)

"PBMs should develop a fee structure...fully disclosing revenues received from manufacturers and implementing an equitable formula for sharing that revenue."

Tim Dickman, CEO of Prime Therapeutics, the PBM owned by several Blue Cross and Blue Shield organizations including ND

Thank you for your support of HB 1332. I would be happy to answer any questions at this time.

Dr. Patricia A. Hill, Executive Vice President
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Tab 8

- ***"Consumers hit harder by medicine copayments"*** by Christopher Rowland, Boston Globe – February 8, 2005
- ***"The myth of mail order: Results show offering patients choice of 90-day prescription supplies at neighborhood pharmacies saves employers more money"*** PR Newswire – February 15, 2005
- ***"Generic drugs by mail can be a raw deal"*** by Barbara Martinez, Wall Street Journal – February 15, 2005
- ***"U.S. Firms losing health care battle, GM Chairman*** says" by Ceci Connolly, Washington Post, February 11, 2005
- ***"Public funding of health care to hit 50%"*** Associated Press, Washington – February 23, 2005
- ***Medco 4th quarter profits rose 12% on mail order*** Bloomberg Press, February 15, 2005

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THIS STORY HAS BEEN FORMATTED FOR EASY PRINTING

Consumers hit harder by medicine copayments

The Boston Globe

By Christopher Rowland, Globe Staff | February 8, 2005

A majority of consumers said the biggest change in their health insurance last year was higher copayments for prescription drugs, according to survey results released yesterday.

The results are another indication that patients are bearing an increasing burden of healthcare costs.

The informal survey of 915 visitors to the website of Weiss Ratings Inc., a financial risk analysis firm in Jupiter, Fla., found that 34.3 percent said the higher drug copayments they must pay reflect the biggest change, while 23.8 percent said the copayment for a visit to the doctor was biggest.

"Absent any real reform in truly managing care, it's going to cost more -- and that is being passed along to individuals," said Melissa Gannon, a vice president at Weiss Ratings, which specializes in health and other forms of insurance.

The findings echoed a major, more scientifically rigorous survey of employers last year by the Kaiser Family Foundation, a nonprofit research organization in Washington, that showed sharp increases in prescription copays over the past five years. That poll broke down patients' share of costs within so-called tiered copayment arrangements, which have become ubiquitous in prescription drug coverage.

In tier 1, which includes the cheapest generic drugs, average copayments rose to $10 in 2004 from $7 in 2000. In tier 2, for brand-name drugs the insurer has designated as the "preferred" choice, average copayments rose to $21 from $13 in 2000. And for the brand-name drugs designated by the insurance company as "nonpreferred" and placed in tier 3, the average copayment nearly doubled, to $33 from $17.

The result is rising sticker shock for people on maintenance medications, particularly the elderly.

"If your copay went up from $10 to $20, and you're taking four or five drugs a month, that can be a big burden," said David Gross, a senior policy adviser in Washington for AARP, the nonprofit group that represents Americans over 50.

Cindy Parks Thomas, senior research scientist at the Schneider Institute for Health Policy at Brandeis University, said incremental changes in drug copayments add up faster than other cost-shifting strategies like higher payments for doctor's office visits and hospitalizations.

"People go to the pharmacy every month -- especially senior citizens. They are going to notice even a little change," she said.

In an editorial in the New England Journal of Medicine in December 2003, Thomas reported on the explosion in tiered copayment systems for prescription drug coverage. A decade ago, the average copayment for all prescriptions was $5.

Today's copayments, she said, averaging as much as seven times more for the most expensive brand names, are derived through contract negotiations between drug companies, insurers, and employers. The details of those contracts are not disclosed to the public, she said.

Thomas also said some people aren't taking their drugs because of the higher out-of-pocket expense. While consumers are given an incentive to choose lower-cost generics, the tiered setups give them an incentive to take less medicine. "With the higher cost-sharing, some people are going without their drugs," she said.

The insurance industry and employers say rising copayments reflect an effort to strike a balance between access to healthcare and affordability.

Tiered plans with their higher prices for certain drugs provide patients with , additional choices that might not be available under more restrictive plans with a single copayment, said Mohit Ghose, spokesman for America's Health Insurance Plans, the industry's Washington lobbying organization. A crucial next step, he said, is improving the spread of information about head-to-head comparisons of drugs within an individual class, so patients and their doctors will know when it is appropriate to switch to the lower-cost generics.

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Press Release Source: Walgreen Co.

The Myth of Mail Order: Results Show Offering Patients Choice of 90-Day Prescription Supplies at Neighborhood Pharmacies Saves Employers More Money

Tuesday February 15, 1:05 pm ET

DEERFIELD, Ill., Feb. 15 /PRNewswire-FirstCall/ -- Employers are saving more money by allowing workers the choice to fill 90-day supplies of chronic medications at retail or mail pharmacies than by requiring workers to exclusively use mail.

ADVERTISEMENT

"It's a myth that mail is always cheaper," said Greg Wasson, president of Walgreens Health Initiatives, the pharmacy benefits manager owned by Walgreens. "Yes, 90-day prescriptions save money, but '90 days' is not synonymous with mail order. We know, because we offer the choice of 90-day prescriptions through mail or retail. Our results show that choice reduces costs for employers without forcing workers to miss the counsel of their neighborhood pharmacist. That's particularly important for patients taking multiple prescriptions."

Walgreens offers retail service in more than 4,700 stores and mail service through three major facilities. In late 2003, Walgreens Health Initiatives introduced its Advantage90 program, which allows employers to offer workers a choice between using retail and mail order pharmacies for 90-day prescription refills.

With more than a year's worth of data from the Advantage90 program, employers and workers are paying on average $15 less for chronic medications at retail pharmacies than through a mail order service.

"As more employers hear about these savings, interest in offering 90-day prescriptions at retail pharmacies is growing," said Wasson. More than 130 drug benefit plans have signed up for Advantage90, which offers a nationwide retail network of more than

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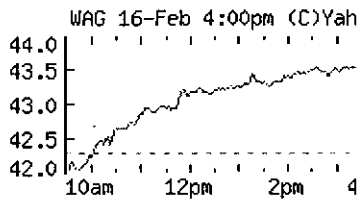

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25,000 pharmacies, nearly half of all pharmacies in the U.S.

A recent Hewitt Associates study showed growth in mandatory mail prescription programs leveling off. "We believe that's because employers are realizing that eliminating choice doesn't work over the long term," said Wasson. "We're actively educating managed care companies, benefits consultants and employers about the greater savings they can see through a 90-day retail prescription option.

"There's more to the story than employers are being told by the big pharmacy benefit managers, who operate their own in-house mail order pharmacies. The biggest savings come from offering 90-day refills at both mail and retail pharmacies."

Through innovative programs like Advantage90 and implementing drug formularies based on effective, low-cost treatment rather than rebate potential from drug manufacturers, Walgreens Health Initiatives is a leader in the PBM industry in controlling the overall rise in prescription drug costs

"Our interest is providing the most appropriate and lowest-cost drug therapy to employees and their companies, which we're able to do because we're not a rebate-driven PBM," said Wasson.

Walgreens Health Initiatives (WHI) is operated by Walgreen Co. (NYSE, Nasdaq: WAG - News), the nation's largest drugstore chain with fiscal 2004 sales of $37.5 billion and 4,714 stores in 44 states and Puerto Rico. In addition to providing pharmacy benefits management through WHI, Walgreens offers services to pharmacy patients and prescription drug plans through Walgreens Mail Service, Walgreens Specialty Pharmacy and Walgreens Home Care.

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As of Tuesday, February 15, 2005

HEALTH

Generic Drugs By Mail Can Be a Raw Deal

By BARBARA MARTINEZ
Staff Reporter of THE WALL STREET JOURNAL
February 15, 2005; Page B1

In an attempt to rein in its employees' fast-rising prescription drug costs, General Motors Corp. requires its workers to fill prescriptions for chronic conditions through the mail-order operation of Medco Health Solutions Inc. But some simple comparison shopping shows that GM, despite its formidable bargaining clout, is paying far higher prices for some drugs than ordinary individuals can get walking into retail pharmacies.

Consider GM's price for ranitidine, the generic form of the popular anti-ulcer pill Zantac. GM pays Medco $176.22 for 90 pills mailed to a worker, who pays an additional $5 co-pay, bringing the total cost to $181.22, according to Medco's Web site for GM employees. If a GM employee were to simply buy the same ranitidine prescription at a retail pharmacy, it would cost a total of $62.88 for the 90 pills. A person without insurance could buy the same medication at Wal-Mart in Secaucus, N.J., for $78.62. At Costco Co.'s online service, Costco.com, the prescription would cost only $22 -- and include 10 extra pills.

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General Motors Corp. (GM)

PRICE	37.14
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PRICE	44.38
CHANGE	0.58
U.S. dollars	10:42 a.m.

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Have a question about managing health-care costs? Write to outofpocket@WSJ.com. Read answers in a new online Q&A column, Out of Pocket, at WSJ.com/Health.

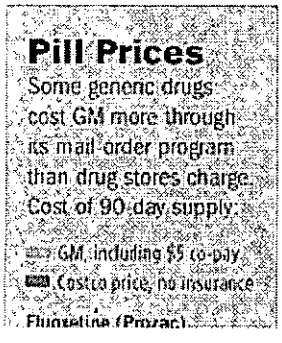
GM pays Medco higher prices for many generic drugs than regular pharmacies charge customers without insurance illustrates the complexities, and potential pitfalls, of prescription-drug coverage. It's also a rare glimpse into how such plans work.

Pharmacy-benefit managers, such as Medco, administer the drug benefits of large employers, acting as the middlemen between the employers and the pharmacies. Such PBMs create large networks of participating pharmacies and use their size to drive down prescription-drug prices. Some, including Medco, also own their own mail-order pharmacies, and prod employers to move more of their workers' prescriptions into the mail business.

PBMs promise to realize savings for their corporate customers by keeping the overall cost of prescription medications down. But they also preserve large profit margins for themselves, as the GM prices show. Th pays for prescription drugs is available to any of its employees or retirees through benefits Web site. The Wall Street Journal reviewed Web page printouts provided pharmacist with access to the site and who is working to get GM to roll back its m mail policy -- in which employers require workers to fill prescriptions through a m

Some companies, like GM, say they are satisfied with the overall savings Medco i But others simply aren't aware of the vast price discrepancies on generic drugs.

Susan Hayes, a consultant with Pharmacy Outcomes Specialists in Lake Zurich, Il helps employers control their drug costs through audits and contracting, says some are surprised when she tells them about the price differential. "It's a big deal," says "Why should you pay more than $1 a pill for generic Prozac to the mail-order pha you could get it for 23 cents in the retail store?" she asks.



GM has used Medco to manage its drug benefit since 1994 maker's drug costs are climbing by more than 15% a year, double the rate of increase of GM's overall healthcare cost

GM's pharmacy chief, Cynthia Kirman says GM is getting from Medco, saving $80 million by using mandatory mail 2003's drug costs of $1.3 billion. GM declined to explain h it would save $80 million. The company spent $1.5 billion prescription drugs in 2004.

U.S. dollars	10:47 a.m.
Walgreen Co. (WAG)	
PRICE	42.49
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U.S. dollars	10:42 a.m.
Caremark Rx Inc. (CMX)	
PRICE	39.12
CHANGE	0.13
U.S. dollars	10:42 a.m.
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Last week GM moved to strengthen Medco's mandatory-mail program further by 1.1 million employees and retirees from filling any prescriptions at the Walgreen chain.

GM's Ms. Kirman says its not fair to "cherry-pick" certain drugs for a price compa she declined to provide a list of GM's most-used generic drugs. "Numbers on the M site may not be reflective of the actual GM prices," a GM spokeswoman said yest subsequently. The GM spokeswoman declined to explain why the numbers may n reflective.

A Medco spokeswoman, too, says it is misleading to look at individual drug price draw any conclusions about overall costs. The spokeswoman, Soraya Rodriguez-E an e-mail response to questions that "mail-service pricing for generics is usually a percentage discount for all drugs and adds value in aggregate."

Because generic drugs are so cheap to begin with, PBMs and retail pharmacies alil make big margins on generic drugs, which account for about half of prescriptions U.S. That's why pharmacies have a big incentive to switch prescriptions for brand their generic versions.

Aggressively switching of branded prescriptions to generics does help reduce emp costs. Employers also believe they are getting better prices on branded drugs throu which is why they are willing to pay bigger markups on generic medications.

Mail-order pharmacies generally fill a three-month's supply of medication at once. benefits greatly from its mail-order pricing system. When a patient fills a prescript Medco's mail pharmacy, the full profit belongs to Medco, rather than having to spl very little when the transaction happens at the retail store. The Franklin Lakes, N.J derives more than half of its corporate profits just from selling generic drugs from order unit.

For example, 90 ranitidine pills usually cost pharmacies about $7. At retail, custor $22. Medco's mail-order price to GM is $181.22. Medco can show its customers a because the list price, called the average wholesale price, quotes ranitidine at abou pills. Medco declined to comment on specific prices on its Web site.

The dizzyingly complex system of drug pricing makes it difficult for employers to whether they are getting the best prices. Generic drug prices in mail programs are average wholesale price, or AWP. AWP is considered an inflated price among tho industry. For example, the average wholesale price for 90 fluoxetine pills, the gen Prozac, is $240.12 but pharmacies usually pay less than $5.

Employers can't choose to use a PBM for only brand-name drugs, where they get and use another service for generic drugs. PBM services are purchased the way en purchase a health plan -- the same health insurer covers all the different physician for a worker.

Medco's generic pricing policy isn't unusual. Caremark Rx Inc., the pharmacy-ben for millions of federal government employees, charges $96.05 for 90 pills of fluox $105.42 for 90 pills of ranitidine from its mail-order pharmacy. The prices are ava

federal employees on Caremark's Web site.

In addition to GM, International Business Machines Corp., Southwest Airlines Co and numerous states and municipalities, have started mandatory-mail programs in A survey by consultant Hewitt Associates found that 22% of employers will have mail plans in place this year, with another 51% considering such programs.

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U.S. Firms Losing Health Care Battle, GM Chairman Says

By Ceci Connolly
Washington Post Staff Writer
Friday, February 11, 2005; Page E01

American manufacturers are losing their ability to compete in the global marketplace in large measure because of the crushing burden of health care costs, General Motors Corp. chairman and chief executive G. Richard Wagoner Jr. said yesterday as he called on corporate and government leaders to find "some serious medicine" for the nation's ailing health system.

In a speech at the Economic Club of Chicago, the auto executive, who is responsible for providing health insurance for more people than any other private employer in the nation, graphically detailed how rising medical bills are eating into his company's bottom line and ultimately threatening the viability of most U.S. firms.

"Failing to address the health care crisis would be the worst kind of procrastination," Wagoner said, "the kind that places our children and our grandchildren at risk and threatens the health and global competitiveness of our nation's economy."

After spending several years on the health policy sidelines, Wagoner is launching a mini media blitz, hoping the competitiveness argument will be the one that finally prompts lawmakers to take on an increasingly expensive system rife with inefficiencies and inequities. Wagoner said he intends to press his case personally in Washington and with the nation's governors.

By the Numbers

1.1 million Number of people General Motors covers for health insurance.

$5.2 billion Amount GM spent to cover these people last year.

$400 million Amount GM expects its overall health care costs to rise this year.

$1,500 Amount added to the price of each GM vehicle to cover health care costs.

THE WASHINGTON POST

Though self-interest may be at the heart of Wagoner's crusade, he and a range of corporate leaders and policy analysts warned that GM's woes are a harbinger of what lies ahead.

"GM is the canary in the coal mine for Medicare and everyone else," said Sean P. McAlinden, chief economist at the nonprofit Center for Automotive Research. "There are many, many more companies out there in trouble because of health care costs than just the auto, steel and airline industries."

McAlinden, a labor expert sympathetic to union views, said many in Washington have mistakenly concluded that GM and other carmakers are simply whining about costly union contracts.

"GM and the United Auto Workers didn't cause this double-digit inflation in health care," he said. And if GM pushed for sharp reductions in health benefits, the powerful union would likely strike and send the company into Chapter 11 bankruptcy protection, he predicted.

Last year the automaker, known for its innovative approach to health care, spent $5.2 billion to cover 1.1 million retirees, employees and their families. Prescription drugs cost GM $1.9 billion, and the company projects overall medical spending will increase by $400 million this year. That could be offset by a provision in the Medicare drug benefit to pick up a portion of firms' retiree drug costs.

But the figure that prompted Wagoner to raise his voice is $1,500. That is the amount of money added to the price of every single vehicle to cover health care, a cost that his foreign competitors do not bear.

"The cost of health care in the U.S. is making American businesses extremely uncompetitive versus our global counterparts," he said. "In the U.S., health care costs have been rising at double-digit rates for many years. In 2003, they were about 15 percent of GDP, at least 30 percent higher than the next-most-expensive country."

Paul Hughes-Cromwick, senior analyst at the nonprofit Altarum Institute in Ann Arbor, Mich., said executives are alarmed that benefit costs are rising far more rapidly than wages.

Total compensation costs for U.S. firms rose about 3.7 percent in 2004, mirroring previous years, he said, citing Bureau of Labor Statistics data. But salaries increased just 2.4 percent, while benefit costs rose 6.9 percent. The gap is the largest he has seen in two decades.

"That huge benefit hit is chewing up the salaries and wages we would be receiving," he said. "That's the key."

Yesterday, Wagoner broke his silence on an idea proposed by Sen. John F. Kerry (D-Mass.) in the 2004 presidential campaign, saying he supports some type of national catastrophic reinsurance program. Senate Majority Leader Bill Frist (R-Tenn.) has also endorsed the concept of a separate government-backed insurance pool to cover the most expensive medical cases.

"If we can create a comprehensive insurance model to better share these catastrophic costs among all consumers, then we can take a big step toward providing affordable health care coverage for all our citizens," Wagoner said.

Wagoner and fellow executives find much to be frustrated with in the health care system.

"It's simply not acceptable for over 45 million Americans to be without health care coverage," he said, echoing a point made recently by Jack O. Bovender Jr., chief executive of health care giant HCA Inc. "And it's unfair for those of us who do provide health care benefits to have to pay higher bills to cover the costs of the uninsured. Talk about 'no good deed goes unpunished.' "

The business leaders cannot understand why the health care industry has been slow to institute the sort of technological changes that helped them improve quality and reduce costs.

"Only in health care does bad service and bad quality get paid for in the same manner as good service and good quality," said Humana Inc. chief executive Michael B. McCallister, chairman of the Business Roundtable's health care task force.

The CEOs agree that the double-digit premium increases will continue as long as individuals are sheltered from the true cost of health care.

"Companies, to manage health care costs, are going to have to have employees who understand that this

is something you are consuming and you have a responsibility for," Wal-Mart Stores Inc. chief executive H. Lee Scott Jr. said in an interview.

Staff writer Michael Barbaro contributed to this report.

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Public funding of health care to hit 50%

Medicare prescription program pushing costs higher

The Associated Press
Updated: 4:50 p.m. ET Feb. 23, 2005

WASHINGTON - Within a decade, the government will be footing the bill for nearly half the nation's medical costs, its share propelled higher by the new Medicare drug program, administration economists estimated Wednesday.

At the same time, total health spending — both private and government — will take an ever-larger portion of America's economic output, said the report from the Centers for Medicare and Medicaid Services.

The rise in federal payments raises "some really, really big issues" about a government budget in which other programs already are being squeezed out, said Urban Institute tax analyst Eugene Steuerle.

The projections were the result of an effort to measure the impact of last year's Medicare law on overall health spending between 2004 and 2014.

Officials said that overall, the growth in health costs was expected to remain stable at around 7 percent per year over that period.

Privately paid portion to fall to 59 percent

But the portion borne by the government will rise due to the Medicare drug benefit that starts next year.

This year, 76 percent of all drug spending — a projected $223.5 billion — is expected to come from private health insurance and out-of-pocket co-payments.

That privately paid portion will fall to 59 percent next year, when the new Medicare benefit starts and there is a shift to Medicare from private payers and from Medicaid, officials said.

"In part because of this funding shift, our projection calls for public funding of health care to exceed 49 percent by" 2014, the report said.

It called that "a record share that could have important implications for the budget as a whole."

By 2014, overall medical payments are projected at about $3.6 trillion, with the government footing 1.8 trillion, or 49.4 percent, and private funding covering just over 50 percent, it said.

The federal share has been rising for decades. In 1965, the government was covering roughly 25 percent of health costs and private parties 75 percent, according to the report. Last year the government paid 45.6 percent of an estimated $1.8 trillion in medical bills.

Health care costs to grow faster than GDP

Eventually, the two sides will reverse roles, with the government paying more than half, said Richard Foster, chief actuary for the Centers for Medicare and Medicaid Services.

The report also said that over the decade health care spending is expected to continue growing faster than the nation's gross domestic product. Therefore, it will account for 18.7 percent of GDP in 2014 compared with 15.3 percent last year.

Under the Medicare changes, participants will pay monthly premiums that are expected to average $35 in 2006 and the first $250 in drug costs. Medicare will pick up 75 percent of the next $2,000 in prescription expenses. After that, a gap is built into coverage during which participants are responsible for the entire drug bills until costs top $5,100, after which the government pays 95 percent.

When Congress narrowly approved the drug legislation in 2003, the administration told wavering lawmakers that the program would cost $400 billion, including expected savings. The White House revised the estimate to $534 billion two months later, after the law was enacted.

Then this month it said the figure was more like $720 billion.

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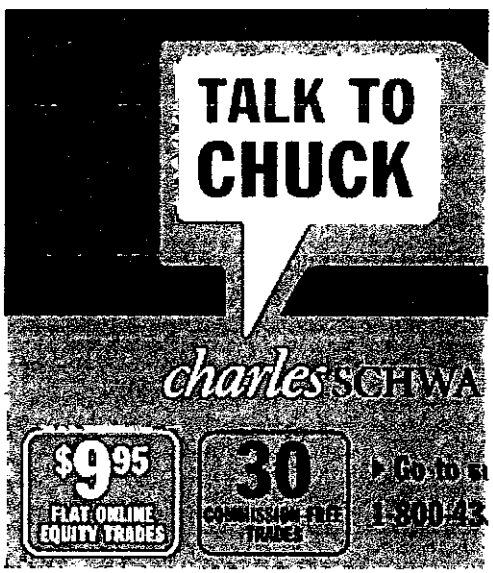
Medco 4th-Qtr Profit Rose 12% on Mail Order, Generics (Update1)



Feb. 15 (Bloomberg) -- Medco Health Solutions Inc., the largest U.S. pharmacy-benefit manager, said fourth-quarter profit rose 12 percent as the company encouraged more members to fill their prescriptions by mail and use cheaper generic drugs.

Net income rose to $132.8 million, or 48 cents a share, from $118.3 million, or 43 cents, a year earlier, the Franklin Lakes, New Jersey-based company said today in a statement. Sales declined 1 percent to $8.9 billion from $9 billion.

Medco is switching more members to mail-order service and generic medicines to cut costs and reduce the effect of lost contracts, including one that ended Oct. 1 with the Teacher's Retirement System of Texas. The company gains about $9 million a year for every $100 million of branded drugs that lose patent protection and are matched by less-expensive generics.

``We know they lost some big customers last year, so the revenue expectations are fairly modest,'' said Larry Marsh, an analyst with Lehman Brothers Holdings in New York, in a telephone interview before Medco released results.

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Medco shares rose $1.12 or 2.6 percent yesterday to $43.80 as of 4 p.m. in New York Stock Excl trading. They gained 22 percent last year. Drugmaker Merck & Co. spun off Medco in August 200

Profit excluding some items was 58 cents a share, Medco said. On that basis, the company was e 56 cents a share, the average estimate of 12 analysts surveyed by Thomson Financial.

Medco and its next two rivals, Caremark Rx Inc. and Express Scripts Inc., administer prescriptior health- insurance plans and employers.

Medco's mail order pharmacies filled 22.3 million prescriptions in the fourth quarter, for a 13.2 p that unit's volume.

Medicare Benefit

Pharmacy-benefit managers are preparing to help administer a new benefit covering prescription next year in the U.S. government's Medicare health-insurance plan for the elderly and disabled. I spend $59.3 billion for the first year of the added benefit in 2006, according to President George proposed budget released Feb. 7.

The additional government benefit, signed into law by Bush in December 2003 will help Medco er effect of contract losses to Caremark, said Marsh, who rates Medco shares ``overweight/neutral. over management of benefits for 3.9 million federal workers in a Blue Cross and Blue Shield Assc plan to Caremark starting Jan. 1.

``Most people are waiting to hear their plan for participating in the drug bill,'' Marsh said.

The company will submit its notice of intent to apply to become a nationwide Medicare Part D Pre Plan sponsor, according to a separate statement released today.

Medco also announced last week that it won a five-year contract from the state of Illinois startinç manage more than $400 million a year in drug claims for more than 230,000 of that program's n including government employees and retirees. Caremark currently handles the contract.

Meantime, Medco is reducing costs and raising margins with steps including switching patients to service from filling prescriptions at pharmacies. Each additional percentage point that mail order total prescriptions adds about 2 cents a share to Medco's earnings, said Kemp Dolliver, an S.G. C Corp. analyst in Boston. Dolliver doesn't use a rating system or own Medco shares.

(To access the company's conference call with investors and analysts at 8:30 a.m. New York tim 949-5383 or (1)(706) 679-3440 outside the U.S. A Web cast of the call will be available at http://www.medco.com)

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Last Updated: February 15, 2005 07:16 EST

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Testimony before the Senate Industry, Business and Labor Committee
Senator Duane Mutch, Chairman
March 21, 2005

RE: Support of HB 1332

Good morning Mr. Chairman and members of the Committee. For the record my name is Patricia Hill. I serve as the Executive Vice President for the North Dakota Pharmacists Association and I am here in support of House Bill 1332.

We're here today to talk about prescription drug prices - one of the fastest growing components of healthcare spending, disproportionately contributing to overall increases in healthcare costs. Three factors fuel this growth:

- more drugs are being prescribed
- new, higher priced drugs are prescribed more frequently, and
- drug costs have been on a steady rise for the past 20 years.

Higher prices affect everyone – employers, insurers, state programs, and of course consumers. Rising costs are especially difficult for our older citizens who rely on prescription drugs more than other age group, yet Medicare estimates one-third of our Seniors have no drug coverage.

- For the elderly - buying drugs, at prices that have outpaced inflation for many years, has become impossible.
- For employers - there is a constant threat of 20 percent increases in their annual premiums and soon this benefit will be not be realistic.
- For employees - the increased cost-sharing, in order to have any healthcare benefit, is becoming unaffordable.
- From consumers – all across the country there has more and more demand for public policy to help alleviate these barriers to quality healthcare including prescription medications.

We are here as consumers, employers and healthcare providers. We appreciate this chance to explain HB 1332 - a public policy that can reduce cost and provide greater access to pharmacy services.

First, let's put the cost of drugs into perspective. A study published in July 2003 looked at the 50 drugs used most often by our elderly, and determined that 25 of the 38 that had been on the market for 5 years (1998 to 2003) - or 66 percent- had at least five price increases during those years. These cumulative price increases ranged from 13 to 360 percent. [1]

1. *Out of Bounds*, Families USA, page 10, Table 2, www.familiesusa.org

If, or when, a person experiences "sticker shock" over the cost of a prescription they're usually at their local pharmacy. And even though there is a complex process involved in the price paid by consumers, they tend to associate rising costs with the pharmacy... but that's not where the increases are coming from.

In your binder behind Tab 1 are two charts, compiled by researchers at the University of Minnesota's Prime Institute. The first diagram is data from Medicaid where state government programs are able to obtain the best possible drug prices in the market. You can clearly see - even at the least expensive rate - that 20 years ago we could attribute 63% of cost to the product and 37% to the pharmacy. Today, the portion of drug costs attributed to the pharmacy is only 10%. That means 90% of the cost of medications comes from other places...and we're going to talk about those in a minute. The second chart is interesting because it compares profits over 30 years for drug companies, pharmacies and Fortune 500 companies. With drug prices increasing faster than the rate of inflation it's not surprising to see drug companies profits that are 3 to 4 times higher than Fortune 500 firms. And please note the pharmacies at the bottom with 3 percent margins.

Hundreds of pieces of legislation have been introduced in every state trying to get a handle on the skyrocketing cost of prescription drugs. HB 1332 is one of those bills. It focuses on pharmacy benefit managers (PBMs), and their contributions to the price of medications. The primary requirement in HB 1332 is transparency, which means PBMs operating in North Dakota would disclose information about their negotiations with drug companies that generates millions of dollars in the form of rebates, discounts, selling data, and other revenues. PBMs would be required to share those savings with consumers, so prices go down and become more affordable to more people.

Under Tab 2 is the original HB 1332 that was first introduced two months ago. Your copy has been marked up to indicate the amendments that followed eight hearings and intense negotiation just before Crossover. I think it's fairly obvious that since we supported the initial bill, this extensive deletion of entire sections and entire pages was not requested by us and certainly required a great deal of compromise on our part.

Following the marked up bill, is a copy the engrossed version of HB 1332 that came to you on February 25. In addition to the deletions, the following provisions remain in the bill:

- Disclosure of rebate, discounts and other revenues, but limited to the ND Insurance Department (requested by the PBMs who did not support the original bill with disclosure to plan sponsors also)
- Full compliance with HIPAA regulations to protect patients in any disclosure of information (supported by all)
- Compliance with ND state law regarding drug substitution to ensure that the physician remains the qualified professional in control of any changes in prescribed drugs (amendment proposed by PhARMA , supported by all)

HB 1332 provides consumer protection oversight by the ND Insurance Department and requires a PBM to:

- Obtain a license under chapter 26.1-27
- Disclose ownership interest other entities such as insurance companies or organizations involved in providing drugs or pharmacy services
- Offer covered entities options to have transaction fees: 1) based on the covered entity receiving all rebates and discounts, or 2) combined with sharing the rebates and discounts, or 3) without sharing rebates or discounts.
- Allow audits to be conducted
- Limit drug substitution to requesting a lower-priced generic or therapeutically equivalent drug to replace a higher-priced prescribed drug, or; for medical reasons that benefit the patient and the doctor has approved.
- Allow pharmacies to participate in one contract without requiring participation in any other contract. Qualified pharmacies would not be excluded from participation solely because they declined to participate in another network or plan.
- Contract with retail and mail order pharmacies using the same co-payments and days of supply.

The Insurance Department will examine contracts between the covered entities and the PBM to determine if the rebates and discounts were applied to reducing rates. Any information disclosed to the Insurance Department is considered a trade secret under state law.

Transparency is the key to HB 1332. The cost of drugs isn't just about expenses the drug manufacturer incurs and then incorporates into the price. There is a complex process involved in the price we see at the counter, and that explanation will be presented next. HB 1332 was modeled after a similar bill that passed last year in South Dakota, which has already saved over $2 million in that state. There is no oversight of PBMs at the state or federal level. They have a prominent and contributing role in the price of prescription drugs, yet they have no accountability. Recent unfair trade allegations led to investigations and lawsuits that have uncovered information about the business practices of PBMs. The discovery of these routine activities at PBMs is what made the next presentation possible.

Patricia A. Hill, PhD
Executive Vice President
ND Pharmacists Association

New

Amendment to HB 1332

Page 3, under
26.1-27.1-03. Disclosure requirements.

Line 28, add

3. The pharmacy benefit manager shall provide to the covered individual a monthly "Explanation of Benefits" which includes an itemized accounting of individual claims indicating the amounts the PBM or any other entity, or both, actually paid each pharmacy or pharmacist for pharmacy services rendered, and any invoice, statement, or remittance seeking any payment or reimbursement for said services.
4. The pharmacy benefit manager shall provide to the covered entity a monthly "Explanation of Benefits" which includes an itemized accounting of individual claims indicating the amounts the PBM or any other entity, or both, actually paid each pharmacy or pharmacist for pharmacy services rendered, and any invoice, statement, or remittance seeking any payment or reimbursement for said services. This report shall ensure HIPAA compliance by using de-identified information wih regard to covered individuals.

This amendment does not disclose any information on rebates or other proprietary details (that remains limited to the Insurance Commissioner). It provides the consumer (in #3) and the employer (in #4) with the same explanation of benefits they currently receive from BCBS when they go to the hospital or clinic or doctor, etc. – for all other healthcare services.

It could also be compared to the monthly VISA bill, that lists each purchase and the obligation of the consumer to pay a certain amount. Consumers don't know or care what % is paid by the store for VISA to administer the program, but they do know what cost is attributed to them and they are responsible for. How would they feel if the VISA bill came and they were charged $125 for the $100 purchase they made but not given an explanation.

It could also be compared to consumers who come into a bank for a loan and the bank must disclose every detail of the cost of securing the loan whether it is the current loan rate, plus closing fees, and all others. It is simply consumer protection and the consumer right to know.

Under current process, the consumer doesn't know where the cost of the drugs or services is coming from. The only information they receive misrepresents the pharmacy because no other details are provided to tell the consumers who is responsible for ALL the costs.

Majority Leader Stenehjem

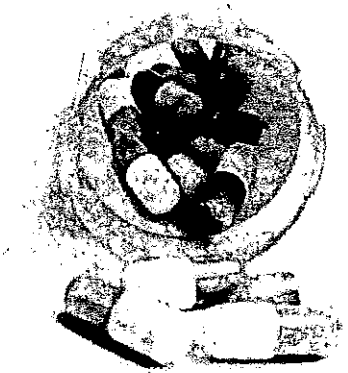
Assigns HB 1332 to Senate IBL

March 2005

Executive Summary

HB 1332 provides for the regulation of pharmacy benefit managers (PBMs). It requires PBMs to disclose the details of their (now secret) negotiations with drug manufacturers, and forward the savings to the consumer. Similar legislation, passed in South Dakota last year, saved the public employees group an initial $800,000 plus a projected savings of $1.5 million over the current biennium (from discounts and rebates that were previously retained by the PBM). You can lower the cost of prescription drugs for North Dakotans with HB 1332.

HB 1332 is the first sign of relief from skyrocketing healthcare costs, and you can provide this relief to your family, friends and neighbors by supporting this legislation.



What does HB 1332 do?

1. Requires full disclosure of all the rebates, discounts, and other revenue streams that come from negotiations with drug companies

2. Guarantees that employers (plan sponsors) who pay the premiums for their employees to have a drug benefit as part of their healthcare coverage, are able to lower their costs by receiving as much of the savings from rebates and discounts as they prefer

3. Limits the ability of PBMs to switch drugs, which often increases costs

4. Gives patients the freedom to choose their pharmacy provider

5. Provides PBM oversight and advocacy for employers by the ND Insurance Department.

What is a PBM and what is the problem?

PBMs are the middlemen in the claims process for prescription medications. They administer benefit programs for employers directly or through insurance companies. PBMs originally received an established fee to provide these services.

Today, PBMs continue to process claims but more importantly they negotiate rebates, discounts and other revenues with drug manufacturers who compete to have their products on the PBM's preferred drug lists (formularies). These formularies drive the market by influencing what drugs are prescribed and purchased.

Recent investigations (in 20 states) revealed that PBMs consistently keep these savings rather than pass them on to the plan sponsors.

Further evidence suggests PBMs switch drugs and receive payments to influence choice of drug products that pay a higher rebate, but often cost the patient and plan sponsor more.

Lower drug costs - HB 1332

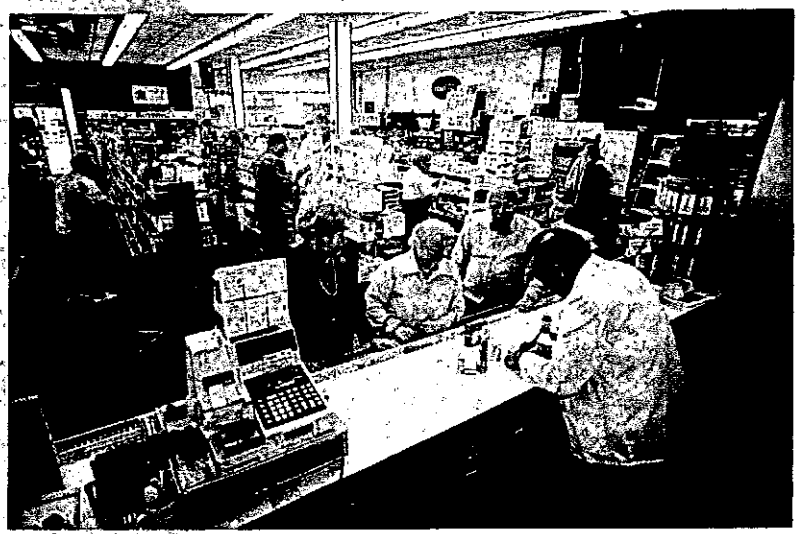
"It's corporate greed like this that's chipping away at the paychecks of hardworking Americans."

Gerald McEntee,
President, AFSCME

How much money is involved and how widespread is the problem?

It is billions of dollars, nationwide. For example:

Texas: State employees are demanding to know why their drug costs have increased 245% over the past four years under the administration of the PBM - Medco Health Solutions. Medco filed suit to keep all the rebate and discount information confidential.



California: Municipal, county and state employees filed suit against the country's four largest PBMs (who control 80% of the market) for inflating prescription drug prices. The PBMs are accused of reaping billions in profits by directing consumers to buy more expensive medications, while they pocketed the rebates and discounts.

Minnesota: AARP filed suit against Caremark for unfair trade practices and expects to receive about $18 for each prescription filled for AARP consumers over a 4-year period.

New York: Filed a suit against Express Scripts for engaging in a series of deceptive schemes - adding millions to the state's health plan. Attorney General Spitzer said, "They lined their pockets at the expense of health plans and consumers, driving up the very costs they were suppose to lower."

Twenty states filed a joint lawsuit against Medco and they received $29 million last spring. Nineteen states have a joint suit against Caremark.

At least seven other states have individual suits. These lawsuits are trying to retrieve funds lost to state employee plans and consumers and kept as profits by the PBMs.

HB 1332 is transparency

When PBMs operate in full transparency the employers of ND will know exactly what the savings will be for the drug benefit in their healthcare plan.

Medications improve the quality of life, but only if you can afford the purchase price! As costs rise, fewer people can buy the drugs they need, especially our elderly and children.

All state legislators are concerned with healthcare costs, and many are considering bills like HB 1332 to decrease cost. HB 1332 protects ND consumers by ensuring they receive the best price for prescription medications.

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SHINING THE LIGHT ON NON-TRANSPARENT PBM CASH FLOWS

By Robert I. Garis, Ph.D.; Bartholomew E. Clark, Ph.D.; and Mark V. Siracuse, Ph.D.

ILLUSTRATION: STEPHANIE CARTER

An overview to assist pharmacists in explaining PBM industry nuances to plan sponsors

The prescription drug benefit is one of the fastest growing segments of our health care bill. With that said, this is perhaps the ideal time to reflect on the pharmacy benefit management (PBM) industry. The PBM industry is made up of several business entities, performing many services that may or may not be in the best interest of the health care purchaser, which in many cases is the employer. Furthermore, it has been our experience as industry consultants and academics, that many employers are unaware of some of the practices of this complex industry.

This article will describe the PBM industry, and will also discuss two cash flows to the PBM: spread pricing and PBM-owned mail order pharmacy. Although PBM cash flows are largely understood by pharmacists, these cash flows may not be readily apparent to the non-insider, and employer groups may find this discussion informative. The goal here is to help pharmacists communicate with their local employer groups.

WHAT IS A PBM?

The PBM industry is the generic term referring to those entities that administer the sponsor's prescription card. Most self-insured plan sponsors in corporate America lack the in-house expertise to manage the pharmacy benefit. Other plan sponsors, such as managed care organizations, have substantial expertise and require only certain components, such as claims processing. Therefore, the PBM provides a valuable service by offering "one-stop shopping" for some clients, while providing only needed components for others.

PBM convenience can come at a high price, especially when the PBM takes cash flows not readily apparent to the employer. For convenience, we call those PBMs that take undisclosed cash flows "non-transparent," as opposed to a full-disclosure, or "transparent" PBM. The cash flows to non-transparent PBMs arise from subtleties in contract language and the basis of pricing drugs. To assist the practicing pharmacist in explaining PBM industry nuances to plan sponsors, we will provide a basic overview that will describe two broad PBM functions. These are:

- Pharmacy network formation and contracting
- The basis of pricing in the industry

Our experience indicates that understanding these basic elements of the PBM industry are well worth the effort required on the part of the employer.

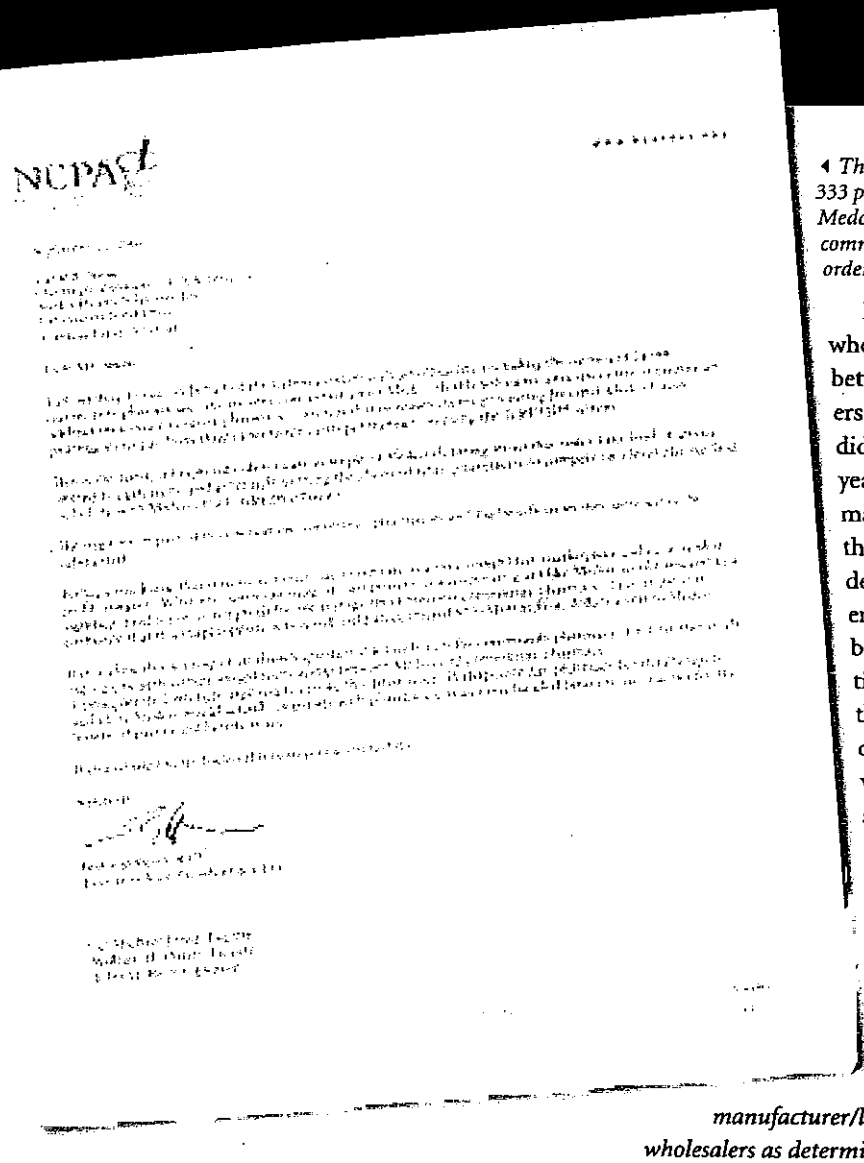
THE PHARMACY NETWORK AND THE BASIS OF PRICING IN THE PBM INDUSTRY

Almost all PBM companies have an extensive pharmacy network that generally allows for plan members to fill prescriptions conveniently. The PBM executes contracts with chain and independent community pharmacies to provide a network of pharmacies for the sponsor's employees.

The PBM is able to obtain network pharmacy participation at deep discounts when contracting because network participation gives the pharmacy potential access to more patients. The PBM offers contracts to the network pharmacies based on a discount off the average wholesale price (AWP minus a percentage [%]) reimbursement for drug products dispensed plus a professional fee. Table 1 (page 23) presents the two components of the pharmacy reimbursement. The pharmacy is reimbursed for the drug ingredient cost as a discount off AWP (for example, AWP minus 15%) and is paid a professional dispensing fee (usually between $1 and $3 per prescription) to compensate the pharmacy for the required resources to dispense the medication (such as pharmacist counseling, technician assistance, inventory management, and other operational resources within the pharmacy).

In performing the middleman function between employers and pharmacies, the PBM forms two contracts: one which specifies how much the PBM will pay the pharmacies for each prescription transaction, and another with the sponsor that specifies how much the sponsor will be charged for each prescription transaction. The sponsor is billed for ingredient cost as a discount off AWP (AWP minus %).

Because the PBM enters into separate contracts with network pharmacies and employer groups, the opportunity for differential pricing exists. This differential pricing has been call the "AWP spread" or simply the "spread." The spread refers to billing the employer a higher price for the drug ingredient than is paid to the network pharmacy. The spread can provide a significant cash flow to the PBM and can be highly variable across medications.


NCPA

This letter from NCPA to Medco, reacting to a 333 percent increase in the claims processing fee Medco charges, illustrates how PBMs disadvantage community pharmacy competitors to their mail order operations.

In actuality, AWP is neither average nor wholesale. Potential fluctuation of AWP between the amounts charged to employers and the amounts paid to pharmacies did not attract much attention in the early years of the PBM industry, because pharmacy spending was a small percentage of the total health care bill. Only in the last decade have pharmacy costs been a large enough part of the overall health care benefit to demand systematic investigation. The sponsor needs to be aware of the variability in AWP prices for each drug product. There is no externally validated standard for AWP prices. Instead, the AWP is the price reported by the manufacturer or other entity with the appropriate license. The AWP is defined as follows in Medi-Span's AWP publication, *Price Alert*:

"The average wholesale price (AWP) is either the published suggested wholesale price obtained from the manufacturer/labeler or the price commonly charged by wholesalers as determined by survey."

We will present the reader with two potentially significant cash flows to the non-transparent PBM. These cash flows are spread pricing, and PBM-owned mail order pharmacy services. Both of these cash flows rely on the AWP, which is the basis of drug ingredient payment in the PBM industry.

TWO CASH FLOWS IN THE PBM INDUSTRY

Spread Pricing

Differential terms of the contracts the PBM executes with pharmacies and employers present opportunities for spread pricing. This differential contracting is complicated because AWP is not a standard price, as many pharmacy benefit purchasers have been led to believe.

As previously described, the spread is the difference between the amount paid to the pharmacist for the drug ingredient and the amount that the plan sponsor is billed for the drug ingredient for the same prescription. See Table 2 (page 23) to augment the following explanation of the spread.

The contract the PBM negotiates with the employer is to provide the generic drug, Enalapril 20 mg #100, that has an AWP of $153 for the reimbursement of (AWP minus 40%), and for the same drug the PBM has a contract to reimburse the pharmacy at the maximum allowable cost (MAC) of $80. In our example, the sponsor's contract specifies the sponsor will pay the PBM (AWP minus 40%) for an ingredient cost of $91.80. Additionally, the PBM has a contract to pay the

Table 1: Two Components of Pharmacy Payment
For a Prescription Filled on a PBM Contract

Drug Ingredient Cost	+	Professional Fee	=	Total Pharmacy Payment
Discounted AWP Price ("AWP minus %") Reimbursement for the Drug Used to Fill the Prescription	+	Costs of Dispensing $2 Per Prescription Filled	=	Total Pharmacy Payment

pharmacy $80 for the same ingredient. These contract terms created a spread of $11.80 on this transaction. In our experience, the employer quite often believes its contract price, in this case $91.80, is the amount the pharmacist received for the ingredient cost of that prescription. It seems reasonable that the nature of the spread taken by the PBM be revealed to the employer by the pharmacist.

Community pharmacists, with generally good professional relationships with employers in their trade area, can serve a valuable educational role to employers on the business practices of the non-transparent PBMs. We believe that the collaboration of the pharmacist and the plan sponsor is key to raising awareness of PBM cash flows. The pharmacist may want to educate the sponsor about the prices of generics and the existence of MAC prices. The Centers for Medicare and Medicaid Services (CMS) MAC price is public and reasonably replicates the MAC price in most proprietary MAC lists. The sponsor may need the pharmacist's help to navigate the sponsor's transaction records. Our research group has found collaboration with plan sponsors to be a very enlightening experience as we attempt to educate the market on PBM business practices.

MAIL ORDER PHARMACY AFFILIATED WITH THE PBM

Because the AWP is not a standard price, an opportunity exists to manipulate AWP without the purchaser's knowledge. Drug pricing can be particularly deceptive in a mail order PBM pharmacy affiliated with a PBM. That is, if a pharmacy wants to buy a container of 10,000 tablets from a drug manufacturer and break up that container into bottles suitable for dispensing (for instance, 30 tablets per bottle), they may do so if they have a Food and Drug Administration (FDA) "Repacker" license. Repackaged products (the bottles of 30 tablets) will have a new national drug code (NDC) number and, as a consequence, the repacker may assign the drug product a new AWP.

What does this mean for the plan sponsor? One, it serves to underscore the reality that AWP is not a standard price and that any contract based on a fictitious price would necessarily leave a lot of room for interpretation. Two, if an affiliate of the PBM is a repacker, the sponsor could be charged a new (and potentially higher) AWP for certain drug products. An example of a repacker and a PBM being affiliated is demonstrated in a PBM that has an "in house" mail order pharmacy.

The PBM that owns a mail order pharmacy can easily obtain a repacker license from the FDA. With the repacker license, the mail order pharmacy can set a new AWP price for any drugs it repackages. From this perspective, it becomes clear how some PBMs can offer an "in-house" mail order option with apparently very large percentage discounts off AWP. The AWP value is artificially inflated before the discount is calculated.

Now, let us compare the prices for the same prescription filled at a retail pharmacy and the PBM's mail order pharmacy that has a repacker license. Table 3 (page 24) shows payment terms of "(AWP minus 13%) + $2.50" for retail pharmacy prescriptions and "(AWP minus 20%) + $1" for mail order prescriptions. Because of AWP manipulation, this comparison might not be as straightforward as it seems.

Table 2: The "Spread" in the Pharmacy Benefit

Amount Paid to Pharmacy	Amount Charged to Sponsor
Contract Terms of the Participating Pharmacy: MAC Reimbursement for the Generic Drug Enalapril 20 mg #100 MAC = $80	Contract Terms of the Sponsor: (AWP minus 40%) for the Generic Drug Enalapril 20 mg #100 AWP = $153
$80 Paid to the Pharmacy	($153 minus 40%) = $91.80 Charged to the Sponsor
"Spread" = $91.80 minus $80 = $11.80	
The PBM made $11.80 on this Prescription via the "Spread"	

Table 3: Retail Pharmacy Versus Mail Order Pharmacy With Repacker License

Retail Pharmacy	Mail Order Pharmacy Affiliated With the PBM (Pharmacy has Repacker License)
Sponsor's Prescription Terms for a Prescription at a Network Retail Pharmacy (AWP minus 13%) + Professional Fee of $2.50	Sponsor's Prescription Terms for a Prescription at the PBM Mail Order Pharmacy (AWP minus 20%) + Professional Fee of $1
AWP = $85/100 Tablets	AWP = $125/100 Tablets
($85 minus 13%) + $2.50 = $76.45 Total Price of the Prescription	($125 minus 20%) + $1 = $101 Total Price of the Prescription
Mail Order Prescription is $24.55 ($101 minus $76.45) higher	
Sponsor May Have a Lower Copay for Mail Order Prescriptions to Take Advantage of the "Seemingly Larger" Discount off AWP	

In our example, we see that the mail order pharmacy sets a higher AWP price on the drug product it repacked. In our example, the drug manufacturer AWP is $85/100 tablets, and the repacker-determined AWP is $125/100 tablets. The sponsor would pay $24.55 more for a prescription from the mail order facility, despite the apparently larger discount off the AWP price. Additionally, because the mail order option appears to be more economical for the sponsor, members are often motivated to use mail order service. The incentive for the member is typically a lower copayment if they use the mail order option.

Table 4 (page 25) presents a sample of audit results from a client with some members in a PBM-affiliated mail order service and some members in the PBM's community pharmacy network. We present the drug ingredient cost charged to the employer by the mail order facility and contrast that amount to the drug ingredient cost charged by a retail pharmacy for the same employer from the same PBM. It shows that the total price for the 22 drugs from the mail order facility was $1,491.12, and the retail pharmacy charge would have been $1,229.14. The difference in price mail and retail was $261.98, or $11.91 per prescription higher from the mail order pharmacy. It appeared from the sponsor's invoice that the sponsor was being charged AWP minus 50%, instead of a much lower MAC price that many PBMs use in a retail pharmacy network. We can compare AWP minus 50% pricing with MAC pricing in Table 4 for Atenolol 50 mg (difference = $26.60), Fluoxetine 20 mg (difference = $67.08), Synthroid 125 mcg (difference = $7.28), and Zocor 80 mg (difference = $15.78).

HOW CAN THE PHARMACIST AND EMPLOYER COLLABORATE?

The sponsor can do much to improve its pharmacy benefit purchasing efficiency by working with the community pharmacist and by keeping in mind our discussion of the spread and AWP manipulation in mail order pharmacy pricing. For instance, the pharmacist can provide an employer with CMS MAC prices, allowing the employer to check its generic drug pricing. Also, the employer might need the pharmacist's help in reading the transactions on its billing statement. With some orientation from the pharmacist, the employer could look at common drugs and quantities filled both in the PBM mail order plan and in the PBM community pharmacy network. The results of this investigation provide the type of information found in Table 4.

There are certainly Health Insurance Portability and Accountability Act (HIPAA) issues, about which the plan sponsor and the pharmacist are well aware. There is also proprietary information in the billing documents and both the pharmacist and the sponsor will have to keep such information confidential. There remains a great deal of information that can be shared between the pharmacist and the plan sponsor. This sharing between provider and payor can work to remove much of the misunderstanding that has for many years been associated with the pharmacy benefit.

CONCLUSION

A number of articles have commented on the PBM spread in recent years. Interest in spreads was heightened in the first quarter of 2003 with a front page story in the *Wall Street Journal* and litigation by a large public employee union, in part, over the spread taken by four well-known PBMs. Although these cash flows can accrue to some PBMs, there are others that do business on a full-disclosure arrangement with the plan sponsor.

The sponsor should be prepared for a greater upfront PBM administration fee in exchange for total disclosure of cash flows. These full-disclosure models avoid the "bargain basement" administration fees of 10 cents to 20 cents that

may be forcing some non-transparent PBMs to generate cash flows that are not readily apparent to the sponsor. The full-disclosure model PBM may not actively promote a mail order pharmacy facility, because with no manipulation of AWP and a fair MAC for both the pharmacist and sponsor, the PBM has no economic advantage. Without a clear financial advantage to the sponsor, there may no longer be a need to actively promote mail order pharmacy to the members.

Table 4: Ingredient Costs* Charged to the Plan Sponsor in a PBM-Owned Mail Order Pharmacy Compared With a Retail Pharmacy Price Within the Same Plan

Quantity	Drug	Strength	PBM-Owned Mail Order Pharmacy	Retail Pharmacy**
90	Alprazolam	1 mg	$44.28	$9.84
90	Atenolol	50 mg	$37.50	$7.90
90	Bisoprodolol/ HCTZ	5/6.25 mg	$51.20	$47.10
90	Clonazepam	1 mg	$38.55	$14.40
90	Doxepin	25 mg	$21.07	$9.59
10	Duragesic		$97.39	$102.89
16	Flonase	50 mcg	$53.81	$56.66
90	Fluoxetine	20 mg	$121.06	$53.98
180	Furosemide	40 mg	$15.84	$11.93
180	Gemfibrozil	600 mg	$111.88	$49.42
180	Generic Darvocet-N	100	$60.45	$63.05
15	Humalog		$97.39	$102.89
60	Levoxyl	100 mg	$20.00	$19.25
90	Prednisone	10 mg	$9.04	$8.20
180	Propranolol	40 mg	$63.20	$48.29
60	Synthroid	125 mcg	$32.53	$25.25
90	Toprol XL	100 mg	$84.23	$91.18
90	Trazodone	50 mg	$18.75	$7.49
360	Trim/HCTZ	37.5/25	$20.00	$17.83
100	Ultracet	37.5/325	$81.93	$88.29
90	Verapamil	240 mg	$72.93	$40.14
90	Zocor	80 mg	$338.09	$353.87
Totals			$1491.12	$1229.14

* All above prices are for drug ingredient cost only. There are no professional fees or PBM administrative fees included.

** The retail pharmacy prices were taken from the same employer for an identical prescription filled in the same date range

The perception of many plan sponsors is that "AWP minus discount" and a "low cost mail order option" are the two key components in evaluating the PBM proposal. Given the competition in the PBM industry and the potential for undisclosed cash flows, we believe that pharmacists and plan sponsors can use the information in this article to their advantage in selecting and monitoring their PBM. From our experience, the plan sponsor should take the time to investigate the cash flows to the PBM. The time invested in PBM selection can return significant cost savings on future pharmacy benefit costs. ■

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Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

Medicaid Recovery of Pharmacy Payments from Liable Third Parties

AUGUST 2001
OEI-03-00-00030

http://oig.hhs.gov/oei/reports/oei-03-00-00030.pdf

INTRODUCTION

PURPOSE

This report (1) quantifies the Medicaid dollars at risk of being lost when Medicaid pays pharmacy claims for beneficiaries who have other insurance, and (2) describes States' experiences with third-party payment of claims.

BACKGROUND

Medicaid Expenditures for Pharmacy Claims

Medicaid is a program, created under Title XIX of the Social Security Act, that pays for medical and health-related assistance for certain vulnerable and needy individuals and families. It is administered by States but financed with State and Federal funds. The Federal Government provides 50 to 83 percent of the funding depending on the State's per capita income.

The annual Federal-State Medicaid expenditure for pharmacy claims is in the billions of dollars. In 1997 it was $11.9 billion, and in 1999 it was $16.4 billion. In 1999, over 32 million beneficiaries were served under the pharmacy benefit.

Medicaid Beneficiaries with Other Insurance

Millions of Medicaid beneficiaries have other health insurance. Pharmacy coverage may be through private health insurance, employment-related health insurance, medical support from non-custodial parents, automobile insurance, State programs such as workers' compensation, or Federal programs such as Medicare. In accordance with Federal regulations, Medicaid beneficiaries "assign to the Medicaid agency their rights to medical support and to payment for medical care from any third party. [However,] the assignment of rights ... is effective only for services that are reimbursed by Medicaid (42CFR433.145)." In other words, if Medicaid paid for a service that is covered by another source of insurance, Medicaid has a legal right to payment from that source.

Most other insurance sources are considered primary payers in relation to Medicaid and may, therefore, be financially liable for claims. Medicaid is a payer of last resort with a few exceptions which are noted in the State Medicaid Manual, Section 3904.4A-B. Medicaid refers to other insurers as third parties and refers to claims for beneficiaries who have other insurance as third party claims. These and other technical terms are defined in Appendix A.

Cost Avoidance

The term cost avoidance is used to describe Medicaid's avoidance of paying claims when beneficiaries have other insurance. Under cost avoidance, if a State Medicaid agency receives a claim, the agency must deny the claim and return it to the provider. The provider can then bill the third party for payment. Medicaid agencies also avoid paying claims by preventing them from being billed to them in the first place. Instead, the agencies alert pharmacies about the existence of the liable third party through their computer systems at the time of purchase.

In order for Medicaid agencies to use cost avoidance effectively, they must take reasonable measures to determine the legal liability of third parties. At a minimum, the agencies must collect insurance information from prospective Medicaid beneficiaries during the initial eligibility interview and the redetermination process. State Medicaid agencies must also conduct data exchanges with Social Security Administration wage and earnings files; and the files of State agencies that keep information on wages, child support, welfare, motor vehicle accidents, and workers' compensation. Any of these files might indicate the existence of other health insurance.

Medicaid agencies are required to notify the Centers for Medicare and Medicaid Services (CMS) of the total amount they avoided paying for all services for beneficiaries who have other insurance. This notification is part of the State's quarterly report of expenditures for their Medicaid program. The notification does not, however, distinguish the amount avoided for pharmacy services from the total amount avoided for all services.

Waivers to Pay and Chase Pharmacy Claims

The CMS grants cost-avoidance waivers for various services including pharmacy. Medicaid agencies with a cost-avoidance waiver for pharmacy services may reimburse pharmacies that serve beneficiaries who have other insurance. After paying the pharmacy, the agency seeks payment recovery from the third party. This process is known as pay and chase. Federal waivers from cost avoidance are granted if the State Medicaid agency can demonstrate that paying and chasing is cost effective.

There are circumstances under which Medicaid agencies pay and chase even when they do not have a waiver. Federal law requires States to pay and chase claims when (1) coverage is through a parent whose obligation to pay support is enforced by the State's child support enforcement agency, (2) the service is prenatal care for pregnant women, and (3) the service is preventive pediatric care. In addition, if a State learns of the existence of third-party insurance after the claim has been paid, the State will chase for payment recovery.

When States submit their quarterly report of Medicaid expenditures to CMS, they include the total amount they recovered from pay and chase activity. The States are not required to notify CMS of the total amount they attempted to recover. Nor are the States required to report the amounts recovered on pharmacy services alone.

Pharmacy Benefit Management Companies

Payers of insurance benefits either process claims in-house or contract the processing to another entity. In the case of pharmacy benefits, many payers have contracts with pharmacy benefit management companies (PBMs). These companies provide numerous client-tailored services for health plans. The PBMs may be responsible for the entire management of the health plan's pharmacy benefit, or they may provide one or more of the following services: process pharmacy claims, provide mail-order prescription services, maintain pharmacy networks, conduct drug utilization reviews, and develop drug formularies. Organizations that contract with these companies include, but are not limited to, insurers, employers, and managed care organizations.

It has been estimated that PBMs handle 70 percent of all prescription orders dispensed for ambulatory care, and that 10 PBMs account for the bulk of covered individuals. What this means for Medicaid is that many payments made on pharmacy claims have to be recovered from PBMs. For the purposes of this report we include PBMs in the term third party.

Problems Recovering Pharmacy Payments from Third Parties

In 1996, the Pharmacy Claims Reimbursement Team, made up of CMS and State Medicaid agency representatives, collaborated on a study called "Medicaid Encounters Barriers to Recovering Payment for Pharmacy Claims from Third Parties." The study found that "58 percent of the States recover less than 40 percent of the money they pursue..." and that a small number of PBMs and TRICARE (health plan for military personnel) stood out as creating the greatest obstacles for payment recovery. One PBM in particular was far and above the most uncooperative entity among third parties. The PBMs were not processing Medicaid claims and were not willing to identify the insurers and employers with whom they contract.

Efforts to Overcome Payment-Recovery Barriers

The Pharmacy Claims Reimbursement Team has been steadily gathering facts and working toward overcoming payment-recovery barriers. One effort of the team has been to identify third parties that contract with the PBM named in their 1996 study as the most uncooperative. Another major step was building a partnership between CMS and States so that information could be shared. A network of State pharmacy representatives was developed and information can now be disseminated to all States.

The team has also been laboring to understand claim formatting problems which prevent the recovery of some pharmacy payments. To this end they have worked with a major PBM, the National Council for Prescription Drug Programs, and with Medicaid claims-processing contractors to find solutions. They are currently trying to help all States move to a commonly-used electronic format for their pharmacy claims.

avoidance as the most successful way to circumvent problems associated with paying and chasing. One State called it a "silver bullet."

States that do not use cost avoidance have concerns about it burdening pharmacies and beneficiaries

Nineteen States that pay and chase a majority or all of their pharmacy claims believe cost avoidance places a financial burden on pharmacies. For example, States reported that some pharmacies have billing systems which prohibit them from billing two payers at the same time (i.e., billing the third party for the claim and Medicaid for the copayment). States also said (1) some third parties pay the policyholder and not the pharmacy; and (2) if coverage information is not accurate the claim could be denied by both Medicaid and the third party, which leaves the pharmacy without reimbursement.

Eight States that pay and chase all of their pharmacy claims also said cost avoidance can negatively impact beneficiary access. They are concerned that pharmacies that are unable to bill two payers at the same time may refuse to serve Medicaid beneficiaries who have third-party insurance. Other State concerns are for beneficiaries in nursing homes who cannot use the third party's network pharmacy as required by the health plan, and for beneficiaries who cannot afford the copayment required by mail order programs that many health plans use.

Despite these concerns, when we collected our data 12 States reported they were switching to cost avoidance, or were considering switching in the future because of all the problems associated with paying and chasing.

Almost three-quarters of States report that third parties refuse to process or pay Medicaid claims

Thirty-six States said that when they try to recover payments, they are faced with the following problems: denials due to incompatible claim formats, unreasonable filing time limits, unprocessed claims with no explanation, vague claim denials, and the inability to identify the liable payer or claims processing entity.

Incompatible claim formats often lead to the denial of Medicaid claims

Twenty-nine States indicated that the lack of universal formatting and data elements on pharmacy claims leads to the denial of Medicaid claims. States said they usually do not have various pieces of information that are required by some third parties. For example, they may not have diagnosis codes, patient's signature, patient's relationship to the policyholder, or physician's Drug Enforcement Agency number. Third parties have different requirements which makes it even harder for States to submit "correctly" formatted claims. Data that we collected from insurers and employers indicates that Medicaid claims do not include all the information required by third parties.

States reported that when their claims are denied for missing data they add the missing data if they have it and resubmit the claim. However, the constant reworking and resubmission of claims puts an added administrative and financial burden on States. We were told one PBM does not point out all the data elements missing from a claim the first time they deny it. After each resubmission the PBM may point out another missing data element from the same claim. States said this same PBM will also deny claims if the data elements are in the wrong sequence. Another State said PBMs were reimbursing their claims at a lower rate as a penalty for being in the wrong format.

Unreasonable filing time limits make it difficult for States to recover payments

Sixteen States said unreasonable filing time limits are a problem because if they submit claims past the third party's filing time limit the claims are automatically denied. States reported that common time limits are 30 to 90 days and the shortest was 7 days. States said they have a hard time meeting time limits when they pay and chase because their pharmacies may have 1 year or longer to submit claims. Therefore, by the time the State receives the pharmacy's claim, pays it, and tries to recover payment from the third party, the third party's filing time limit may have passed.

Unprocessed claims and vague denials keep Medicaid from recovering payments

Twelve States said their claims were not processed or were returned with vague denial codes from third parties. Some States reported getting back claims with no explanation as to why they were not processed. Other unprocessed claims are never returned and there is also no explanation. States also said that some third parties will only process claims that are submitted by a provider or a policyholder. While some States speculate that third parties may not understand Medicaid's pay and chase activity, or that Medicaid is the payer of last resort, 93 percent of the employers and insurers that provided us with data said they know that Medicaid is the payer of last resort.

States reported that when a claim denial code is vague or represents several possible reasons for the denial, the State cannot determine what information needs to be corrected in order to resubmit the claims. This has the effect of terminating the State's attempt to recover payments. One of these States reported receiving a batch of 21,000 claims from a PBM with such a denial code.

Inability to identify liable payers and claims processing entities makes recovery of payments almost impossible

Twelve States said that if liable payers and their claims processors are not identified correctly, States risk sending claims to the wrong entity and not recovering payments. Despite efforts to identify beneficiaries' other insurance, States said that information in their third-party files can be incomplete or erroneous. This is because the State may not receive complete and accurate information about the beneficiary's other coverage; the State may not be notified of coverage changes; or the beneficiary may have more than

one other insurer and the State may not know which one is primary and which is secondary.

States also have difficulty identifying the liable payer's claims processing entity. This is often due to insurers changing claims processors without notifying the State. In addition, States are sometimes given the name of an entity without the address. This is a problem because some entities have similar names and some have multiple billing addresses. Identifying the correct claims processor can be a problem for payers as well. One employer reported having multiple medical plan carriers. This employer said Medicaid claims do not identify the carrier and therefore the employer does not know which carrier is responsible for the claims.

More States had problems with pharmacy benefit management companies than with all other types of third parties combined

Thirty-two States experienced problems with pharmacy benefit management companies. As shown in Table 2 below, more States had problems with these companies than with all other types of third parties combined. In addition to having all the same problems with PBMs that they have with other third parties, 14 States said some PBMs will not process Medicaid claims because the PBMs' clients have not authorized them to do so. Furthermore, States reported that these companies have not been willing to identify the names and addresses of the liable payers. This is a serious problem for Medicaid given the volume of pharmacy claims processed by pharmacy benefit management companies. When PBMs do not process Medicaid claims and will not identify the liable payer, States cannot recover their payments.

Table 2. COMPARISON OF "PROBLEM" THIRD PARTIES

Type of Third Party	Number of States that Experienced Problems
PBM	32
Insurer/Carrier	13
TRICARE Standard*	6
Self-insured plan	4
Point-of-sale plan	1
Medicare	1

*The fee-for-service health care program for active duty and retired members of the uniformed services, their families, and survivors (formerly called CHAMPUS).

Source: State Medicaid agency data provided to OIG

The data we collected from insurers and employers indicates that 15 percent of those who contract with a pharmacy benefit management company had not given them authorization to process Medicaid claims. We have also learned that a list provided to CMS of over 600 organizations that contract with one of the largest PBMs indicated that 75 percent of these organizations do not authorize the PBM to process Medicaid claims.

Twenty-six States mentioned one particular pharmacy benefit management company as a problem. Two States said the company has not paid them for years. One of these States said they stopped sending claims to this pharmacy benefit management company because "they just ignored them." Another State said they had "talked with [the PBM's] attorneys and gotten a complete run around." The same State reported losing "tens of millions" of dollars because of this company. This company had also been identified as the biggest problem for States in the 1996 study by CMS and State Medicaid agencies.

While States have difficulty recovering payments, methods such as sharing information with third parties, using effective billing practices, and taking legal action have been successful for some States

While 33 States reported that less than half their efforts to recover payments from third parties were successful, some States mentioned recovery methods that have been successful. These methods include sharing information with third parties, using effective billing practices, and taking legal action.

Sharing information with third parties

Working with third parties can be a successful method for recovering payments according to 31 States. Some States said communication with third parties helps them keep beneficiary coverage information complete and accurate. This is done through a verification process or the matching of eligibility files. Under the verification process, States phone or write to the carrier to verify coverage information. The matching of eligibility files, on the other hand, can be done via tape sharing, database sharing, or on-line matching. Thirty-eight States said they match files with some insurers, 13 match with some self-insured plans, and 11 match with certain PBMs. Of the 88 insurers and employers that sent us data, 56 said they did not match their eligibility files with Medicaid files. Of those 56 respondents, 70 percent said they did not match files because Medicaid had not asked them to do so.

Information sharing with third parties has advantages beyond updating beneficiary coverage. For example, one State said an insurance carrier notifies them when they change PBMs so that the State can submit claims to the right PBM. Another State said a PBM provided a list of group insurance plans which the States could bill directly. Open communication also makes follow-up regarding claim issues easier for States.

APPENDIX A

Technical Terms Used in This Report

Below is an alphabetical list of some of the technical terms used in this report.

Cost avoidance: Method for processing claims for Medicaid beneficiaries who have other insurance. When Medicaid receives a claim from a provider, the claim is denied and the provider is informed that the beneficiary has another insurer who is financially liable for the claim. Cost avoidance also occurs when the provider knows of the Medicaid beneficiary's other insurer and sends the claims directly to that other entity and not to Medicaid.

Cost-avoidance waiver: When a Medicaid agency has been granted a cost-avoidance waiver it means that the requirement to use cost avoidance is waived, and the agency may pay for the claims and recover the payments from the liable insurers. Waivers are granted if the State can show that another method of processing claims is as, or more, cost-effective than cost avoidance.

Pay and chase: A method for processing claims wherein Medicaid pays the claims for a beneficiary who has other insurance and then, later, tries to recover the payments from the liable party.

Pharmacy benefit management company (PBM): Companies that manage prescription drug coverage for insurance carriers, self-insured employers, managed care organizations, and other entities. Services provided by PBMs include claims processing, pharmacy network development, drug utilization review, and formulary development.

Point-of-sale plan: An insurance plan which has a special electronic claims processing arrangement with pharmacies. The arrangement allows pharmacists to determine on-line, while a customer is waiting, whether the customer's insurance plan will pay for the prescription.

Self-insured plan: Many employer insurance plans are self-insured, i.e., the employer bears a portion of the risk for employees' medical claims. While health insurance plans are usually regulated by State Governments, self-insured plans are regulated by the U.S. Department of Labor under the Employee Retirement Income Security Act.

Third party: Any individual, entity, or program that is, or may be, liable to pay all or part of the medical cost for any medical benefit provided to a beneficiary. Third parties include private insurance plans or carriers, employer insurance plans, State insurance plans such as workers' compensation programs, and Federal insurance programs such as Medicare. In this report the term third party also refers to PBMs.

Third-party liability: A third party's financial responsibility for medical services provided to a Medicaid beneficiary.

APPENDIX B

1999 Medicaid Pharmacy Data for 50 States

States that pay and chase send claims to third parties they believe are responsible for the claims. However, due to Medicaid beneficiaries' changing coverage, or health plans not covering certain services, third parties may deny some of the claims. Therefore, the amount paid and chased for third-party pharmacy claims in the table below includes claims that could be denied for valid reasons.

State	Total Pharmacy Expenditures	Amount Paid and Chased for Third-party Pharmacy Claims	
AK	$45,881,080.83	$5,183,492.88	$817,471.04
AL	$314,946,162.00[d]	$5,018,902.00[cd]	$1,742,770.00[cd]
AR	$202,913,489.62[d]	$811,127.00[d]	$60,411.00[d]
AZ	$1,812,951.68	unavailable	$141.72
CA	$1,825,318,419.00	unavailable	unavailable
CO	$125,412,087.00	unavailable	unavailable
CT	$220,673,450.00[c]	unavailable	unavailable
DC	$43,419,240.00[c]	unavailable	unavailable
DE	$56,065,026.00	unavailable	$840,089.46
FL	$1,164,493,522.00	$28,452,000.00[b]	$3,625,500.00[b]
GA	$439,419,153.00[c]	$21,091,378.38[bc]	$2,277,868.87[bc]
HI	$52,477,014.00	$1,208.00	$1,208.00
IA	$179,987,630.03	$3,221,655.16	$1,929,713.16
ID	$72,370,224.00	unavailable	unavailable
IL	$718,299,628.00[d]	$70,512,870.00[d]	$9,336,728.00[d]
IN	$407,752,363.00	$27,170,728.00	$2,608,454.00
KS	$152,053,655.00	$2,937,187.00	$885,738.00
KY	$384,078,336.00[d]	$23,899,069.00[d]	$2,143,461.00[d]
LA	$430,423,799.00	$33,615,322.00	$2,278,064.00
MA	$600,192,000.00[c]	$13,272,730.00[ce]	$1,821,495.00[c]
MD	$180,000,000.00[b]	unavailable	unavailable
ME	$136,637,381.57[c]	$5,090,000.00[c]	$2,100,000.00[bc]
MI	$353,574,000.00	unavailable	unavailable
MN	$215,926,180.34	$4,940,572.17	$2,258,155.66
MO	$468,598,424.00[c]	$9,469,752.00[c]	$1,152,785.00[c]
MS	$294,754,745.46	$4,604,196.00	$1,594,088.00
MT	$45,500,000.00[c]	unavailable	$1,400,000.00[bc]
NC	unavailable	$28,902,407.19	$9,168,690.33

APPENDIX B

State	Total Pharmacy Expenditures	Amount Paid and Chased for Third-party Pharmacy Claims	Amount Recovered from Third Parties
ND	$33,931,400.00	unavailable	unavailable
NE	$126,866,802.45	$9,556,047.28	$3,869,239.38
NH	$73,332,966.00[d]	$4,713,111.00[d]	$2,827,866.00[bd]
NJ	$499,216,374.00[cc]	unavailable	unavailable
NM	$41,233,834.16	unavailable	unavailable
NV	$41,447,640.91	unavailable	unavailable
NY	$2,026,870,651.00[c]	$13,680,000.00[b]	$1,280,000.00[b]
OH	$831,871,859.89[c]	$3,109,904.11[d]	$59,699.71[d]
OK	$175,195,447.00[c]	unavailable	unavailable
OR	$119,205,296.00	$8,176,048.00	$4,206,869.00
PA	$662,431,412.00[c]	$9,393,597.00	$59,700.00
RI	$79,285,625.88	$221,595.24	$143,580.29
SC	$310,394,000.00	$12,262,009.50	$4,572,710.30
SD	$39,934,762.30[d]	unavailable	$421,062.00
TX	$900,000,000.00[b]	$45,000,000.00[b]	$2,800,000.00[b]
UT	$89,374,417.00[c]	unavailable	$2,802,415.26[bcc]
VA	$323,272,462.00[b]	$11,905,623.00[b]	$1,575,372.00[b]
VT	$75,241,758.00	$1,586,916.39[b]	$645,293.31[b]
WA	$339,500,000.00[d]	unavailable	unavailable
WI	$298,783,778.00	$23,721,457.00	$4,815,255.00
WV	$196,538,451.09[d]	$8,236,095.00[d]	$387,116.00[d]
WY	$24,298,621.59[b]	$400,000.00[b]	$128,563.73[b]
50[a]	**$16,441,207,520.80**	**$440,157,000.30**	**$78,637,574.22**

a. We collected data from 49 States and the District of Columbia. Data was not collected from Tennessee because their entire Medicaid population is in managed care.
b. Figure given is an estimate.
c. Figure given is for the fiscal year.
d. Figure given includes data for more than outpatient prescription drugs (e.g., inpatient pharmacy, over-the-counter drugs, syringes).
e. Figure given includes $8,652,082 that Massachusetts deemed "unrecoverable."

Source: State Medicaid agency data provided to OIG

APPENDIX C

Medicaid Pharmacy Dollars at Risk for 32 States

The table below shows the percentage of Medicaid dollars at risk in States that were able to provide the dollar amounts they paid and chased as well as the dollar amounts they recovered in 1999. The table lists States in descending order by total pharmacy expenditures.

States that pay and chase send claims to third parties they believe are responsible for the claims. However, due to Medicaid beneficiaries' changing coverage, or health plans not covering certain services, third parties may deny some of the claims. Therefore, the amount paid and chased for third-party pharmacy claims in the table below includes claims that could be denied for valid reasons.

State	Total Pharmacy Expenditures	Amount Paid and Chased for Third-party Pharmacy Claims	Amount Recovered from Third Parties	Percent of Dollars at Risk
NY	$2,026,870,651.00[b]	$13,680,000.00[a]	$1,280,000.00[a]	91%
FL	$1,164,493,522.00	$28,452,000.00[a]	$3,625,500.00[a]	87%
TX	$900,000,000.00[a]	$45,000,000.00[a]	$2,800,000.00[a]	94%
OH	$831,871,859.89[c]	$3,109,904.11[c]	$59,699.71[c]	98%
IL	$718,299,628.00[c]	$70,512,870.00[c]	$9,336,728.00[c]	87%
PA	$662,431,412.00[b]	$9,393,597.00	$59,700.00	99%
MA	$600,192,000.00[b]	$13,272,730.00[bd]	$1,821,495.00[b]	86%
MO	$468,598,424.00[b]	$9,469,752.00[b]	$1,152,785.00[b]	88%
GA	$439,419,153.00[b]	$21,091,378.38[ab]	$2,277,868.87[ab]	89%
LA	$430,423,799.00	$33,615,322.00	$2,278,064.00	93%
IN	$407,752,363.00	$27,170,728.00	$2,608,454.00	90%
KY	$384,078,336.00[c]	$23,899,069.00[c]	$2,143,461.00[c]	91%
VA	$323,272,462.00[a]	$11,905,623.00[a]	$1,575,372.00[a]	87%
AL	$314,946,162.00[c]	$5,018,902.00[bc]	$1,742,770.00[bc]	65%
SC	$310,394,000.00	$12,262,009.50	$4,572,710.30	63%
WI	$298,783,778.00	$23,721,457.00	$4,815,255.00	80%
MS	$294,754,745.46	$4,604,196.00	$1,594,088.00	65%
MN	$215,926,180.34	$4,940,572.17	$2,258,155.66	54%
AR	$202,913,489.62[c]	$811,127.00[c]	$60,411.00[c]	93%
WV	$196,538,451.09[c]	$8,236,095.00[c]	$387,116.00[c]	95%
IA	$179,987,630.03	$3,221,655.16	$1,929,713.16	40%
KS	$152,053,655.00	$2,937,187.00	$885,738.00	70%
ME	$136,637,381.57[b]	$5,090,000.00[b]	$2,100,000.00[ab]	59%
NE	$126.866.802.45	$9.556.047.28	$3.869.239.38	60%

PRICEWATERHOUSECOOPERS

****CONFIDENTIAL****

The Value of Pharmacy Benefit Management
And the National Cost Impact of Proposed PBM Legislation

Prepared for

Pharmaceutical Care Management Association

June 15, 2004

PRICEWATERHOUSECOOPERS

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PRICEWATERHOUSECOOPERS

I. Introduction and Summary

The Pharmaceutical Care Management Association (PCMA) retained PricewaterhouseCoopers (PwC) to estimate the value of pharmacy benefit management as well as the potential impact, including higher health insurance premiums and loss of health insurance coverage, from enactment of proposed legislation that would restrict pharmacy benefit management (PBM) activities for consumers, private employers, health plans, unions, and state and federal governments.

- PricewaterhouseCoopers estimates that, on average, pharmacy benefit management reduces prescription drug costs by 25 percent compared to retail purchases with no pharmacy benefit management support.
- Pharmacy benefit management activities in 2005 will reduce costs by $147 per enrollee in private plans, or about $53 billion in total.
- PwC estimates that total savings from pharmacy management over the next 10 years, 2005-2014, will amount to about $1.3 trillion.

The practices of pharmacy benefit managers are the subject of numerous legislative proposals under consideration in the various state legislatures. Each of these restrictions on PBM operations has the potential of reducing the savings from pharmacy benefit management. PricewaterhouseCoopers estimated the national impact of five legislative proposals that are representative of the bills under consideration in various states. As shown in Table 1, each of these illustrative legislative options, if enacted at the national level, would increase private drug costs managed by PBMs by a wide range, from as little as 3.0 percent to as much as 10.2 percent. These increases translate into a range of $97 to $328 billion over the 2005 to 2014 period. Higher drug costs would increase insurance premiums. Higher premiums, in turn, cause a reduction in the number of employers and consumers purchasing health insurance because of the added costs. As a result of each of these legislative proposals, the number of uninsured individuals would increase by between 100,700 and 321,000 in 2005 alone.

Table 1. National Impact of Legislative Proposals on PBM-Managed Drug Costs And Number of Uninsured

Legislative Proposal	Change in Managed Drug Spending (2005-2014)		Change in Uninsured Population, in thousands 2005
	Billions of Dollars	Percent Change	
Option 1: Limit Therapeutic Interchange	$167	5.2%	172.8
Option 2: Limit Drug Management Techniques	$158	4.9%	158.6
Assuming Therapeutic Interchange included	$309	9.6%	321.0
Option 3: Limit Mail-Service Incentives	$97	3.0%	100.7
Option 4: Require PBM Disclosure	$225	7.0%	204.8
Option 5: Require Fiduciary Responsibility	$99	3.1%	103.0
Assuming Disclosure required	$328	10.2%	313.7

Source: PricewaterhouseCoopers calculations.

II. Background

Beginning in the mid-1980s, spending on prescription drugs began increasing faster than spending on healthcare overall. Even though prescription drug therapy may have substituted in some cases for other, more expense medical treatments, the sheer increase in this cost category prompted employers and health plans to seek solutions on how to better manage their drug benefits. Employee benefit managers, who are responsible for ensuring that their members or employees have access to affordable healthcare coverage, began to shift administration of their pharmaceutical benefits to companies that have the expertise to handle this complex area.

These companies have evolved and today are known as pharmacy benefit managers or PBMs. Beginning around 1990, these PBMs provided real-time electronic claims adjudication. Many also provided and managed networks of pharmacies willing to accept negotiated discounts on drug prices and dispensing fees. PBMs' services have expanded to include clinical services, such as preventing dangerous drug interactions through drug utilization review. Mail-service pharmacy also has become a prominent part of PBMs' techniques for cost reduction. In addition, other organizations—such as health plans or employers—have moved to adopt PBM-like techniques to control spending. For the purposes of this report, we include the impact of all organizations involved in managing pharmacy care through these techniques.

A. The Role of PBMs

PricewaterhouseCoopers estimates that 200 million people, or about 68 percent of the U.S. population, are in private plans with pharmacy benefit management. Some public programs, such as Medicaid, also contract with PBMs to manage the prescription drug benefit. Government health programs, which have the power to set prices, do not usually use many of the key pharmacy benefit management services as described below. For that reason, this study omitted public insurance programs from all of the analyses reported below.[1]

The percentage of seniors in PBMs is much lower than the non-elderly population. Only about 50 percent of the elderly population are estimated to be in plans in which the pharmacy benefit is managed, while about 74 percent of the non-elderly are in PBM-managed plans. On average, approximately 68 percent of all prescription drug spending is done through privately managed plans. In our calculations, we estimate that the share of elderly individuals with managed private pharmacy benefits will increase as a result of the Medicare Prescription Drug Coverage, Improvement, and Modernization Act of 2003 (MMA). The Act calls for prescription drug coverage to be provided and/or administered through PBMs and managed care organizations. Because most Medicare beneficiaries will have private health insurance plans, the number of people in plans managed by PBMs or similar organizations, is expected to jump to 217 million, or about 76 percent of the U.S. population.

Competing PBMs contract with union-sponsored plans, small and large businesses, health plans, state and federal-employee benefit plans, and state Medicaid plans. PBMs may be independent entities, subsidiaries of health plans, or operated by large retail chain drug stores. Since 2000, the PBM industry is estimated to have grown 30 percent as measured by membership.[2]

PBMs provide purchasers a variety of tools and techniques that promote quality, improve outcomes, and help drive down the cost of prescription drugs. PBMs typically offer clients a set of core services designed to contain and improve the value of drug expenditures. PBMs also provide clients with clinically based services designed to improve the appropriateness, safety, and quality of pharmacy benefits. Taken together, these tools can help improve the cost-effectiveness of the drug benefit and include such activities as:

- Electronic claims processing;
- Formulary development and management;
- Networks of pharmacies;
- Generic substitution;
- Rebates and discounts;
- Therapeutic interchange;

- Mail-service pharmacy option;
- Drug utilization review (DUR);
- Disease management;
- Consumer information; and
- Consumer compliance programs.

PBMs use different approaches to optimize their ability to deliver on those practices. For example, one such approach is cost sharing with the patient. Optimally, cost sharing, in the form of copays or coinsurance, is used to encourage the use of certain "preferred" drugs. Low levels of cost sharing may encourage overutilization while higher levels of cost sharing may discourage patients from filling necessary prescriptions. Organizations that contract with PBMs strive to establish cost-sharing structures that are "just right," accomplishing their specific cost, quality and efficiency goals regarding prescription drug benefits. Other approaches offered to health plan sponsors by PBMs help promote cost-effective drug therapies. For example, a recent report from the U.S. Department of Health and Human Services cited methods such as generic incentive programs, prior authorization and drug utilization review as moderating drug spending starting in the late 1990s.[3]

Generally, the higher the level of management in the pharmacy benefit, the higher the savings. For example, health plans that limit coverage to drug on a "closed" formulary would be expected to produce more savings than health plans that allow patients to have access to all prescriptions drugs. However, "tighter" management may encroach on some patients' choices, and some plan-sponsor PBM clients choose arrangements, such as "tiered" copayments, that allow patients to have access to a wider range of prescription drugs, with a corresponding higher costs for the plan sponsor and/or consumers. Just as managed care networks have moved to less restrictive networks and more consumer choice, so are many pharmacy benefit plans offering clients a broader choice of a variety of drug benefit options as well.

PBMs take on the complex tasks of evaluating thousands of competing drugs – both in terms of cost and efficacy. The sheer complexity of this role requires an intermediary that can focus on the thousands of drugs available. Spending on pharmaceuticals is determined by more than price of individual drugs. The volume and selection of drugs also bear considerable weight in how much is spent on drugs. Selecting the right drug for the right diagnosis is the essence of efficient healthcare spending. While physicians prescribe drugs, they are not in a position to negotiate prices or calculate the price differentials between competing drug therapies.

B. Purpose and Outline for This Report

While drug spending has been tempered in part by PBMs, health plans and employers continue to refine and seek innovation regarding how drug spending is managed to ensure appropriate use of the health benefit dollar.

This report provides an objective analysis of the savings achieved by PBMs and organizations that provide PBM functions. These savings could be at risk, depending on the outcome of various legislative proposals. Knowing the savings achieved through various pharmacy benefit methods, policymakers can make better decisions about the outcomes of such legislative proposals.

Some of these legislative proposals would intervene in benefit design issues, the scope of which private and public purchasers determine for PBMs. Dictating certain benefit design through legislation could limit an employer's ability to offer health insurance if it makes the benefit more expensive. As health insurance premiums have increased in recent years for a variety of reasons, more employers are opting not to offer insurance, or to raise the employees' contribution to health insurance premiums. Both cases contribute to rising levels of uninsured.

The following section of the report will provide estimates of the savings currently provided through pharmacy benefit management activities like those carried out by PBMs. Next, we will present our estimates of five illustrative legislative proposals to limit pharmacy benefit management.

III. Savings from Pharmacy Benefit Management

PBMs, as discussed in the previous section, reduce the cost of prescription drugs through a variety of techniques including formularies, disease management, retail pharmacy networks, manufacturer rebates, and management of prescription drug utilization. This section presents PricewaterhouseCoopers' estimates of the magnitude of these savings relative to spending on prescription drugs and in terms of total dollar savings to U.S. consumers and third-party payers.

A. Estimated Percent Savings From Pharmacy Benefit Management

The total savings from pharmacy benefit management varies across health plans and depends on the level of PBM services elected by clients. Some clients contract with PBMs only for administrative services, such as claims and benefit administration. Others adopt a whole range of PBM services, such as formulary, clinical control and disease management. The level of

PBM services utilized depends on the client, which may be an employer, health plan, union, or state or federal government.[4]

Health plans that agree to the narrowest retail networks, tighter formularies, and most aggressive management techniques are able to reduce prescription drug costs by 40 percent or more. Alternatively, plans that have broad networks, completely open formularies, and little management intervention probably save only 15 percent or less, compared to retail purchases with no management. (see Table 2 below).[5]

Table 2. Savings Generated by PBMs
(Relative to Unmanaged Sales at Average Retail Prices)

	Level of Management		
	Low	**Medium**	**High**
Total Reduction in Costs	**15%**	**25%**	**40%**

Source: PricewaterhouseCoopers.

PBMs rely upon a variety of tools and techniques to help lower the cost of prescription drugs for consumers and health care purchasers:

- **Network discounts and dispensing fees.** Network discounts are negotiated by PBMs and are taken at the time the prescription drug is dispensed. Pharmacies may be willing to give discounts in exchange for the increased business that PBMs can bring. Health plans that restrict their enrollees to a relatively small network usually receive the greatest discounts. Offsetting the network discount, PBMs pay retail pharmacies a dispensing fee as part of their retail pharmacy network contracts. The dispensing fees for prescriptions dispensed through mail-service pharmacies are often much lower. Costs are lower in highly managed drug benefit plans, in which clients may choose options such as mandatory mail-service pharmacy for maintenance drugs related to managing chronic conditions. In part because mail-service pharmacies are automated, the cost of dispensing prescriptions is much lower.
- **Formularies**. Among the most important tools developed by PBMs to manage prescription drug benefits are formularies. A formulary is a list of prescription drugs approved for reimbursement by the plan sponsor contracting with a PBM. In developing a formulary, the primary considerations are safety, efficacy and clinical appropriateness.

PBMs use panels of experts, called Pharmacy and Therapeutics (P&T) committees, to develop their formularies. P&T Committees are comprised of physicians, pharmacists, and individuals with other appropriate clinical expertise. Often, individuals with special expertise are consulted when considering medications within particular therapeutic classes. Development and maintenance of formularies is an ongoing activity, as they must be continually updated to keep pace with new therapies, recent evidence from clinical research, changes in medical practice, and FDA guidance.

Once a drug is evaluated and classified by the P&T committee, it can be further classified as preferred, non-preferred or generic. Such classification is known as tiering. Tiered formularies are developed based on the needs of the plan sponsor and what co-pay structure and cost sharing they wish to include in their prescription drug benefit. Often, generic drugs are assigned the lowest co-payment, followed by preferred, and finally non-preferred drugs.

- **Therapeutic interchange programs.** PBMs use formularies reviewed by their P&T committees that identify drug pairs that are therapeutically equivalent. PBMs contact the prescribing physician when a non-preferred formulary drug has been written and suggest that the physician authorize the interchange of the original drug to the preferred drug. Therapeutic interchange always requires the approval of the prescribing physician and a new prescription from the physician.
- **Utilization management** – PBMs also rely upon a variety of other tools to help lower the cost of prescription drugs, including generic substitution, prior authorization for classes of drugs that are often prescribed in a manner inconsistent with accepted best medical practice and other specific classes of drugs, drug utilization review, disease management and patient education. Clients seeking greater savings will seek higher levels of intervention by their PBM. Savings in this area require more intervention by the PBM than either network discounts or rebates, both of which come from the client's willingness to put in place certain plan features in the initial plan design. Savings from higher and more intensive levels of management require continual input and monitoring by PBMs to assure appropriate utilization of cost-effective and clinically proven drugs.
- **Rebates** – Rebates lower the overall cost of prescription drugs. Pharmaceutical manufacturers typically provide larger rebates to PBMs for inclusion of a therapeutically equivalent drug on a formulary when other equivalent drug therapy options exist to the PBM. To increase the utilization of a specific drug in a therapeutic class requires that the PBM encourage enrollees to utilize that drug instead of other therapeutic alternatives. PBMs rely upon a variety of approaches, including perhaps placing that drug in a less expensive – and hence more desirable – tier for the enrollee and/or by demonstrating to prescribing physicians that the drug is clinically equivalent, but more cost-effective than others in the same therapeutic class.

Rebates are substantially lower for plans that have "loose" formularies and do not rely upon incentives to encourage the use of specific drugs compared to those plans that have "tighter" formularies and use a wide variety of techniques to encourage utilization of certain specific drugs.

- **Other administrative costs** – Like other businesses, PBMs have other costs in sales and benefit administration and a required return. Some of the functions that PBMs must pay for include call centers, clinical staff, information technology and robotics. In some cases these costs are reimbursed through a direct fee while in other instances PBMs subtract administrative costs from the rebates they receive from pharmaceutical companies before sharing them with clients.

B. Total Savings from Pharmacy Benefit Management Activities, 2005-2014

PricewaterhouseCoopers estimates that the total savings in drug costs from pharmacy benefit management are $53 billion in 2005 and $1.3 trillion dollars over the decade, 2005-2014. The details behind this estimate are presented in Table 3 below. (Total savings may not add up due to rounding.)

PricewaterhouseCoopers derived the total savings from PBMs based on the following factors:

- The official estimates of prescription drug spending 2004-2013 from the National Health Accounts as published by the Centers for Medicare and Medicaid Services (U.S. Department of Health and Human Services). CMS forecasts that national spending on prescription drugs will grow from $234 billion in 2005 to $567 billion in 2014, for a total over the 10-year period of $3.9 trillion dollars.[6]
- PricewaterhouseCoopers estimates that prescription drug spending managed by private, third-party payers (that almost universally rely on PBM arrangements) will account for 68 percent of prescription drug spending in 2005, or about $158 billion. The proportion managed by PBMs will jump to 84 percent when most Medicare beneficiaries enroll in private, prescription drug plans under the MMA.
- PricewaterhouseCoopers estimates that savings in the private plans, as discussed in detail above, is about 25 percent.
- When combined with our estimate of how many dollars are managed by PBMs, PricewaterhouseCoopers estimates that total savings are $53 billion in 2005, rising to $88 billion when most Medicare beneficiaries are brought under PBM arrangements in 2006, and reaching $194 billion in 2014, for a total over the decade of $1.3 trillion in savings.

Table 3. Total Savings Generated by PBMs
(In billions of dollars)

	2005	2005-14
Total Drug Spending		
Total	$234	$3,868
Non-Medicare	$133	$2,205
Medicare	$100	$1,663
Managed Private Spending		
Total	$158	$3,220
Non-Medicare	$106	$1,749
Medicare	$52	$1,470
Managed Private Spending as a Share of Total		
Total	68%	84%
Non-Medicare	79%	79%
Medicare	52%	88%
PBM Discount on Managed Private Spending		
Total	$53	$1,288
Non-Medicare	$36	$595
Medicare	$18	$693

Source: PricewaterhouseCoopers calculations.

The savings generated by PBMs are not only large relative to prescription drug spending, they are also an important element of managing private insurance costs overall. According to the official CMS forecasts, total spending by private insurance companies will total $25 trillion over the 2005 to 2014 period. Without the savings from PBMs, those total overall health care costs would rise throughout the entire system by about 4 percent and premiums would have to rise correspondingly to cover that increase.

The importance of PBM savings is also illustrated by calculating the per capita costs—roughly, $147 for each person enrolled in private health plans in 2005. Because Medicare beneficiaries use more prescription drugs, the savings are about $448 per Medicare beneficiary in private plans in 2005.[7]

IV. Impact of Legislation That Would Restrict Pharmacy Benefit Management Activities

While the tools and techniques PBMs rely upon have been embraced by a broad spectrum of private and public purchasers – most dramatically and recently through the Medicare Modernization Act – some groups have been critical of PBMs. A number of states are considering legislation that would further regulate, restrict, or eliminate PBM operations. The interest that states have in PBMs may well be a reflection of the dominance they have demonstrated in the marketplace. In one form or another, PBMs administer nearly all private drug plans and, increasingly, a larger share of public programs' drug plans. With $234 billion expected to be spent on pharmaceuticals in 2005, consumers, physicians, pharmacists, health plans, PBMs, small and large employers, labor unions, drug distributors, and drug manufacturers all have a financial interest in how resources are allocated.

As PBMs have emerged in the marketplace, their opponents have lobbied in the legislative arena for restrictions on certain practices of the PBM industry. Some groups argue that PBMs are interfering with the care that providers give to their patients in the interest of controlling costs. Others criticize PBMs for appearing to be more interested in boosting profits over controlling costs on behalf of purchasers. As a result, some states are now considering legislation to place limits on the activities of PBMs, although several states already in 2004 – most notably Florida, Maryland, and Vermont – have rejected legislative proposals calling for additional PBM regulation.

PricewaterhouseCoopers reviewed a range of legislative proposals that have been introduced in various states and developed a list of the most common ones, especially those that would appear to be the most far reaching in terms of impact on savings. Table 4 and the content of this section present PricewaterhouseCoopers' findings with respect to the impact of five illustrative legislative proposals that would place new restrictions on certain pharmacy management activities:

1. Limit Therapeutic Interchange
2. Limit Other Drug Management Techniques
3. Limit Mail-Service Pharmacies
4. Require PBMs to Disclose Contract Terms
5. Require PBMs to Bear Fiduciary Responsibility

We describe each of the options and the basis for our estimates below. Note that in every case, these estimates are consistent with our estimates of the overall savings generated by PBMs, and our estimates assume the legislation will be enacted on a national scale.[8]

Also, note that the impact varies by year for three reasons:

- The baseline share of generic drugs increases over time, and the effects of the legislation is different for generic drugs and brand drugs.
- The increase in mail order is expected to increase over time, affecting the savings.
- The introduction of the MMA drug benefit in 2006 causes a jump in the impact of each proposal. For example, PwC expects rebates to increase significantly for the Medicare population once they are covered by the Medicare benefit. For the legislative proposals that affect rebates (all but Mail Order and Fiduciary w/o disclosure), the impact of the legislation would be larger once the MMA benefit is in effect.

Table 4. Impact of Legislative Proposals on PBM-Managed Drug Costs And Number of Uninsured, 2005

Legislative Proposal	Change in Managed Drug Spending			Change in Uninsured Population, in thousands 2005
	2005 (in billions)	2005-14 (in billions)	Percent Change	
Option 1: Limit Therapeutic Interchange	$6.9	$167	5.2%	172.8
Option 2: Limit Drug Management Techniques	$6.4	$158	4.9%	158.6
Assuming Therapeutic Interchange included	$12.9	$309	9.6%	321.0
Option 3: Limit Mail-Service Incentives	$4.0	$97	3.0%	100.7
Option 4: Require PBM Disclosure	$8.2	$225	7.0%	204.8
Option 5: Require Fiduciary Responsibility	$4.1	$99	3.1%	103.0
Assuming Disclosure required	$12.6	$328	10.2%	313.7

Source: PricewaterhouseCoopers calculations.

A. Option 1: Limits on Therapeutic Interchange

Background

PBMs currently use therapeutic interchange to provide maximum flexibility in substituting therapeutically equivalent drugs, often at a cost-savings. Therapeutic interchange programs give patients incentives to try lower-cost alternatives before moving on to a more expensive medicine. Therapeutic interchange programs are a critical component of formulary management because they directly impact the market share of preferred versus non-preferred drugs. These lower-priced treatments may prove successful, saving both the plan and the patient. Critics of this practice believe that PBMs are interfering with the treatment prescribed by physicians.

The actual interchanges often result in lower net costs to health plans (i.e, the discounted price less the associated rebate.) For consumers to move from one drug to another, PBMs must obtain a new prescription from the prescribing physician or other health care provider. While PBMs work to educate, physicians always make the final prescribing decisions.

This legislation would prohibit PBMs from recommending therapeutically equivalent drugs unless all of the following conditions are met:

- The substitution must be made for medical reasons that benefit the patient;
- The substitution must benefit the client;
- PBMs must obtain prior authorization from the prescribing physician or other health care provider;
- The PBM must disclose to the patient and client the cost of both drugs and any benefits or payments directly or indirectly accruing to the PBM because of the interchange.

Finally, if the substitution follows the above standards, the PBM must transfer in full to a covered entity all benefits or payments received because of the substitution under the above requirements.

Cost Impact Analysis

PricewaterhouseCoopers assumes that this proposal would essentially eliminate prescription interchange. This legislation would reduce the incentives for PBMs to encourage consumers to utilize lower-cost drugs by increasing the administrative costs of doing so. The legislation would also limit the ability of PBMs to encourage individuals to move into different therapies and receive rebates from manufacturers whose therapeutically equivalent products are favored by the therapeutic interchanges.

Therapeutic interchange can lower drug spending by as much as 15 percent or more in drug classes where it is utilized. The limiting of therapeutic interchange would also decrease the amount of rebates that manufacturers pay associated with formulary compliance. Taken together, these two effects would lower the average discount on PBM-managed sales by 3.3 percentage points.[9]

- This change results in an increase in drug costs for individuals in PBM-managed plans of 4.4 percent, or $6.9 billion in 2005. [10]
- Over the 2005 to 2014 period, this increase would translate into additional costs of $167 billion (see Table 4), a 5.2 percent increase. This would increase in 2006 as more Medicare beneficiaries join PBMs.

- Higher prescription drug prices would have wider economic effects. PwC estimates that the 4.4 percent increase in prescription drug costs would increase health insurance premiums by about 0.4 percent in 2005 and lead to nearly 172,800 individuals losing health insurance in 2005.[11] Employers who purchase health insurance for their employees and consumers who purchase individual health plans would attempt to avoid the higher costs of health insurance by changing benefits or dropping health insurance coverage altogether.

B. Option 2: Limitation of Drug Management Techniques

Background

PBMs use prescription transmission intervention in a variety of ways, including assuring compliance with the client's formulary and benefit design as well as quality protections such as detecting dangerous drug interaction. For example, the PBM might ask the doctor whether a certain drug is medically appropriate for the condition being treated. PBMs are required to obtain the approval of the prescribing physician in order to affect a therapeutic interchange; however, consumers may or may not need to explicitly approve the interchange, depending on the specific interchange program employed (although they have the right to reject the interchange after it has occurred). Proponents of the legislation argue that this intervention is inappropriate because it interferes with the treatment the prescribing physician believes is the best course of action.

This legislation would restrict the ability of PBMs to manage a prescription by prohibiting any intervention prior to dispensing a prescription. Specifically, the legislation would require that:

- A PBM could not intervene prior to dispensing a prescription without express written authorization of the prescribing health care provider and the insured consumer.
- A PBM could not enter into a contract with a pharmacy or insurer that requires a pharmacist to alter an insured consumer's prescription without the express written authorization of the prescribing healthcare provider and the insured.

This prohibition would hinder the ability of PBMs to review prescriptions in a timely manner to enforce formularies and preferred drug lists. Prohibiting PBMs from intervening in the delivery or transmission of a prescription could affect the following common prescription management tools:

- Clinical prior authorization: Requiring prescribing physician or other health care provider to obtain approval for a particular drug before it is dispensed. Again, this mechanism facilitates the formulary and preferred drug list system by requiring approval for drugs not included on these lists.

- Drug utilization review: Programs designed to review drug-prescribing patterns; provide educational information to health providers on cost-effective therapeutic care; and perform rapid-fire quality checks, such as drug interaction and fraud detection.

Cost Impact Analysis

We assume that this proposal would eliminate the ability of PBMs to use prior authorization requirements and drug utilization reviews to control costs. PBMs believe they are able to suggest alternative treatments, which the prescribing physician may not have considered. Requiring the sign-off of both the physician and the patient would cause undue delay and decrease the likelihood of alternative treatments (which may be more cost effective). Preventing PBMs from encouraging patients to utilize less costly treatments under the benefit design will also limit rebates paid by manufacturers for formulary compliance.

Prior authorization can lower drug costs by up to 80 percent in certain drug categories (the savings would be offset in part by some PBM costs for administering the program). Drug utilization review can also result in significant savings.

- PricewaterhouseCoopers estimates that the elimination of these management techniques would decrease discounts by about 2.5 percentage points, and rebates would also fall by 0.6 percentage points.[12]
- Overall, this provision would increase drug costs for individuals in PBM-managed plans by 4.0 percent, or about $6.4 billion in 2005.
- Over the 2005 to 2014 period, this increase would translate into additional costs of $158 billion, a 4.9 percent increase.
- PwC estimates that the 4.0 percent increase in prescription drug costs would increase health insurance premiums by about 0.4 percent in 2005 and lead to almost 158,600 individuals losing health insurance in 2005.

Inclusion of Limiting Therapeutic Interchange

- If this proposal also limited the ability of PBMs to utilize therapeutic interchange, the increase in drug costs would reach 9.6 percent increase, about $309 billion over the 2005 to 2014 period.[13]
- PwC estimates that the 8.1 percent increase in prescription drug costs would increase health insurance premiums by about 0.4 percent in 2005 and lead to 321,000 individuals losing health insurance in 2005.

C. Option 3: Limit Incentives for Mail Service Pharmacies

Background

PBMs reduce the costs of dispensing drugs by using high-volume, automated mail-service facilities. Mail-service dispensing also makes other tools that PBMs use more effective as well. For example, utilization review and therapeutic intervention with the prescribing physician is easier to do effectively if the patient is not standing at the counter waiting for the drug to be dispensed. To encourage the use of mail service, health plans often charge lower copayments for mail-service prescriptions and allow longer prescriptions (i.e., 90 days instead of 30 days). Some plan designs have moved to a more aggressive model in which members are required to use mail service for prescriptions that treat certain chronic conditions. Some unions have adopted mandatory mail service as a trade-off to retain other healthcare benefits.[14]

Proponents of the legislation believe incentives provided to encourage mail-service offer unfair advantages to mail-service pharmacies over retail pharmacies. This legislation would prohibit differential reimbursement or other agreements that encourage mail-service delivery of prescriptions. Specifically, clients would be prohibited from offering economic benefits, or any other incentives, to encourage patients to move their prescriptions away from retail pharmacies to mail order.

Cost Impact Analysis

This proposal would essentially eliminate any incentives PBMs currently use to encourage the use of mail-service pharmacies because few patients will use mail service when they can go to a retail outlet for the same prescription at the same price. We estimate that mail-service discounts are about 11 percentage points higher than discounts on retail drugs, and that mail-service represents about 16 percent of total spending. We expect that this share will increase to 20 percent by 2014.[15]

- We estimate that this provision would increase drug costs for individuals in PBM-managed plans by 2.6 percent, or about $4.0 billion in 2005.[16]
- Over the 2005 to 2014 period, this increase would translate into additional costs of $97 billion, a 3.0 percent increase.
- PwC estimates that the 2.6 percent increase in prescription drug costs would increase health insurance premiums by about 0.2 percent in 2005 and lead to more than 100,700 individuals losing health insurance in 2005.

D. Option 4: Require Disclosure of Contract Terms & Pricing Data

Background

PBMs reduce pharmaceutical costs through direct negotiation with large retail drug stores for discounted reimbursement rates and with pharmaceutical manufacturers for rebates and other retrospective utilization discounts. These negotiations and resulting pricing structures are currently private information and are not publicly available. The parties do not disclose the details of contract negotiations because such information could affect their competitive position in future negotiations.

Proponents of the legislation believe that increasing the transparency of PBM and manufacturer interactions will provide plans and patients with more information that they can use to assess the actual discounts they receive on drugs. Some consumer advocates and third-party payers believe that they have not been paid all the discounts that PBMs have negotiated on their behalf, and they believe that this legislation would give them the necessary information to ensure that they receive all the discounts to which they are contractually entitled.

The type of disclosure mandated in legislation generally is not required of other healthcare organizations. In a competitive environment, the ability to negotiate in confidentiality is paramount. Without such confidentiality, competition, and the benefits derived from it, is eroded. Those benefits include lower costs achieved through a competitive model.

Under this legislation, PBMs would be required to provide to covered entities all financial and utilization information relating to the provision of benefits and services. Specifically, the legislation would require PBMs to disclose publicly the following agreements:

- Negotiated agreement with a manufacturer to provide rebates, discounts, incentives, retrospective utilization discounts, or other economic incentives.
- An agreement with a manufacturer that favors one manufacturer's product over another's product.
- An agreement to place a product on a formulary or preferred drug list.
- An agreement to encourage the prescribing of a preferred drug over another within a given therapeutic class.
- An agreement to bill a client at amounts higher or lower than the amount a PBM reimburses a pharmacy.
- Any other revenue sharing agreements.

Cost Impact Analysis

This legislation would restrict the ability of PBMs and pharmaceutical companies to have a private contractual relationship relating to pricing and incentives. This information would alter the nature and/or structure of those agreements. If required to make their private concessions public, pharmacy networks and drug manufacturers may be less willing to offer terms as generous as they currently do. In addition, if a PBM knows the pricing offered by a competing PBM, the ability to negotiate a lower price is virtually eliminated. As a result, we estimate that the network discounts and manufacturer rebates will decline significantly. The Congressional Budget Office estimated that a similar provision considered as part of the debate on the Medicare prescription drug bill would have increased the cost of the Medicare drug benefit by nearly 10 percent.

- Drug costs for individuals in PBM-managed plans would rise by 5.2 percent or about $8.2 billion in 2005.
- Over the 2005 to 2014 period, this increase would translate into additional costs of $225 billion, a 7.0 percent increase.
- PwC estimates that the 5.2 percent increase in prescription drug costs would increase health insurance premiums by about 0.5 percent in 2005 and lead to about 204,800 individuals losing health insurance in 2005.

E. Option 5: Require PBMs to Have a Fiduciary Duty

Background

Currently, PBMs contract with health plans and large employers to manage the prescription drug portion of health benefits offered. Decisions relating to the scope of those pharmaceutical benefits (or indeed, whether to offer them at all), are made by a plan sponsor, normally the employer or union. PBMs serve in an administrative and advisory role for their clients, performing claims processing and other administrative tasks. PBMs are private entities with duties to their shareholders and contractual business relationships with their clients – the covered entities.

This legislation changes those contractual relationships and transforms each PBM into a "fiduciary" of its clients. This state-imposed creation of a "fiduciary duty" is applicable to the entirety of the relationship between the PBM and its clients. In addition, creating fiduciary responsibilities for PBMs will require them to change the way they contract with manufacturers for rebates and other fees and require them to publicly disclose their contract terms.

Imposing such fiduciary duties on PBMs could subject them to broader legal liabilities than under current law because it transforms an arms' length contractual relationship into one where one party is responsible for assets that belong to another, such as a trustee relationship.

In addition, the laws imposing such fiduciary duties also require the PBM to discharge its duties with respect to the covered entity for the "primary purpose of providing benefits to covered individuals." That provision can create inconsistencies between its obligation to its client (the covered entity) to assure that a formulary and choice of drugs is cost-effective versus its obligation to the ultimate beneficiary, where cost-effectiveness is not normally an issue. Further, legislative creation of a fiduciary duty imposes obligations on PBMs to (1) disclose all financial terms and arrangements with manufacturers, pharmacies, and others; and to (2) pass through any payments or benefits to the covered entity, regardless of the terms of the contracts.

Under proposed legislation, specifically, a PBM would have to fulfill the following obligations:

- Act in good faith and in the best interest of a covered entity.
- Show duties of loyalty, care, and reporting to a covered entity.
- Notify in writing to a covered entity any activity, policy, or practice that directly or indirectly presents any conflict of interest with a covered entity.
- Provide to a covered entity financial and utilization information requested by the covered entity relating to the provision of benefits to covered individuals through that covered entity and financial and utilization information relating to services to that covered entity.

Cost Impact Analysis

Requiring PBMs to owe a fiduciary duty to covered entities would expose PBMs to increased legal risk that may result in the need to adopt defensive business and operating strategies to avoid the threat of litigation. The added cost of increased insurance exposure could drive pharmaceutical costs higher for patients.

Additionally, mandating fiduciary status could lead to the disclosure of proprietary business information and trade secrets. As described under Option 4, such disclosure would dramatically undercut the negotiating advantage of PBMs with drug companies and retail pharmacies, thereby increasing drug costs for health plans and their enrollees. Lastly, mandating fiduciary status for PBMs would require that plan design decisions and authority that currently resides with the health plan be extended to PBMs. The difficulty with these proposals is that they presume PBMs are managing the assets of the payer, rather than two entities operating at arms' length.

Operationally, we believe that an important impact of the legislation may expose PBMs to legal liability for the drug benefits that they manage. PBMs would have to boost their liability insurance and might limit the use of utilization techniques to avoid potential lawsuits.

In 2001, total insurance premiums for liability insurance represent about 1.5 percent of total health spending.[17] We estimate that PBMs would be forced to purchase broader liability insurance and that would lower the average discount by 0.5 percent of spending. Further, we expect that PBMs would be less likely to exercise management techniques, cutting the discount by another 1.5 percentage points.[18]

- Overall, we estimate that these effects would combine to increase drug costs for individuals in PBM-managed plans by 2.6 percent, or about $4.1 billion in 2005.
- Over the 2005 to 2014 period, this increase would translate into additional drug costs of $99 billion, a 3.1 percent increase.
- PwC estimates that the 2.6 percent increase in prescription drug costs would increase health insurance premiums by about 0.2 percent in 2005 and lead to about 103,000 individuals losing health insurance in 2005.

Fiduciary & Disclosure Combined

- If, additionally, this legislation required PBMs to disclose publicly the results of negotiations with pharmacy networks and drug manufacturers, the overall impact of the legislation in such a case would be the combination of the 2.6 percent increase mentioned above and the 5.2 percent increase estimated for the disclosure legislation, or 7.9 percent, about $12.6 billion in 2005.
- Over the 2005 to 2014 period, this increase would translate into additional drug costs of $328.0 billion, a 10.2 percent increase
- PwC estimates that the 7.9 percent increase in prescription drug costs would increase health insurance premiums by about 0.7 percent in 2005 and lead to nearly 313,700 individuals losing health insurance in 2005.

[1] Excluding public programs from the analysis reduces the overall savings attributed to PBMs and probably reduces the lost savings estimates in Section IV but only to the extent that legislation also includes public programs, which in some cases it may not.

[2] Market-share analysis shows changing PBM climate, growth as Medco spins off, Drug Cost Management Report, Aug. 29, 2003.

[3] Trends in US Healthcare Spending, 2001, Health Affairs, Katharine Levit, Cynthia Smith, Cathy Cowan, Helen Lazenby, Art Sensenig, and Aaron Catlin, January/February 2003.

[4] As noted previously, this report does not include state or federal government use of pharmacy benefit management in its analysis or estimates.

[5] These figures are based on reports and testimony from the General Accounting Office, Congressional Research Service reports, financial reports from PBMs, discussion with industry consultants, conversations with PBMs, and other private research.

[6] CMS estimates for prescription drug spending by source of payment, 2004-2013 can be found on their website at: http://www.cms.hhs.gov/statistics/nhe/projections-2003/t11.asp. The National Health Accounts do not include projections for 2014. The growth in prescription drug spending is slowly declining and the projection for 2014 reflects this decline.

[7] As a percent of retail spending without management, the savings from private prescription care management in 2004 is probably about the same in both Medicare and nonMedicare population. The dollar savings is much higher for Medicare beneficiaries because spending per capita is higher for Medicare beneficiaries who are either elderly or else have disabilities.

[8] State regulations generally only apply to plans and entities not covered under Federal ERISA rules. For the purposes of this study, we have assumed that the legislative proposals will be implemented at the national level and therefore apply to all plans managed by PBMs. Once we have calculated the national estimate, we allocate the impacts to the state level. If an individual state were to implement the proposal, the impact on that particular state could differ from our estimates.

[9] We estimate that therapeutic interchange currently saves about 2.7 percent of retail drug costs across all spending in private plans. These savings would be lost under the proposal, as would an additional 0.6 percent from lost rebates from drug manufacturers (we assume half of rebates are driven by movement of market share to particular drugs, and that those rebates would fall by 25 percent, so rebates relative to retail drug costs fall by 0.6 percentage points).

[10] Instead of being 25 percent, the overall discount under this proposal would fall to 21.8 percent. Total spending rises by 4.4 percent (= (1- 21.8%)/(1-25%) -1).

[11] Our estimates are based on the assumption that a one percent increase in health insurance premiums causes a 0.3 percent reduction in health insurance coverage. We view this as a

conservative estimate. The Congressional Budget Office estimated that a premium increase of one percent would increase the number of uninsured by about 200,000, a change of about 0.14 percent. However, the CBO estimate specifically addressed the loss of coverage due to a mental health parity mandate, not a change that reflected an increase in premiums with no increase in coverage. This is an important distinction because people are less likely to drop insurance coverage if the increase in cost is accompanied by an increase in benefits as opposed to solely an increase in costs.

In other cases, the Congressional Budget Office assumes an elasticity of minus 0.6 for premium increases not accompanied by increases in benefits. In other words, a 1 percent increase in health insurance premiums leads to a 0.6 percent reduction in the purchase of health insurance. The PwC estimate is based on a minus 0.6 percent elasticity offset by a 33 percent reduction to account for those would obtain insurance through another family member's employer-sponsored plan, private insurance, or public insurance programs. See *CBO's Estimates of the Impact of the Mental Health Parity Amendment in H.R. 3103* (Washington, DC: May 13, 1996) and *Behavioral Assumptions for Estimating the Effects of Health Care Proposals* (Washington, DC: November 1993).

[12] We estimate that the combination of prior authorization and drug utilization review currently saves about 2.5 percent of retail drug costs across all spending in private plans. These savings would be lost under the proposal, as would an additional 0.6 percent from lost rebates from drug manufacturers (we assume half of rebates are driven by movement of market share to particular drugs, and that those rebates would fall by 25 percent, so rebates relative to retail drug costs fall by 0.6 percentage points).

[13] We assume that elimination of therapeutic interchange, prior authorization, and drug utilization review would lower the average discount across all managed drugs by 5.2 percentage points and lower average rebates by 0.6 percentage points.

[14] Mail Order Prescriptions Poised for Growth, Bank of America Securities, March 15, 2004.

[15] According to a recent Bank of America study, the share of mail-order prescriptions could rise as high as 50 percent, based on current drug utilization patterns. See Bank of America Securities, "Mail Order Prescriptions Poised for Growth," March 15, 2004.

[16] The elimination of mail order incentives will eliminate any additional discounts attained currently under mail order. The elimination of the 11 percent differential will lower the overall discount by 1.8 percentage points (an average of 19 percent of drug spending in mail order over the period * 11 percent).

[17] A study from the Joint Economic Committee of the U.S. Congress estimated that the direct costs of premiums for medical liability insurance were $21 billion in 2001 (See Joint Economic Committee, "Liability for Medical Malpractice: Issues and Evidence," May 2003). These premiums represent almost 1.5 percent of total health spending in the National Health Accounts. The ratio must be adjusted to estimate the liability insurance premiums that PBMs would have to pay under the proposal. The ratio sums premiums across all providers, and some providers (such as physicians) face more risk than others, resulting in higher liability premiums. Also, some of the risks PBMs will face under a fiduciary duty will be new risk, but some will be risk that other providers already

faced (and insured against). We feel that PBM premiums of 0.5 percent of drug spending represent a conservative estimate.

[18] Researchers have found that defensive medicine raises health costs by 5 to 9 percent (see Kessler, D. & McClellan, M, "Do Doctors Practice Defensive Medicine," *Quarterly Journal of Economics*, 111(2): 353-390, 1996). Assuming a similar relationship between the low end of the range and average liability premiums, we estimate that PBMs would adjust their drug management techniques to lower discounts by 1.5 percentage points (5 percent (lower bound of defensive medicine costs) / 1.5 percent (overall liability premium) * 0.5 percent (assumed PBM premium) is approximately equal to 1.5 percent).

NORTH DAKOTA

The Value of Pharmacy Benefit Management & Cost of Proposed PBM Legislation[1]

KEY FINDINGS

PBM Cost Savings in North Dakota

- In 2005, the number of North Dakota residents with prescription drug coverage administered through PBMs is estimated to be 456,000.
- In 2005, drug spending managed by PBM arrangements in North Dakota is estimated to be $330 million.
- In 2005, PBMs are estimated to save North Dakota consumers and employers $112 million on the cost of their prescription drugs.
- From 2005-2014, PBMs are estimated to save North Dakota consumers and employers $2.7 billion on the cost of their prescription drugs.

Cost of PBM Legislation in North Dakota

Legislative Proposal	Change in Managed Drug Spending			Increase in Uninsured Population, 2005
	2005 (in millions)	2005-14 (in billions)	Percent Change	
Option 1: Limit Therapeutic Interchange	$15 million	$352 million	5.2%	329
Option 2: Limit Drug Management Techniques	$13 million	$335 million	4.9%	302
Assuming Therapeutic Interchange included	$27 million	$653 million	9.6%	610
Option 3: Limit Mail-Service Incentives	$8.5 million	$206 million	3.0%	192
Option 4: Require PBM Disclosure	$17 million	$475 million	7.0%	389
Option 5: Require Fiduciary Responsibility	$8.7 million	$209 million	3.1%	196
Assuming Disclosure required	$27 million	$693 million	10.2%	597

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[1] Source: PricewaterhouseCoopers, 2004

Constitutional Problem with HB 1332 ????

Bills similar to HB 1332 have been passed in Maine, the District of Columbia, and recently in South Dakota. It's important to note that SD's law does not include the "fiduciary duty" requirement. However, it still has the disclosure part involved in the "Takings" argument. There have been two US District Court challenges of the constitutionality of similar pharmacy benefit management regulatory bills. In both cases, (Maine & DC), preliminary injunctions have been issued. In the DC case, (Pharmaceutical Care Management Association v. The District of Columbia and Anthony A. Williams, Mayor of the District of Columbia), the court stated, "As noted, enforcement of Title II may actually have the opposite of its intended effect and drive up the price of healthcare. In addition, the court has already concluded that the plaintiff has demonstrated a substantial likelihood that at least part of Title II may be unconstitutional." Please note the language similarity of the DC Injunction and HB 1332.

Memorandum Opinion Granting the plaintiff's motion for Interim Injunctive Relief.	**Text from HB 1332**
"Specifically, Title II dictates that PBM's owe **a fiduciary duty** to their customers, which they must **discharge in accordance with all applicable laws**."	Page 3, lines 12-13. "A pharmacy benefits manager has **a fiduciary duty** to a covered entity and shall **discharge that duty within the provisions of state and federal law**..."
"Title II also imposes several disclosure requirements. For instance, PBM's must disclose to their customers "**information showing the quantity of drugs purchased by the covered entity and the net cost to the covered entity for the drugs. This information shall include all rebates, discounts, and other similar payments**." Furthermore, PBM's must also disclose to its customers "**all financial terms and arrangements for remuneration of any kind that apply between the [PBM] and prescription drug manufacturer or labeler, including, without limitation, formulary management and drug substitution programs, educational support, claims processing and data sales fees.**""	Page 4, lines 1-7, "...a pharmacy benefits manager...shall disclose to the covered entity **all financial and utilization information related to services under contract, including all rebate revenues and the nature, type, and amounts of all other revenues that the pharmacy benefits manager receives from each pharmaceutical manufacturer or labeler**... Page 4, lines 7-22, "...The pharmacy benefits manager shall disclose in writing ...**The nature, type, and amount of all other revenue received by the pharmacy benefits manager, directly or indirectly, from each pharmaceutical manufacturer or labeler for any other products or services provided, including formulary management and drug-switch programs, educational support, claims processing, and pharmacy network fees that are charged from retail pharmacies and data sales fees**..."

PCMA
PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

Lessons Learned from PCMA v. DC--Why Disclosure Requirements Imposed on PBMs are Unconstitutional

- Serves as a warning to other states that might be considering similar misguided and unconstitutional legislation.

- Legislation requiring disclosure requirements like Title II's will likely be found by the courts to amount to a taking of trade secrets without just compensation in direct violation of the U.S. Constitution.

- The Court held that the terms and conditions of PBM contracts with pharmaceutical manufacturers are trade secrets.
    - PBMs derive economic value from keeping contract terms confidential and they take reasonable efforts to maintain the secrecy of the arrangements; and
    - Title II of AccessRx creates interference with the reasonable investment-backed expectations the PBMs have in these contracts.

- Disclosure legislation cannot be saved by merely including a purported right of PBMs to label their disclosed trade secrets "confidential". Once the disclosure is made, the value of trade secret may be completely destroyed.

- Cites PCMA v. Rowe: "[W]here a state statute protected trade secrets from disclosure, legislation requiring PBMs to disclose financial arrangements with pharmaceutical companies interferes with the PBMs' reasonable investment-backed expectations."

- Highlights the benefits PBMs provide to the consumers of the District of Columbia: "The evidence before the court indicates that the PBM industry is highly competitive, enhances drug safety by alerting pharmacists to dangerous drug interactions and saves customers money by controlling costs."

PCMA
PHARMACEUTICAL CARE
MANAGEMENT ASSOCIATION

U.S. District Court, District of Columbia Decision in PCMA v. The District of Columbia

On December 21, 2004, the U.S. District Court for the District of Columbia blocked DC from enforcing Title II of AccessRx (B15-569). Passed by the DC Council on March 2, 2004, the District Court found that Title II's disclosure requirements constitute a constitutional violation by imposing a "taking" of PBM trade secrets without just compensation.

Title II requires PBMs to completely disclose "all financial terms and arrangements for remuneration of any kind that apply between the [PBM] and prescription drug manufacturers or labelers, including, without limitation, formulary management and drug substitution programs, educational support, claims processing and data sales fees."

The Court concluded that the broad scope of the disclosures mandated by Title II compels PBMs to disclose trade secrets. Because the value of the information would be destroyed upon its disclosure, the Court issued this injunction. The Court also noted that Title II cannot be saved merely by allowing PBMs to label their information confidential under the disclosure requirements.

By granting the preliminary injunction, the Court determined that PCMA has a substantial likelihood of success on the merits of its case. The threshold for granting an injunction is quite high and PCMA has shown its members would suffer irreparable injury if the injunction were not granted. The Court also noted that "the evidence indicates, that if enforced, Title II could have the unintended effect of actually driving the PBM business and its attendant benefits out of the District of Columbia."

Additionally, the court's order states that "[t]he evidence before the court indicates that the PBM industry is highly competitive, enhances drug safety by alerting pharmacist to dangerous dug interactions and saves customers money by controlling costs."

The D.C. District Court's opinion marks the second Federal Court (including two federal judges in Maine) that has issued a preliminary injunction against state legislation limiting or eliminating cost-saving PBM tools and techniques as unconstitutional.

ASSEMBLY BILL No. 1960

Introduced by Assembly Members Pavley and Frommer
(Coauthors: Assembly Members Chu, and Ridley-Thomas)

February 12, 2004

An act to add Article 8 (commencing with Section 4130) to Chapter 9 of Division 2 of the Business and Professions Code, relating to pharmacy benefits management.

LEGISLATIVE COUNSEL'S DIGEST

AB 1960, as introduced, Pavley. Pharmacy benefits management.

Existing law, the Pharmacy Law, creates the California State Board of Pharmacy and makes it responsible for the regulation and licensure of persons engaged in pharmacy practices relating to the furnishing of dangerous drugs, as defined. Under existing law, a violation of the provisions of the Pharmacy Law is a crime.

This bill would define the term "pharmacy benefits management" as negotiating the purchase of dangerous drugs on behalf of specified entities and administering or managing the prescription drug benefit programs of those entities. The bill would also define the term "pharmacy benefits manager" as an entity that performs pharmacy benefits management. The bill would impose on that entity a fiduciary duty to the person employing or contracting with the entity.

Because the bill would specify an additional requirement under the Pharmacy Law, a violation of which would be a crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state.

Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Article 8 (commencing with Section 4130) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

Article 8. Pharmacy Benefits Management

4130. "Pharmacy benefits management" means negotiating the purchase of dangerous drugs on behalf of an entity that provides health care services, including a health care service plan or a health insurer, or an entity that purchases those services and administering or managing the prescription drug benefit program provided or purchased by those entities. The administration or management of a prescription drug benefit program includes all of the following:

(a) Providing mail pharmacy services.

(b) Claims processing, managing a retail network, and paying claims to a pharmacy for dangerous drugs dispensed to an enrollee or insured.

(c) Rebate contracting and administering the rebates.

(d) Therapeutic intervention and generic substitution programs.

(e) Disease management programs.

4131. A "pharmacy benefits manager" means an entity that performs pharmacy benefits management and includes a person or entity acting for a pharmacy benefits manager in a contractual or employment relationship in the performance of pharmacy benefits management.

4132. A pharmacy benefits manager owes a fiduciary duty to the person who contracts with, or employs, the pharmacy benefits manager.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

CORRECTIONS

Heading — Authors.

O

Thank you for inviting my comments on the comparison of California's bill (AB 1960) and ND's proposed HB 1332.

I would say that "in concept" the policymakers of California and ND (and dozens of other states!) are trying to address shared concerns about rising drug prices and the perceived contributions (to prices) made by PBMs. In more specific terms, the legislation proposed in ND (HB 1332) is NOT the same as California and I will highlight some of those aspects in a minute, but first some clarifications are in order ---

- The FTC report (page 8) cites the GAO report filed in 2003 and accepts these findings as conclusive evidence in support of PBMs and the theory that they provide the lowest drug prices. If you look at Senator Dorgan's public criticism of this research (provided in this package) he clearly addressed the report's questionable validity, knowing that the GAO publicly acknowledged that they had not independently verified the data used for their analysis because the PBMs would not disclose the information.

- The FTC report only footnotes (no.33) the major lawsuits all across the US and does not include the findings of the US Justice Department in the settlement with Medco in 2004, which clearly identified unfair trade practices in 20 states. Medco AGREED to accept fiduciary responsibility as well as provide disclosure, and to forward a larger percentage of the various revenues from rebates and discounts to the plan sponsors as part of their negotiated settlement with the states and federal government. It appears they do not perceive an undue burden from this disclosure and sharing of revenues, or they would not have agreed.

- The FTC report cites the existence of 60 PBMs in California, including the country's 3 largest (used to be 4 until 2 merged in 2004). These numbers indicate an open, competitive market which in market theory provides opportunity for consumers to shop around and obtain the best price. It also states that most plan sponsors use these market conditions to take bids and evaluate proposals based on cost and services offered (et al, page 7). North Dakota does not have these competitive market conditions to serve the best interest of plan sponsors nor consumers. For example, the ND Public Employees Retirement System did the official RFP process last summer and only received ONE proposal that could be considered...BCBS. Our near-monopoly is not comparable to 60 PBMs in California, competing to provide consumer choice to millions. And even in those more competitive market conditions, the public employees union is suing the largest PBMs for inflating drug prices (see attachment AFSCME).

- FTC footnote #5 states that the disclosure regulations in AB 1960 will not raise the competitive concerns that the FTC perceives will result from regulations to pass through more savings to plan sponsors. To me that doesn't make much sense...If "telling" the plan sponsor what level of revenues are generated from rebates and discounts does not affect the PBM's ability to continue negotiations with drug companies, how does sharing a larger portion of those profits threaten them?

Differences between North Dakota's HB 1332 and California'a AB 1960 are significant:

1. The argument that California already requires prior prescriber approval of therapeutic interchange and so limits risk to drug switching by PBMs – is not the case in ND. The FTC cites California's existing law to be sufficient consumer protection when drug switching helps the PBM implement their formulary by "steering utilization toward or away from a particular pharmaceutical" (page 6).

   (See attachments CenturyCode Chapter 19 a and b). It is just the opposite in ND – unless the prescriber (the physician) has written "brand necessary" on the original prescription, or provides oral instructions to dispense brand necessary as communicated, there IS NOT a built-in protection in statute to limit substitutions.

   An example of how this affects price was described in a 2 real life situations in the letter to Kupchella, a TV station reporter in Minneapolis who did a story on PBMs (in the exhibits from Dr. Hill's testimony on 1-25-05 and attached) last November. As you can see, even though ND law authorizes a pharmacist to provide a less expensive generic alternative, the PBM retains the power to deny the patient access to that drug through the claims process. The PBM also retains authority to "direct" the purchase of brand over generic through disincentives in co-pays, and increased costs to the plan sponsor.

2 California's AB 1960 requires disclosure of information prior to drug substitutions, and the FTC interprets this to include any and all possible substitutions including substituting a generic for an equivalent brand name. California also requires a patient monitoring component with quarterly reporting functions by the PBM.

   HB 1332 specifically identifies the circumstances when SUBSTITION IS ALLOWED, including the option to get a less expensive generic in place of a more expensive brand name, and when the substitution is confirmed by a physician to be in the best medical interests of the patient. And there is NO burden to provide monitoring & reporting.

3. The FTC perceives the disclosure requirements in AB 1960 to include extensive public access, which may impact the negotiations between PBMs and drug companies. ND has not taken this approach.

   HB 1332 specifically limits disclosure to the plan sponsor who would have access to data that affects only the healthcare plan and pharmacy benefit provided by that employer/sponsor. There is also a confidentiality clause provided to give the PBMs the protection they insist upon, so plan sponsors are deterred from ever sharing their own information. It includes injunctive relief and liability considerations.

   Obviously, the Insurance Commission – as the regulatory entity - will have access too... but no other disclosure is requested.

4. AB 1960 includes different disclosure requirements among PBMs offering integrated or nonintegrated services to the plans. The FTC report suggests this defeats the purpose of providing information to help purchasers make more informed choices, when some are not regulated by the law and others are.

HB 1332 includes ALL PBMs choosing to operate in ND. State laws cannot be applied to health plans that are governed by federal ERISA laws (self funded plans for example), **but ERISA already requires disclosure and the information is available to more than just the plan sponsors if requested.** So, HB 1332 applies to all the healthcare plans, with a pharmacy benefit administered by PBMs, that ARE required to abide by state law. And in doing so, offers all plans in ND at least the same protections given in ERISA.

1 of 1 DOCUMENT

MAINE REVISED STATUTES

ARCHIVED DATA

*** THIS DOCUMENT IS CURRENT THROUGH ALL 2003 LEGISLATION ***

TITLE 22. HEALTH AND WELFARE
SUBTITLE 2. HEALTH
PART 5. FOODS AND DRUGS
CHAPTER 603. PRESCRIPTION DRUG ACCESS
SUBCHAPTER 4. PRESCRIPTION DRUG PRACTICES

22 M.R.S. § 2699 (2003)

§ 2699. Prescription drug practices

Pharmacy benefits managers shall and contracts for pharmacy benefits management must comply with the requirements of this section.

1. DEFINITIONS. As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings.

A. "Covered entity" means a nonprofit hospital or medical service organization, insurer, health coverage plan or health maintenance organization licensed pursuant to Title 24 or 24-A; a health program administered by the department or the State in the capacity of provider of health coverage; or an employer, labor union or other group of persons organized in the State that provides health coverage to covered individuals who are employed or reside in the State. "Covered entity" does not include a health plan that provides coverage only for accidental injury, specified disease, hospital indemnity, Medicare supplement, disability income, long-term care or other limited benefit health insurance policies and contracts.

B. "Covered individual" means a member, participant, enrollee, contract holder or policy holder or beneficiary of a covered entity who is provided health coverage by the covered entity. 'Covered individual' includes a dependent or other person provided health coverage through a policy, contract or plan for a covered individual.

C. "Generic drug" means a chemically equivalent copy of a brand-name drug with an expired patent.

D. "Labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations, 270.20 (1999).

E. "Pharmacy benefits management" means the procurement of prescription drugs at a negotiated rate for dispensation within this State to covered individuals, the administration or management of prescription drug benefits provided by a covered entity for the benefit of covered individuals or any of the following services provided with regard to the administration of pharmacy benefits:

1) Mail service pharmacy;

2) Claims processing, retail network management and payment of claims to pharmacies for prescription drugs dispensed to covered individuals;

3) Clinical formulary development and management services;

4) Rebate contracting and administration;

5) Certain patient compliance, therapeutic intervention and generic substitution programs; and

6) Disease management programs.

F. 'Pharmacy benefits manager' means an entity that performs pharmacy benefits management. 'Pharmacy benefits manager' includes a person or entity acting for a pharmacy benefits manager in a contractual or employment relationship in the performance of pharmacy benefits management for a covered entity and includes mail service pharmacy.

2. REQUIRED PRACTICES. A pharmacy benefits manager owes a fiduciary duty to a covered entity and shall discharge that duty in accordance with the provisions of state and federal law.

A. A pharmacy benefits manager shall perform its duties with care, skill, prudence and diligence and in accordance with the standards of conduct applicable to a fiduciary in an enterprise of a like character and with like aims.

B. A pharmacy benefits manager shall discharge its duties with respect to the covered entity for the primary purpose of providing benefits to covered individuals and defraying reasonable expenses of administering health plans.

C. A pharmacy benefits manager shall notify the covered entity in writing of any activity, policy or practice of the pharmacy benefits manager that directly or indirectly presents any conflict of interest with the duties imposed by this subsection.

D. A pharmacy benefits manager shall provide to a covered entity all financial and utilization information requested by the covered entity relating to the provision of benefits to covered individuals through that covered entity and all financial and utilization information relating to services to that covered entity. A pharmacy benefits manager providing information under this paragraph may designate that material as confidential. Information designated as confidential by a pharmacy benefits manager and provided to a covered entity under

this paragraph may not be disclosed by the covered entity to any person without the consent of the pharmacy benefits manager, except that disclosure may be made in a court filing under the Maine Unfair Trade Practices Act or when authorized by that Act or ordered by a court of this State for good cause shown.

E. With regard to the dispensation of a substitute prescription drug for a prescribed drug to a covered individual the following provisions apply.

1) The pharmacy benefits manager may substitute a lower-priced generic and therapeutically equivalent drug for a higher-priced prescribed drug.

2) With regard to substitutions in which the substitute drug costs more than the prescribed drug, the substitution must be made for medical reasons that benefit the covered individual and must benefit the covered entity. If a substitution is being made under this subparagraph, the pharmacy benefits manager shall obtain the approval of the prescribing health professional or that person's authorized representative after disclosing to the covered individual and the covered entity the cost of both drugs and any benefit or payment directly or indirectly accruing to the pharmacy benefits manager as a result of the substitution.

3) The pharmacy benefits manager shall transfer in full to the covered entity any benefit or payment received in any form by the pharmacy benefits manager as a result of a prescription drug substitution under subparagraph (1) or (2).

F. A pharmacy benefits manager that derives any payment or benefit for the dispensation of prescription drugs within the State based on volume of sales for certain prescription drugs or classes or brands of drugs within the State shall pass that payment or benefit on in full to the covered entity.

G. A pharmacy benefits manager shall disclose to the covered entity all financial terms and arrangements for remuneration of any kind that apply between the pharmacy benefits manager and any prescription drug manufacturer or labeler, including, without limitation, formulary management and drug-switch programs, educational support, claims processing and pharmacy network fees that are charged from retail pharmacies and data sales fees.

3. COMPLIANCE. Compliance with the requirements of this section is required in all contracts for pharmacy benefits management entered into in this State or by a covered entity in this State.

4. ENFORCEMENT. A violation of this section is a violation of the Maine Unfair Trade Practices Act, for which a fine of not more than $ 10,000 may be adjudged.

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 22 MRSA c. 603, sub-c. 4 is enacted to read:

SUBCHAPTER 4

PRESCRIPTION DRUG PRACTICES

§2699. Prescription drug practices

Pharmacy benefits managers shall and contracts for pharmacy benefits management must comply with the requirements of this section.

1. Definitions. As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings.

A. "Covered entity" means a nonprofit hospital or medical service organization, insurer, health coverage plan or health maintenance organization licensed pursuant to Title 24 or 24-A; a health program administered by the department or the State in the capacity of provider of health coverage; or an employer, labor union or other group of persons organized in the State that provides health coverage to covered individuals who are employed or reside in the State. "Covered entity" does not include a health plan that provides coverage only for accidental injury, specified disease, hospital indemnity, Medicare supplement, disability income or other long-term care.

B. "Covered individual" means a member, participant, enrollee, contract holder or policy holder or beneficiary of a covered entity who is provided health coverage by the covered entity. "Covered individual" includes a dependent or other person provided health coverage through a policy, contract or plan for a covered individual.

C. "ERISA" means the Employee Retirement Income Security Act of 1974, 29 United States Code, Sections 1001 to 1461 (1988).

D. "Generic drug" means a chemically equivalent copy of a brand-name drug with an expired patent.

E. "Labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a

labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations, 270.20 (1999).

F. "Pharmacy benefits management" means the procurement of prescription drugs at a negotiated rate for dispensation within this State to covered individuals, the administration or management of prescription drug benefits provided by a covered entity for the benefit of covered individuals or any of the following services provided with regard to the administration of pharmacy benefits:

(1) Mail service pharmacy;

(2) Claims processing, retail network management and payment of claims to pharmacies for prescription drugs dispensed to covered individuals;

(3) Clinical management formulary development and management services;

(4) Rebate contracting and administration;

(5) Certain patient compliance, therapeutic intervention and generic substitution programs; and

(6) Disease management programs.

G. "Pharmacy benefits manager" means an entity that performs pharmacy benefits management. "Pharmacy benefits manager" includes a person or entity acting for a pharmacy benefits manager in a contractual or employment relationship in the performance of pharmacy benefits management for a covered entity and includes mail service pharmacy.

2. Required practices. A pharmacy benefits manager owes a fiduciary duty to a covered entity and covered individuals and shall discharge that duty in accordance with the provisions of ERISA, state and federal law and this section.

A. A pharmacy benefits manager shall perform its duties with care, skill, prudence and diligence and in accordance with the standards of conduct applicable to a fiduciary in an enterprise of a like character and with like aims.

B. A pharmacy benefits manager shall discharge its duties with respect to the covered entity and covered individuals solely in the interests of the covered individuals and for the primary purpose of providing benefits to covered individuals and defraying reasonable expenses of administering health plans.

C. A pharmacy benefits manager shall notify the covered

entity in writing of any activity, policy or practice of the pharmacy benefits manager that directly or indirectly presents any conflict of interest with the duties imposed by this subsection.

D. A pharmacy benefits manager shall provide to a covered entity all financial and utilization information requested by the covered entity relating to the provision of benefits to covered individuals through that covered entity and all financial and utilization information relating to services to that covered entity. A pharmacy benefits manager providing information under this paragraph may designate that material as confidential. Information designated as confidential by a pharmacy benefits manager and provided to a covered entity under this paragraph may not be disclosed to any person without the consent of the pharmacy benefits manager, except that disclosure may be made in a court filing under the Maine Unfair Trade Practices Act or when authorized by that Act or ordered by a court of this State for good cause shown.

E. With regard to the dispensation of a substitute prescription drug for a prescribed drug to a covered individual the following provisions apply.

(1) The pharmacy benefits manager may substitute a lower-priced generic drug for a higher-priced prescribed drug.

(2) The pharmacy benefits manager may not substitute a higher-priced generic drug for a lower-priced prescribed drug.

(3) The pharmacy benefits manager shall consult with the prescribing health professional or that person's authorized representative and shall:

(a) Disclose the costs of both drugs to the covered individual and the covered entity and any benefit or payment directly or indirectly accruing to the pharmacy benefits manager as a result of the substitution; and

(b) Obtain the approval of the prescribing health professional or that person's authorized representative for the substitution.

(4) The pharmacy benefits manager shall transfer in full to the covered entity or covered individuals any benefit or payment received in any form by the pharmacy

benefits manager as a result of the prescription drug substitution.

F. A pharmacy benefits manager that derives any payment or benefit for the dispensation of prescription drugs within the State based on volume of sales for certain prescription drugs or classes or brands of drugs within the State shall pass that payment or benefit on in full to the covered entity or covered individuals.

G. A pharmacy benefits manager shall disclose to the covered entity all financial terms and arrangements for remuneration of any kind that apply between the pharmacy benefits manager and any prescription drug manufacturer or labeler, including, without limitation, formulary management and drug-switch programs, educational support, claims processing and pharmacy network fees that are charged from retail pharmacies and data sales fees.

3. Prohibition. A pharmacy benefits manager may not in a contract with a covered entity or a prescription drug manufacturer or labeler accept or agree to an obligation that is inconsistent with the fiduciary duties imposed by subsection 2, ERISA or other state or federal law.

4. Waiver prohibited. Any agreement to waive the provisions of this section is against public policy and void.

5. Enforcement. A violation of this section is a violation of the Maine Unfair Trade Practices Act. Compliance with this section may be enforced through private action or action by the Attorney General.

A. A covered entity, covered individual or other person injured as a result of a violation of this section is eligible to bring a private action as a person pursuant to the Unfair Trade Practices Act.

B. An action by the Attorney General pursuant to this subsection is subject to the provisions of this paragraph and the Maine Unfair Trade Practices Act. Each violation of this section is a civil violation for which the Attorney General may obtain, in addition to other remedies, injunctive relief and a fine in an amount not to exceed $10,000 per violation, plus the costs of suit, including necessary and reasonable investigative costs, reasonable expert fees and reasonable attorney's fees.

SUMMARY

This bill specifies the fiduciary duties of pharmacy benefits managers and the obligation to serve the covered entities with whom they contract and the covered individuals provided health care benefits by the covered entities. The bill prohibits contractual terms that are inconsistent with the pharmacy benefits manager's fiduciary duties. The bill requires payment to a pharmacy benefits manager based on volume of certain drugs or as a result of substitution of drugs to be passed on to the covered entity or covered individuals. The bill requires disclosure of financial terms that apply between a pharmacy benefits manager and a manufacturer or labeler. The bill requires consultation with and agreement of the prescribing health professional or a representative of that professional before a pharmacy benefits manager may switch a prescription drug to be dispensed to a covered individual. The bill prohibits agreements to waive provisions of the law. Violations of the law are violations of the Maine Unfair Trade Practices Act and are enforceable by private action or the Attorney General.

FROM Drug Benefit News
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Legal Matters

Legal Matters: U.S. Court Bars Enforcement of Maine Statute Regarding PBMs

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Pharmacy benefit managers (PBMs) obtained a key legal victory in March when a federal judge temporarily enjoined the state of Maine from implementing a new law that would have restricted certain industry practices and required disclosure of pricing and rebate information regarded as trade secrets by PBMs. The ruling was in response to a lawsuit brought by the Pharmaceutical Care Management Association (PCMA), the trade organization representing PBMs.[1] The PCMA is challenging the Maine law "An Act to Protect Against Unfair Prescriptive Drug Practices," or the Unfair Prescriptive Drug Practices Act (UPDPA), on the basis that the statute is preempted by the federal Employee Retirement Income Security Act of 1974 (ERISA) and that it violates the Takings Clause and Commerce Clause of the US Constitution.

In granting the preliminary injunction to bar enforcement of the law pending the outcome of the lawsuit, the court was persuaded that the PCMA demonstrated a substantial likelihood of success in having the law invalidated. In addition, the PCMA demonstrated that potential harm to its members might result from implementation of the statute. While this is not an ultimate ruling on the legality of the statute, the injunction maintains the status quo while litigation continues. The ultimate outcome of this case undoubtedly will be significant, as other states contemplate regulation of PBMs.

Maine's Unfair Prescriptive Drug Practices Act

The statute that prompted the PCMA's challenge was passed by the Maine legislature and signed into law in June 2003.[2] The UPDPA was self-described as intended to "establish ethical standards and disclosure requirements" for PBMs and address what the statute's sponsor termed "questionable practices," including conflicts of interest, side deals and undisclosed payments made to PBMs, failure to pass through discounts

to consumers, and drug switching.[3]

Under the UPDPA, the relationship between a PBM and its clients (eg, health plans or HMOs, referred to as "covered entities") is defined as a fiduciary one, whereby the PBM must perform its duties with due diligence as it would in a financial relationship.[4] The statute also prescribes that a PBM's duties with respect to covered entities are "for the primary purpose of providing benefits to covered individuals and defraying the reasonable expenses of administering health plans."[5] This fiduciary designation therefore imposes a high standard of performance on PBMs.

The statute creates various disclosure requirements for PBMs, including a duty to disclose any activities, policies, or practices that directly or indirectly present conflicts of interest; all financial and utilization information requested by a covered entity relating to the provision of benefits; and "all financial terms and arrangements for remuneration of any kind" between a PBM and a drug manufacturer or drug marketer. Such remuneration includes, without limitation, payments for formulary management and drug-switching programs, educational support and claims processing, and pharmacy network fees charged from retail pharmacies and data sales fees.[6]

PBM practices involving drug substitutions are restricted under the UPDPA. A PBM is prohibited from making a substitution when the cost of the drug to be substituted is higher than that of the prescribed drug, unless the substitution is made for medical reasons that benefit the covered person and the covered entity.[7] Before a substitution for medical reasons may be made, the PBM must obtain the approval of the prescribing health professional and disclose to both the covered person and covered entity the cost of both drugs and any resulting benefit or payment that would be received by the PBM. No restriction applies when the substitution involves a lower-priced drug (eg, a generic) for a higher-priced one.[8]

Any benefit or payment received by a PBM as a result of any drug substitution must be "transfer[red] in full" to the covered entity.[9] Moreover, any payment or benefit derived by a PBM for prescription drugs dispensed in the state based on volume of sales for certain drugs, classes, or brands similarly is required to be passed on "in full" to the covered entity.[10]

Failure by a PBM to comply with the UPDPA would constitute a violation of the Maine Unfair Trade Practices Act, which carries a maximum fine of

$10,000. The UPDPA was to apply to all PBMs that enter into management contracts with health plans and other covered entities in the state, effective September 13, 2003. However, enforcement of the statute has been temporarily blocked.

The Federal Court Ruling

Shortly before the UPDPA was to take effect, the PCMA filed suit on behalf of its membership (which includes Medco, AdvancePCS, Express Scripts, Inc, and Caremark Inc) to block the law's enforcement. While the lawsuit challenges the overall statutory scheme and scope of the state's regulation of PBMs, by far the most controversial element of the law was the required disclosure by PBMs of utilization and financial information, including the terms of financial arrangements with pharmaceutical manufacturers.

Regulatory "Taking" of Trade Secrets

The PCMA argued that the confidential terms of PBMs' contracts, as well as other financial and utilization information, constitute trade secrets from which the PBMs derive independent economic value. If information regarded as confidential, such as rebate data, were to become generally known, PBMs would be at a disadvantage in their ability to negotiate rebates and other discounts with drug manufacturers and pharmacies, the PCMA maintained. The economic value of the information would be destroyed upon dissemination. The court agreed that PBMs consider such information highly confidential and strive to maintain its secrecy and found that the PCMA met its initial burden of demonstrating that the information required to be disclosed under the UPDPA are trade secrets. (The court's conclusion on this and other issues were made only for purposes of its decision whether to temporarily bar enforcement of the UPDPA. The issues will be revisited when the court subsequently reviews the merits of the PCMA's challenge to the statute.)

On determining that the information held by PBMs are trade secrets, the court next reviewed whether the UPDPA's disclosure requirements constitute a regulatory taking of property, for which just compensation is due under the US Constitution. The court examined the economic impact of the disclosure requirements, whether the requirements would interfere with reasonable investment-backed expectations that the information at issue would not be disclosed, and the balance between the state's interest in regulation versus the PBMs' interest in protecting their trade

secrets.

The UPDPA contains 2 separate disclosure provisions. The first requires a PBM to disclose, at the request of a health plan or other covered entity with which it has a pharmaceutical management contract, all financial and utilization information relating to the services provided by the PBM to the covered entity or to the provision of benefits to covered persons. In addition, a covered entity that receives information under this provision is prohibited from disclosing any information designated as confidential by the PBM. The second provision requires a PBM to disclose to a covered entity "all financial terms and arrangements for remuneration of any kind" between the PBM and any pharmaceutical manufacturer or marketer.

With regard to the first disclosure provision, the court found the requirement sufficiently limited in scope so as not to constitute a taking of property. Moreover, because the provision prohibits a covered entity from disclosing any of the PBM's confidential information received, the court found that the provision likely would sustain a constitutional challenge. In contrast, the court took issue with the statute's second, seemingly broader disclosure provision. Unlike the first provision, this particular disclosure requirement fails to protect against further dissemination of information that "goes to the heart" of what the PBMs contend are trade secrets. The court agreed with the PCMA that PBMs have reasonable investor-backed expectations that their trade secrets would not be subject to "untrammeled and unprotected disclosure."

In balancing the economic interest of the PBMs with the state's interest in regulating public health, the court favored the PBMs. The court weighed the potentially significant economic consequences to the PBMs of unprotected disclosure against the benefits of disclosure, benefits that the PBMs contend are only speculative. Based on the factors before it, the court ruled that the PCMA adequately demonstrated that the UPDPA violates the Takings Clause of the US Constitution. (The court disagreed with the PCMA's other constitutionality argument that the UPDPA violates the Commerce Clause. The court concluded that because the UPDPA's disclosure requirements only applied to PBM contracts that were entered into in the state of Maine, the UPDPA did not impermissibly affect out-of-state commerce. The court also determined that the UPDPA on its face did not discriminate against out-of-state commerce.)

Preemption by ERISA

The other basis of the court's decision to temporarily bar enforcement of

the UPDPA was the statute's apparent conflict with federal ERISA policy and regulation of employee welfare benefit plans. Under ERISA, Congress set forth a single uniform federal scheme for governing the operation and administration of employee benefit plans.[11] Among its many purposes, such uniformity was intended to avoid a multiplicity of regulation and conflict in law between federal and state regulatory systems. The PCMA argued that the new and broad regulations imposed by UPDPA relate to employee benefit plans, a regulatory field that is exclusively a federal concern under ERISA. In addition, the PCMA argued that the UPDPA undermines the exclusivity of ERISA's civil enforcement scheme.

The court examined the restrictions and requirements imposed on PBMs by the UPDPA and raised a number of concerns about the potential controversies that may arise. In particular, the court identified an "inherent conflict" between a PBM's fiduciary duties to a covered entity and the interests of patients, for example, with respect to drug substitutions. The statute requires that a substitution involving a more expensive drug be made for medical reasons that benefit the patient and the covered entity. The court believed that the UPDPA's various notice and enforcement provisions "virtually invite litigation" over such situations, among many others. The court thus concluded that the potential issues—fiduciary duty, financial interest, medical necessity, and coverage—that would arise under the UPDPA, as well as the statute's enforcement mechanisms, "intrude too far into the ambit of federal regulation of health benefits by ERISA plans."

The UPDPA was also found to have an impermissible "reference to" ERISA plans. In evaluating the impact of the state statute on ERISA plans, the court noted that the large number of persons in Maine who are served by PBMs—and therefore considered covered under the UPDPA—receive drug benefits pursuant to ERISA-regulated employee welfare benefit plans. The regulatory scheme set forth in the UPDPA is similar to that of ERISA's, which also is premised on defining and imposing fiduciary duties and penalizing noncompliance. Even the definitions used in the UPDPA are similar to ERISA terminology. In the court's view, the UPDPA is a state attempt at mimicking ERISA's regulatory scheme with respect to "an emerging and important player" that is not currently regulated by ERISA. The court found this problematic in light of the national impact and significant economic weight of the PBM industry, its centrality in the delivery and cost of health care benefits, and the vital nature of the health care benefits that the PBM industry affects.

Based on what it viewed as the profound impact of the UPDPA on ERISA plans and the ERISA regulatory and enforcement scheme, the court concluded that the PCMA demonstrated a substantial likelihood of success in its argument that Maine's statute was preempted by ERISA.

Implications for Future State Regulation of PBMs

Maine's UPDPA is the first statute of its kind in the extent to which it seeks to regulate PBMs. The impetus for the UPDPA was the state legislature's perception that the PBM industry operates in a largely insulated and unregulated environment that garners enormous profits at the expense of consumers. This perception likely is shared by a growing number of states considering some form of PBM regulation. Last year, 22 states introduced bills to regulate PBMs, compared with 8 states in 2002.[12] The final outcome of the UPDPA will affect whether similar state regulation will follow. However, even if states ultimately are preempted by ERISA from regulating PBMs, the void eventually may be filled by specific federal oversight in this area.

References

1. Pharmaceutical Care Management Association v Rowe, Civ 03-153-B-W (D Me) March 9, 2004. Available at: www.med.uscourts.gov/site/opinions/woodcock/2004/jaw_03092004_1-03cv153_pharma_v_rowe.pdf. Accessed April 1, 2004.
2. c456 A7(LD 554) (2003) (codified at 22 MRSA A72699).
3. Testimony of Sharon Anglin Treat, Maine Senate Majority Leader, March 24, 2003. Available at: www.mainesenate.org/Press/2003-03-24%20LD%20554%20Unfair%20Prescription%20Drug%20Practices.html. Accessed April 1, 2004.
4. 22 MRSA A72699(2)(A) (2004).
5. 22 MRSA A72699(2)(B) (2004).
6. 22 MRSA A72699(2)(C), (D), (G) (2004).
7. 22 MRSA A72699(2)(E)(2) (2004).
8. 22 MRSA A72699(2)(E)(1) (2004).
9. 22 MRSA A72699(2)(E)(3) (2004).
10. 22 MRSA A72699(2)(F) (2004).
11. 29 USC A71001 et seq.
12. Brierton J. Regulation of Pharmacy Benefit Managers.

Connecticut General Assembly, Office of Legislative Research; Hartford, Conn. January 15, 2004. Available at: www.cga.state.ct.us/2004/rpt/2004-R-0071.htm. Accessed April 1, 2004.

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NEWS FROM MAINE
ATTORNEY GENERAL STEVEN ROWE

ANOTHER MAINE PRESCRIPTION DRUG LAW SURVIVES INDUSTRY CHALLENGE

Magistrate says State can cut through PBM "layer of fog."

http://www.med.uscourts.gov/Opinions/Kravchuk/2005/MJK_02022005_1-03cv153_PCMA_v_Rowe.pdf

FEBRUARY 3, 2005

CHARLES DOW, DIRECTOR, COMMUNICATIONS & LEGISLATIVE AFFAIRS, 207-626-8577

Attorney General Steven Rowe announced today that U.S. Magistrate Judge Margaret Kravchuk has handed Maine a win in a recommended decision in the case challenging Maine's Unfair Prescription Drug Practices Act (UPDPA). The decision recommends that the U.S. District Court for Maine grant the Attorney General's motion for summary judgment and deny the motion for summary judgment filed by the Pharmaceutical Care Management Association (PCMA), the national trade association representing pharmaceutical benefits management companies (PBMs). PCMA sued Attorney General Rowe in 2003 alleging that the UPDPA is preempted by federal law; that it would effect a regulatory taking of trade secrets, revenues, and contractual rights; that it violates PBMs' civil rights; and that it is unconstitutional for violations of due process, the Commerce Clause, and freedom of speech. Yesterday, after more than a year of intense litigation between industry lawyers and the Attorney General's Office, U.S. Magistrate Margaret Kravchuk found in favor of the Attorney General on all claims.

The UPDPA requires PBMs to disclose to health plans any conflicts of interest, side payments from drug companies, and details about drug switching programs. These requirements are described generally as promoting "transparency" in the PBM industry, that is, they allow the health plan clients of PBMs to see through the otherwise secret arrangements that PBMs had with other market players. Yesterday's decision summarized the PBM industry in these words: "[A]lthough PBMs afford a valuable bundle of services to benefits providers, they also introduce a layer of fog to the market that prevents benefits managers from fully understanding how best to minimize their net prescription drug costs." (at page 5)

Attorney General Rowe said, "The persistence and patience of Maine people have been rewarded for the second time in a week. Last Friday's favorable decision on Maine Rx Plus and yesterday's decision on the Unfair Prescription Drug Practices Act both vindicate our long-standing support for efforts to reduce prescription drug prices. Maine leads the nation in these efforts. Maine people know that the first person down a trail has to expect to clear a few trees. I'm thrilled to report that we *are* clearing the trees laid in the trail by the drug industry and that the trail *does* lead to lower prices for prescription drugs. Thanks to all people of Maine who stand behind us in this important work."

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Close Window

UNITED STATES DISTRICT COURT

DISTRICT OF MAINE

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION, Plaintiff, v. G. STEVEN ROWE, IN HIS OFFICIAL CAPACITY AS ATTORNEY GENERAL OF THE STATE OF MAINE, Defendant.	)	Civil No. 03-153-B-H

RECOMMENDED DECISION ON CROSS-MOTIONS FOR SUMMARY JUDGMENT

The plaintiff, Pharmaceutical Care Management Association (PCMA), is a national trade association representing pharmaceutical benefits management companies (PBMs).[1] PCMA brings this action on behalf of its members to obtain an order enjoining enforcement of Maine's Unfair Prescription Drug Practices Act (UPDPA), as amended, 22 M.R.S.A. § 2699. According to PCMA's complaint, the UPDPA may not be enforced because it, by count:

(1) is preempted by the Employee Retirement Income Security Act;

(2) is preempted by the Federal Employee Health Benefits Act;

(3) would effect a regulatory taking of industry trade secrets;

(4) would effect a regulatory taking of revenues and other contractual rights and violates Due Process;

(5) violates the Contracts Clause;

(6) violates the Commerce Clause;

[1] (Docket No. 94, ¶ 1.)

(7) violates free speech rights; and

(8) subjects PCMA's members to the deprivation of "rights, privileges and immunities secured by the Constitution," in violation of 42 U.S.C. § 1983.

Now before the court are cross-motions for summary judgment. In its motion, PCMA moves the court to enter summary judgment against the Maine Attorney General with respect only to its ERISA preemption claim and takings claim. (Docket No. 85.) In his motion, the Attorney General moves the court to enter summary judgment against all of PCMA's claims, with the exception of the claims related to takings of revenues and other contractual rights and alleged violation of the Contracts Clause (counts 4 and 5), both of which have been waived by PCMA. (Docket No. 88.) I recommend that the court enter summary judgment in favor of the Attorney General on all claims.

FACTS[2]

PCMA is a national trade association representing PBMs. (Docket No. 104, ¶ 1.) The parties are in agreement that it is the business of PBMs to act as transactional intermediaries or "middlemen" in the multi-billion dollar trade in prescription drugs. Among their customers are insurance companies, health maintenance organizations and private and public health plans and programs (collectively, what I will call 'benefits providers"), including employee benefit plans subject to the Employee Retirement Income Security Act (ERISA), 29 U.S.C. §§ 1001-1461. Generally speaking, the services that PBMs extend to these benefits providers are designed to facilitate the provision of prescription drug benefits to the benefits providers' insureds, participants or subscribers. For example, a PBM might provide its benefits provider customers with access to an established network of pharmacies, including mail order pharmacies, or with

[2] The facts set forth herein are drawn from the parties' Local Rule 56 statements of material facts in accordance with the local rule.

certain formulary services, all of which permit the benefits provider customers to obtain drugs at established prices.[3] (Docket No. 94, ¶ 4; Docket No. 89, ¶ 164.) Conceptually, by pooling the prescription drug purchasing power of a number of benefits providers, a PBM can negotiate substantial volume discounts and rebates from drug manufacturers and pharmacies, and thereby not only provide its customers with savings on prescription drugs and other pharmaceutical products, but also ensure a profit for itself and its shareholders or stakeholders. (Docket No. 89, ¶ 165; Docket No. 94, ¶ 4; Docket No. 101, ¶ 4.) Additional services that a PBM might extend to a benefits provider include "drug utilization review services" and "therapeutic interchange programs." (Docket No. 94, ¶ 4.)

As intermediaries, PBMs provide services to pharmacies and drug manufacturers (the supply-side of the trade) as well as to benefits providers (the demand side of the trade). (Docket No. 89, ¶¶ 8-20.) In particular, when it comes to drug utilization services and therapeutic interchange programs, PBMs are as apt to be serving pharmacies and manufacturers as health benefits providers. For example, "therapeutic interchange" refers to the practice of substituting a drug for the one actually prescribed by a doctor. This may involve substituting an equally efficacious and cheaper generic drug for a brand name drug, which might benefit a provider. On the other hand, the practice may involve substituting a more expensive brand name drug for the benefit of the manufacturer, a pharmacy and/or the PBM. Thus, for instance, a brand name drug might be substituted so that a pharmacy or PBM can obtain a "reward" or "incentive" from the manufacturer for helping increase the manufacturer's market share within a certain drug category. (Docket No. 89, ¶¶ 37-38, 42-44, 83.) Similarly, a PBM might be paid a rebate or fee by a drug manufacturer in exchange for including a drug on the PBM's formulary or for

[3] Except when operating mail order pharmacies, PBM's do not actually acquire or handle prescription drugs. (Docket No. 89, ¶ 166.)

"featuring" or "preferring" that drug, sometimes to the exclusion of others. (Docket No. 89, ¶¶ 12, 39-41.)

Whether and how a PBM actually saves an individual benefits provider customer money with respect to the purchase of a particular prescription drug is largely a mystery to the benefits provider. To illustrate the concern raised by the lack of transparency that typifies the PBMs' dealings with drug manufacturers and pharmacies, the Attorney General offers expert testimony from Stephen W. Schondelmeyer, a professor at the University of Minnesota's College of Pharmacy. (Id., ¶ 123-125.) I credit this testimony, over PCMA's foundation objection. The objection is not briefed and the foundation objection was not preserved during the deposition questioning, which was conducted by PCMA's counsel. According to Professor Schondelmeyer, it is difficult for a benefits provider to know whether it is getting a lower net cost for a drug received through a PBM due to a lack of transparency in the PBM market. (Id., ¶ 124, citing Ex. O at 52.) For instance, if a drug manufacturer provides a higher rebate to a PBM on a $100 drug than it does on a $20 drug and the PBM shares the rebate with the benefits provider, it may appear to the benefits provider as though it is saving money. However, it is just as likely that the amount of rebate received by the benefits provider does not make up for the higher base price of the more expensive drug, so that the net economic effect to the benefits provider is a loss. (Id., ¶ 123, citing Schondelmeyer Deposition, Exhibit O, at 50-51.) This lack of transparency also has a tendency to undermine a benefits provider's ability to determine which is the best proposal among competing proposals from PBMs. For example, if a benefits provider had proposals from three different PBMs for pharmacy benefits management services, each guaranteeing a particular dollar amount of rebate per prescription, the PBM proposal offering the highest rebate for each prescription filled could actually be the worst proposal as far as net cost savings are concerned,

because that PBM might have a deal with the manufacturer that gives it an incentive to sell, or restrict its formulary to, the most expensive drugs. (Id., ¶ 125, citing Ex. O at 58.) In other words, although PBMs afford a valuable bundle of services to benefits providers, they also introduce a layer of fog to the market that prevents benefits providers from fully understanding how best to minimize their net prescription drug costs.

In an effort to help control prescription drug costs and increase public access to prescription drugs (Docket No. 94, ¶ 17), the Maine Legislature enacted into law what is now known either as "An Act to Protect Against Unfair Prescription Drug Practices" or the "Unfair Prescription Drug Practices Act," 22 M.R.S.A. § 2699 (UPDPA). The UPDPA regulates "pharmacy benefit managers" (PBMs) and "contracts for pharmacy benefits management." Id.[4] The UPDPA imposes on PBMs certain fiduciary duties and "required practices," which duties and obligations are owed to the PBMs' benefits provider customers, whom the UPDPA labels "covered entities." Id., § 2699(1)(A) & (2)(A). Among other duties, the UPDPA requires that PBMs "shall notify the covered entity in writing of any activity, policy or practice of the pharmacy benefits manager that directly or indirectly presents any conflict of interest with the

[4] The UPDPA defines pharmacy benefit management as follows:

> E. "Pharmacy benefits management" means the procurement of prescription drugs at a negotiated rate for dispensation within this State to covered individuals, the administration or management of prescription drug benefits provided by a covered entity for the benefit of covered individuals or any of the following services provided with regard to the administration of pharmacy benefits:
>
> 1) Mail service pharmacy;
>
> 2) Claims processing, retail network management and payment of claims to pharmacies for prescription drugs dispensed to covered individuals;
>
> 3) Clinical formulary development and management services;
>
> 4) Rebate contracting and administration;
>
> 5) Certain patient compliance, therapeutic intervention and generic substitution programs; and
>
> 6) Disease management programs.

22 M.R.S.A. § 2699(1)(E).

duties imposed by this subsection." Id., § 2699(2)(C). The UPDPA also compels PBMs to disclose the following information to covered entities:

> (1) "[A]ll financial and utilization information requested by the covered entity relating to the provision of benefits to covered individuals through that covered entity and all financial and utilization information relating to services to that covered entity," id., § 2699(2)(D);
>
> (2) "[T]he cost of both drugs and any benefit or payment directly or indirectly accruing to the pharmacy benefits manager as a result of the substitution," in the event that the PBM "makes a substitution in which the substitute drug costs more than the prescribed drug," id., § 2699(2)(E)(2); and
>
> (3) "[A]ll financial terms and arrangements for remuneration of any kind that apply between the pharmacy benefits manager and any prescription drug manufacturer or labeler, including, without limitation, formulary management and drug-switch programs, educational support, claims processing and pharmacy network fees that are charged from retail pharmacies and data sales fees," id., § 2699(2)(G).

The first category of information need be disclosed only upon request by a covered entity. Id., § 2699(2)(D). The latter two categories of information must be disclosed even in the absence of a request. Id., § 2699(2)(E)(2) & (2)(G). In the event of any disclosure under the first or third category, the PBM may designate the information disclosed as confidential. Id., § 2699(2)(D) & (2)(G). "Information designated as confidential by a pharmacy benefits manager and provided to a covered entity . . . may not be disclosed by the covered entity to any person without the consent of the pharmacy benefits manager" or in the absence of a court order or an investigative demand made by the Attorney General in an effort to police compliance with the UPDPA. Id. A violation of the UPDPA "is a violation of the Maine Unfair Trade Practices Act, for which a fine of not more than $10,000 may be adjudged." Id., § 2699(4). In addition to compelling the disclosure of such information, the UPDPA requires PBMs to pass on, in full, to covered entities "any payment or benefit" that is received "based on volume of sales for certain prescription drugs or classes or brands of drugs within the State," id., § 2699(2)(F), as well as for drug substitution,

including substitution of "a lower-priced generic and therapeutically equivalent drug for a higher-priced prescribed drug," id.,§ 2699(2)(E)(3).

In support of its regulatory takings claim, PCMA offers evidence relating to four (now three through a merger or other combination) of its ten PBM members (a small sample in a market occupied by 40-50 PBMs). Those members are Express Scripts, Inc., Medco Health Solutions, Inc., and Caremark Rx, Inc. (Docket No. 94, ¶ 2.) To illustrate the confidentiality of PBM contracts and the uniqueness of each PBM's contract with a given manufacturer or pharmacy, PCMA even more narrowly offers a contract from each of its three representative PBMs, all of which contracts were entered into with one manufacturer, Pfizer, in either 2003 or 2004. (Id., ¶ 20.) Relying on this evidence, PCMA maintains that the terms of all PBMs' agreements with pharmacies and drug manufacturers constitute trade secrets, the forced disclosure of which would constitute a regulatory taking of the PBMs' property. In my view, it is impossible for the court to make a finding as to the practices of the entire PBM market when it comes to keeping secret the terms of agreements with pharmacies and manufacturers based on this limited evidence.[5] However, the Attorney General appears willing to concede that contracts between PBMs and pharmacies or manufacturers generally include provisions that are designed to avoid transparency, so that the PBMs' provider customers are incapable of ascertaining the full extent of the discounts, rebates and drug substitution incentives PBMs negotiate or otherwise obtain and, by extension, the extent to which PBMs retain or generate revenues from discounts, rebate and drug substitutions above and beyond what they pass through to their benefits provider customers in the way of savings. (Docket No. 94, ¶ 18; Docket No. 101, ¶ 18.) According to

[5] The Attorney General asserts in his statement of material facts, and PCMA admits, that PCMA maintains that the discovery of trade secret information from all of PCMA's members was not relevant to the claims or defenses of any party and that PCMA objected to any discovery beyond information related to its three member representatives (Medco, Caremark and ESI). (Docket No. 104, ¶¶ 172-174.)

PCMA, confidentiality provisions in such contracts are also designed to ensure competition and prevent one PBM from learning about another PBM's "unique" agreement with a given manufacturer or pharmacy. (Docket No. 94, ¶ 20.) That any given manufacturer or pharmacy actually preserves the secrecy of one PBM's contract terms when dealing with another PBM is something the court is apparently supposed to assume. PCMA offers only that PBMs endeavor to maintain the secrecy of their agreements. (Docket No. 94, ¶¶ 6-8.)

PCMA offers additional statements that are designed to have the court enter a finding that enforcement of the UPDPA would either destroy competition among PBMs in the marketplace or else enable the PBMs' larger benefits provider customers to essentially cut the PBMs out of the market and deal directly with the pharmacies and manufacturers. (Id., ¶ 19.) In addition, PCMA would have the court find, as a material fact, that "PBMs are likely to cease doing business in Maine and with Maine covered entities to the extent necessary to avoid application of the UPDPA." (Id., ¶ 23.) As to the likely implications of the UPDPA on the PBM market, the Attorney General offers numerous statements designed to support a finding that entrance into the PBM market is not as simple as knowing a PBM's drug costs, financial and utilization data and how it arranges for direct remuneration from manufacturers and pharmacies for the services it provides. (Docket No. 89, ¶¶ 26-34.) Moreover, there is a contract in the record that expressly prohibits the manufacturer from entering into rebate agreements directly with the PBMs' benefits provider customers. (Docket No. 89, ¶ 86.) On the issue of market impact, neither party has marshaled the kind of evidence that would reliably, in PCMA's words, "speak to the ability [let alone the likelihood] of any individual plan, employer or other PBM customer to self-provide or provide to others certain PBM services." (Docket No. 104, ¶¶ 26-34.) As to the admonition that PBMs are "likely" to withdraw from the Maine market, I make no finding. The statement

offered by PCMA is inherently speculative and, in the context of PCMA's motion for summary judgment, the court is constrained to infer that any given PBM is equally likely not to withdraw from the market. Moreover, although disputed by the Attorney General, this is not the sort of fact that is readily susceptible to trial on the merits or, for that matter, even material to the disposition of this motion. For the same reason, I decline to make any finding on broader health care policy questions or, with respect to competing expert opinions, on the UPDPA's likely impact on the prescription drug market in Maine. (See, e.g., Docket No. 89, ¶¶ 118, 123-130, 170; Docket No. 104, ¶¶ 118, 123-130, 170; Docket No. 94, ¶ 19 (last sentence), ¶ 20 (last paragraph) & ¶¶ 21-22; Docket No. 101, ¶¶ 19-22.)

PCMA's member PBMs do not exercise any discretionary authority or discretionary control respecting the management of employee benefit plans. (Docket No. 89, ¶ 159.) PCMA's member PBMs do not exercise any discretionary authority or discretionary control respecting management or disposition of the assets of employee welfare benefit plans. (Id., ¶ 160.) PCMA's member PBMs do not have any discretionary authority or discretionary responsibility in the administration of employee welfare benefit plans. (Id., ¶ 161.) PCMA's member PBMs are not ERISA fiduciaries. (Id., ¶ 162.) PBMs enter contracts with drug manufacturers that require the manufacturers to supply drugs to the PBMs' benefits provider customers. (Id., ¶ 163; Docket No. 104, ¶ 163.) PBMs enter contracts with pharmacies whereby the pharmacies agree to charge certain prices to the customers of the PBM. (Docket No. 89, ¶ 164.) PBMs enter contracts with health plans that allow the health plans' members to obtain drugs at certain prices and that provide financial rebates to the health plans based on volume of utilization. (Id., ¶ 165.) Except when operating mail order pharmacies, PBMs do not actually acquire or handle prescription drugs. (Id., ¶ 166.) PBMs do not make final determinations of whether health plan

members are entitled to receive drug benefits under the plan. (Id., ¶ 167.) PBMs may perform ministerial tasks associated with the processing of drug claims under a health plan. (Id., ¶ 168.)

Facts Submitted Under Seal[6]

[6] I have included this portion of the facts separately because the documents from which these facts are drawn are confidential business records that were filed under seal. I have placed these material facts under seal until such time as the court has an opportunity to rule upon any objections to this recommended decision. I would recommend that this section be unsealed after review by the court.

DISCUSSION

I. ERISA Preemption

In its motion for summary judgment, PCMA maintains that the UPDPA is preempted by ERISA because it "attempts to dictate the terms under which . . . ERISA plans and their sponsors may contract with PBMs to administer [prescription drug benefit] programs and to define the duties and liabilities of PBMs to such plans, their sponsors and participants." (Docket No. 85 at 4.) According to PCMA, the UPDPA undermines the congressional goal of "establishing a uniform regulatory scheme" (Id. at 7) because it adds an additional layer of regulation to important administrative functions that PBMs perform for, among other entities, ERISA plans and plan sponsors (Id. at 6-7) and because it would afford plans and plan sponsors rights and remedies against PBMs that Congress did not speak of in ERISA (Id. at 11). For his part, the Attorney General argues that the UPDPA is not preempted because it applies to all entities providing pharmacy benefit management services in Maine, regardless of whether such benefits arise out of a plan subject to ERISA (Docket No. 88 at 9), because PBMs are not ERISA fiduciaries or entities (which the Attorney General refers to as "primary" ERISA entities) and because the only burdens the UPDPA imposes fall on PBMs, whom the Attorney General describes as "merely third-party service providers," rather than on any ERISA fiduciary or entity (Id. at 10). According to the Attorney General, acceptance of PCMA's logic would mean that ERISA preemption would foreclose state regulation of any service enterprise that is necessary to the provision of ERISA benefits (such as medical, legal, and accounting services), even though the market for such services extends beyond the ERISA universe. (Id. at 12-13.)

Both parties analyze the preemption issue through the three lenses prescribed by the Supreme Court: (1) whether the UPDPA has a "connection with" an ERISA plan or plans; (2)

whether the UPDPA "refers to" an ERISA plan or plans; and (3) whether the UPDPA's remedial scheme conflicts with the "exclusive" remedial scheme set forth by Congress in ERISA. See Carpenters Local Union No. 26 v. United States Fid. & Guar. Co., 215 F.3d 136, 139-40 (1st Cir. 2000) (outlining the development of ERISA preemption doctrine based on the Supreme Court's interpretation of the "relates to" language of ERISA § 1144(a)); Hampers v. W.R. Grace & Co., 202 F.3d 44, 49-51 (1st Cir. 2000) (discussing circumstances in which a state law cause of action may be deemed to impermissibly conflict with ERISA's exclusive remedial scheme). I follow their lead.

A. "Connection with"

Whether a state law is preempted by ERISA by virtue of an impermissible connection with an ERISA plan or ERISA plans, is determined by judicial interpretation of congressional intent. New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 656-57 (1995). Essentially, the inquiry is whether a state law would interfere with the congressional purpose to "avoid a multiplicity of regulation in order to permit the nationally uniform administration of employee benefit plans." Id. at 657. Thus, state laws that prescribe specific benefits that an employee benefit plan must afford are preempted, as are state laws that restrict the ability of an employee benefit plan to use or enforce terms in plans or plan documents or state laws that would prevent plans from using a uniform set of rules or formulae for computing benefits. See id. at 657-58 (discussing the holding of Shaw v. Delta Air Lines, Inc., 463 U.S. 85 (1983), and FMC Corp. v. Holliday, 498 U.S. 52 (1990)). In such cases, state laws are said to be preempted because they "mandate[] employee benefit structures or their administration." Id. at 658. In contrast to such cases are state laws that would impose an indirect cost on plan administration in a given state, but would in no way circumscribe the ability of plan

administrators to structure or administer their ERISA plans in that state. Id. at 658-59. Thus, in Travelers, the Supreme Court held that a New York law that "requires hospitals to collect surcharges from patients covered by a commercial insurer" and that "subjects certain health maintenance organizations (HMO's) to surcharges that vary with the number of Medicaid recipients each enrolls," id. at 649, does not have an impermissible connection with ERISA because the law "does not bind plan administrators to any particular choice and thus function as a regulation of an ERISA plan itself" and does not "preclude uniform administrative practice or the provision of a uniform interstate benefit package if a plan wishes to provide one." Id. at 659. In concluding on the issue, the Court observed:

> In sum, cost uniformity was almost certainly not an object of preemption, just as laws with only an indirect economic effect on the relative costs of various health insurance packages in a given State are a far cry from those "conflicting directives" from which Congress meant to insulate ERISA plans. See [Ingersoll-Rand Co. v. McClendon, 498 U.S. 133, 142 (1990)]. Such state laws leave plan administrators right where they would be in any case, with the responsibility to choose the best overall coverage for the money. We therefore conclude that such state laws do not bear the requisite "connection with" ERISA plans to trigger pre-emption.

Id. at 662.

The question presented by the instant litigation is whether the UPDPA, in placing fiduciary duties and administrative burdens on PBMs operating in Maine, thereby precludes the ability of employee bene fit plan administrators to administer their plans in a uniform fashion. PCMA contends that it does because it: "attempts to dictate the terms" of contracts between ERISA plans and PBMs, including by redefining the "duties and liabilities of PBMs to such plans, their sponsors and participants" (Docket No. 85 at 4); "attempt[s] to regulate [plans'] relationship[s] with PBMs when PBMs perform administrative functions for such plans" (Id. at 6); and "attempt[s] to supplement ERISA's fiduciary duty and disclosure provisions" so that plan

administrators cannot "predict the legality of proposed actions without the necessity of reference to varying state laws" (Id. at 7, citation omitted). The Attorney General rejects these arguments. According to him, the UPDPA does not undermine the congressional goal of uniform plan structure and administration because it does not mandate benefits and because PBMs are not ERISA entities. (Docket No. 88 at 10.) I agree with the Attorney General on this issue.

The UPDPA imposes fiduciary and reporting obligations exclusively on PBMs, not on plans, plan sponsors or plan participants and their beneficiaries.[7] And with respect to the provision of prescription drug benefits by employee benefit plans, the UPDPA "does not bind plan administrators to any particular choice and thus function as a regulation of an ERISA plan itself" and does not "preclude uniform administrative practice or the provision of a uniform interstate benefit package if a plan wishes to provide one." Id. at 659. The fact that the UPDPA requires PBMs to engage in certain "required practices" in Maine, such as divulging the terms of contracts with pharmaceutical manufacturers and labelers does not restrict the freedom of employee benefit plans to administer or structure their plans in Maine precisely as they would elsewhere. Nor does it obligate any plan to act upon, or even consider, any of the information that might be disclosed pursuant to the operation of the UPDPA. Because the UPDPA leaves ERISA plans, sponsors, participants, beneficiaries, and the duties and obligations running among them untouched, and because the record does not permit the court to ascertain whether or in what ways the UPDPA would require employee benefit plans to implement unique measures in Maine in connection with plan structure or administration, I conclude that the UPDPA does not have an impermissible "connection with" ERISA plans or plan administration.

[7] PCMA dismisses any suggestion that PBMs serve as ERISA fiduciaries in the performance of their services. (Docket No. 104, ¶¶ 159-162; see also Docket No. 85 at 4, 6-7, 13.)

B. "Reference to"

A state law is preempted by ERISA by virtue of an impermissible "reference to" an ERISA plan "where a State's law acts immediately and exclusively upon ERISA plans . . . or where the existence of ERISA plans is essential to the law's operation." Cal. Div. of Labor Standards Enforcement v. Dillingham Constr., 519 U.S. 316, 325 (1997). See also Carpenters Local, 215 F.3d at 143. PCMA argues that the "reference to" test is met here because the UPDPA "purports to regulate the relationship between health benefit plans, plan sponsors and PBMs . . .[,] relationships that cannot exist without the plans themselves." (Docket No. 85 at 9.) In addition, PCMA argues that the UPDPA impermissibly refers to ERISA because "[a]ll of these provisions depend on the existence of health benefit plans." (Id. at 10.) The Attorney General argues that the Dillingham standard makes the "refers to" issue an easy one to call because the obligations imposed on PBMs under the UPDPA apply irrespective of whether PBMs are serving ERISA plans. (Docket No. 88 at 8.) I conclude that the UPDPA does not impermissibly refer to an ERISA plan or plans because it applies with respect to pharmacy benefits management services supplied to a broad spectrum of health care institutions and health care benefits providers, including but not limited to employee benefit plans, see 22 M.R.S.A. § 2699(1)(A),(B) & (E), and, therefore, neither acts immediately and exclusively upon ERISA plans nor depends on the existence of ERISA plans in order to have meaning. PCMA's invocation of District of Columbia v. Greater Washington Board of Trade, 506 U.S. 125 (1992), does not dissuade me from this conclusion. In that case, the Supreme Court affirmed a finding that ERISA preempted a singular section of a District of Columbia workers' compensation amendment that required employers providing health insurance coverage to their workers to obtain insurance that would extend health insurance coverage for up to 52 weeks while a worker

was receiving workers' compensation benefits. Id. at 128. The statute thus exclusively concerned employee benefits (the District of Columbia did not even contest that the statute related to ERISA) and also mandated specific benefits. See id. at 130 (finding that the only health insurance programs the statute applied to were ones "subject to ERISA regulation"). The same distinction is applicable to the statute at issue in Mackey v. Lanier Collection Agency & Service, Inc., the other opinion primarily relied upon by PCMA in support of its position. See 486 U.S. 825, 829 (1988) ("The Georgia statute at issue here expressly refers to—indeed, solely applies to—ERISA employee benefit plans."). The UPDPA is not of the same species.

C. Remedial conflict

In addition to impermissible connections and references, a third category of ERISA preemption applies to state laws that would have the effect of affording to an ERISA entity, most commonly an ERISA beneficiary, an "alternative enforcement mechanism [or] remedy for the violation of a right expressly guaranteed and exclusively enforced by the ERISA statute." Carpenters Local, 215 F.3d at 141 (citing Ingersoll-Rand v. McClendon, 498 U.S. 133, 145 (1990)). Preemption of this sort does not extend to state laws that merely "touch upon enforcement but have no real bearing on the intricate web of relationships among the principal players in the ERISA scenario (e.g., the plan, the administrators, the fiduciaries, the beneficiaries, and the employer)." Id. (citing Woodworker's Supply, Inc. v. Principal Mut. Life Ins. Co., 170 F.3d 985, 990 (10th Cir. 1999)).

PCMA argues that the UPDPA runs afoul of the exclusive enforcement/remedy test because it "purports to create a new fiduciary breach cause of action against a specific category of ERISA plan service provider," when no ERISA remedy would be afforded against [them] under ERISA. (Docket No. 85 at 13.) For his part, the Attorney General argues that conflict

preemption does not arise because the UPDPA has "no real bearing on the intricate web of relationships among the principal players in the ERISA scenario" and because "PCMA's member PBMs are not ERISA fiduciaries." (Docket No. 88 at 15.) I agree with the Attorney General that the UPDPA does not impermissibly intrude upon the remedial scheme Congress devised to govern the relationships among ERISA entities. Although ERISA prescribes the duties that are owed by ERISA entities to one another, and prescribes remedies for their breach, it is not designed to regulate or afford remedies against entities that provide services to plans. Furthermore, PCMA has failed to present any set of circumstances in which enforcement of the UPDPA's "required practices" against a PBM would undercut ERISA's civil enforcement scheme. Finally, it seems to me that there is no logical basis to infer that Congress intended for ERISA to foreclose state regulation of third-party pharmacy benefits management services engaged in by non-ERISA fiduciaries or to preclude ERISA plans from employing state-created remedies against PBMs on an equal footing with other consumers of such services.

II. FEHBA Preemption

PCMA maintains that the UPDPA is preempted by the Federal Employee Health Benefits Act (FEHBA). (Docket No. 85 at 14-15.) The Attorney General argues that it is not. (Docket No. 88 at 16-18.) Both agree that whether the FEHBA preempts the UPDPA depends on essentially the same analysis as the question of whether ERISA preempts the UPDPA. (Docket No. 85 at 15; Docket No. 88 at 18.) Based on the parties' concessions that the analysis would be redundant, I conclude that the FEHBA does not preempt the UPDPA for the same reasons I set forth with regard to ERISA preemption.

III. Regulatory Taking

According to PCMA, information concerning the discounts and other contract terms that PBMs are able to negotiate with drug manufacturers and pharmacies are "classic trade secrets." (Docket No. 85 at 19.) Because the UPDPA requires PBMs to disclose these trade secrets to their benefits provider customers in Maine, PCMA contends that the UPDPA requires PBMs to surrender trade secrets as a condition of doing business in Maine. (Docket No. 85 at 18-19.) For his part, the Attorney General does not categorically argue that information and terms developed through contract negotiations are never trade secrets.[8] Instead, the Attorney General argues that PCMA's takings claim is misconceived at a fundamental, jurisdictional level because it seeks injunctive relief rather than just compensation. (Docket No. 88 at 20-26.) On a somewhat related note, the Attorney General argues that whether or not a trade secret exists or is taken depends on a number of individualized findings that cannot be made in the context of a lawsuit brought by a trade association, as opposed to a lawsuit brought by one or more PBMs individually. (Docket No. 88 at 19-32; Docket No. 100 at 8-10.) In addition to this concern over PCMA's associational standing to pursue its takings claim, the Attorney General argues that PCMA's facial challenge to the constitutionality of the UPDPA cannot succeed because PCMA cannot prove that there is no set of circumstances under which the UPDPA would be valid – because PCMA has offered evidence pertaining only to three existing PBMs and because that evidence suggests that the information that would be disclosed under the UPDPA is not always secret. (Docket No. 88 at 32-33; Docket No. 100 at 9-10.) Finally, the Attorney General argues that the confidentiality protections afforded by the UPDPA "inoculate" the disclosure provisions. (Docket No. 88 at 33-42.) Before addressing the merits of the takings claim, I pause to address the jurisdictional and prudential concerns raised by the Attorney General.

[8] The Attorney General does not concede that they are, either. (Docket No. 88 at 33 n.15.)

A. Ripeness

The Attorney General contends that this court does not have jurisdiction to enjoin enforcement of the UPDPA before there has been an effort to enforce it against a PBM or, at least, before a PBM can demonstrate that state law remedies are inadequate to redress any alleged injury to the PBM's interests in its trade secrets. (Docket No. 88 at 20-26.) As the court observed in its order granting preliminary injunctive relief, the current controversy is ripe for adjudication because PCMA brings a "facial" takings claim rather than an "as applied" takings claim. Pharm. Care Mgmt. Ass'n v. Rowe, 307 F. Supp. 2d 164, 180 n.17 (D. Me. 2004). However, as discussed below, the scope of a facial takings claim must be restricted to the theory that the challenged regulation does not substantially advance a legitimate state interest, or that recourse to state procedures for obtaining just compensation would be futile. Yee v. City of Escondido, 503 U.S. 519, 534 (1992) ("As this [facial challenge] does not depend on the extent to which petitioners are deprived of the economic use of their particular pieces of property or the extent to which these particular petitioners are compensated, petitioners' facial challenge is ripe."); Sinclair Oil Corp. v. County of Santa Barbara, 96 F.3d 401, 406-407 (9th Cir. 1996), cert. denied, 523 U.S. 1059 (1998) (discussing Williamson County Reg'l Planning Comm'n v. Hamilton Bank, 473 U.S. 172 (1985) and Yee, supra, and explaining the different kinds of facial takings claims at issue in each); Daniels v. Area Plan Comm'n, 306 F.3d 445, 458 n.13 (7th Cir. 2002) ("Litigants are not required to meet the Williamson County ripeness requirements when solely mounting a pre-enforcement facial challenge to the constitutionality of a statute under the Fifth Amendment."); See also Philip Morris, Inc. v. Reilly, 312 F.3d 24, 52 (1st Cir. 2002) (Lipez, dissenting) (discussing the stringent burden placed on plaintiffs presenting only facial

takings claims). Whether the takings claim that PCMA advances in its memoranda of law actually adheres to this limitation is an interesting question.

The real focus of the Attorney General's jurisdictional objection goes to PCMA's request for injunctive relief. According to the Attorney General, "[n]o court prior to this case has . . . found" that there exists such a thing as a "'facial per se takings claim for which there was no adequate state compensatory remedy and thus the claim was ripe for federal court equitable relief." (Docket No. 88 at 23.) In response, PCMA assures the court that it need not be concerned over this issue because PCMA "challenges the UPDPA's generic condition, without exception and applicable to PBMs as a class, requiring surrender of property rights in return for the ability to do business in Maine." (Docket No. 103 at 15.) According to PCMA, the First Circuit recognized an "unconstitutional condition" doctrine in Philip Morris, Inc. v. Reilly that bars state legislation that attempts to impose a taking as a quid pro quo for access to state markets. (Id. at 17.) Thus, PCMA cites a footnote in Justice Torruella's primary opinion to the effect that it creates an "unconstitutional condition" when a state puts the sellers of products in the "untenable position of having to choose between relinquishing their valuable trade secrets or pulling their products out of [a state market]," Philip Morris, 312 F.3d at 39 n.11, and Justice Selya's more emphatic statement in concurrence that "companies are left with a Hobson's choice: either comply with the Disclosure Act and forfeit your valuable trade secrets or withdraw from the . . . market. This constitutes an unconstitutional condition on [a] compan[y's] right to sell [its] products . . . . Id. at 50. I agree with PCMA that the Philip Morris opinion appears to assert that there is a constitutional right under the Takings Clause to access a state's markets without having first to satisfy a taking condition, and that a federal court has jurisdiction, at the very

least, to declare a statute imposing such a condition unconstitutional.[9] Thus, PCMA's facial takings claim is ripe for adjudication.

B. Associational standing

The Attorney General argues that, even if the court has jurisdiction to evaluate a facial challenge to the constitutionality of the UPDPA under the Takings Clause, PCMA does not have associational standing to litigate the claim because "the nature of the takings claim is extraordinarily individualized, there is no commonality of relief because just compensation . . . is the appropriate remedy, and . . . the associational standing vehicle was not intended . . . to make it more difficult for defendants, and particularly sovereign states, to defend themselves." (Docket No. 88 at 26.) In support of this position, the Attorney General points to evidence obtained during discovery that tends to demonstrate voluntary divulgence of some trade secret information by certain PBMs to some of their customers, most commonly in the context of annual audits. (Id. at 27-28.) Because some of PCMA's members would likely have extra difficulty proving that the terms they have negotiated with drug manufacturers are "classic trade secrets," and therefore that the UPDPA subjects them to a taking, the Attorney General argues that PCMA cannot stand in for the PBMs in this litigation. (Id. at 28-30, arguing at page 30 that "[a]s long as there is one hypothetical contract between a PBM and the thousands of customers out there allowing access, there is no standing.") PCMA sees things quite differently. In PCMA's view, "[i]t would be sufficient for associational standing purposes if every PCMA member but one had abandoned their trade secrets." (Docket No. 103 at 23.)

[9] Justice Torruella made it clear in his opinion that the Court only affirmed the district court's award of equitable relief because the State of Massachusetts failed to challenge the award of such relief on appeal. Philip Morris, 312 F.3d at 47 n.22. Justice Torruella also made it clear that his opinion did not rely on the Due Process Clause, although he did not rule out the possibility of a due process violation. Id. at 47.

In Warth v. Seldin, the Supreme Court first recognized associational standing, holding that:

> The association must allege that its members, or any one of them, are suffering immediate or threatened injury as a result of the challenged action of the sort that would make out a justiciable case had the members themselves brought suit. So long as the nature of the claim and of the relief sought does not make the individual participation of each injured party indispensable to proper resolution of the cause, the association may be an appropriate representative of its members, entitled to invoke the court's jurisdiction.

422 U.S. 490, 511 (1975). Thus, the Attorney General focuses on the need for individual participation to prove the existence of a trade secret and individualized damages, whereas PCMA focuses on the fact that only one of its members need suffer a threatened injury that would generate a justiciable case if it brought suit in its own name. It seems to me that both parties are correct, but each of their statements focuses on a different aspect of the associational standing test. PCMA is correct that the mere fact one or more of its members might not be able to independently sustain a takings claim does not preclude PCMA from meeting the associational standing test, so long as one of its members does suffer injury to a cognizable interest. That fact goes to the first prong of the test (whether at least one of the association's members would have standing to sue on its own), but not the third, prudential, prong that the Attorney General's argument focuses on (whether the nature of the litigation requires the participation of individual members). See United Food & Commer. Workers Union Local 751 v. Brown Group, Inc., 517 U.S. 544, 554-557 (1996). Thus, although I credit PCMA's point, in my view it does not carry the day because it remains a basic fact of this litigation that at least one of PCMA's members must participate in this litigation in order for PCMA to prove that compliance with the UPDPA's disclosure provision will effectively "take" a trade secret and that the resultant injury to that member is sufficiently weighty to override the State's legislative prerogative. Whether or not the

information PBMs would have to divulge under the UPDPA deserves constitutional protection under the Takings Clause, i.e., whether or not justice and fairness require the payment of compensation for the disclosure of such information, Penn Central Transp. Co. v. New York City, 438 U.S. 104, 124 (1978), depends on a host of factors and PCMA cannot prove that the interest of trade secret protection is sufficiently compelling to require compensation for the UPDPA's disclosure provisions except by introducing evidence pertaining to how, inter alia, one or more of its members develops, and maintains the secrecy of, its information and how one or more of its members would be injured by disclosure. Thus, in my view, PCMA fails to meet the third, prudential,[10] prong of the Supreme Court's standing test because its claim "requires the participation of [at least one] individual member[] in the lawsuit," Hunt v. Wash. State Apple Adver. Comm'n, 432 U.S. 333, 343 (1977), and cannot be determined without individualized evidence.

I recognize, of course, that an association can pursue a claim even though it must submit some evidence drawn from its members, as is demonstrated by Hunt, in which the trial court entered findings about the effects a North Carolina statute had upon some Washington apple growers, id. at 343-44. But here, unlike Hunt, the viability of PCMA's takings claim varies member-by-member, not based on the threshold question of whether a given member does business in Maine and complies with the statute, but based on the highly individualized, underlying factual questions of whether and how a given member protects the information at issue and whether the confidential disclosure of the information to specific benefits providers or "covered entities" strips the information of all value as a trade secret or causes economic injury

[10] The Supreme Court has concluded that "the associational standing test's third prong is a prudential one," rather than a jurisdictional one. United Food, 517 U.S. at 555. "Hence the third prong of the associational standing test is best seen as focusing on these matters of administrative convenience and efficiency, not on elements of a case or controversy within the meaning of the Constitution." Id. at 557.

of constitutional proportion. By comparison, to dispose of the Commerce Clause claim in Hunt, it appears that the only evidence the association plaintiff had to put forward from its members was that the North Carolina statute had the "consequence of *raising the costs* of doing business in North Carolina for Washington apple growers and dealers," a generic condition imposed on every member participating in the North Carolina market.[11] In the instant case, however, there is a genuine issue of material fact whether the mere fact of a PBM's compliance with the UPDPA by disclosure of information, subject to confidentiality, at the request of a given provider customer, will cause appreciable economic injury, let alone effectuate a taking. In my view, prudence cautions against further entertaining PCMA's Takings Clause challenge to the UPDPA because the determination of this aspect of the litigation requires the court to evaluate highly-individualized evidence and circumstances, so much so that it is strange to even conceptualize this aspect of the litigation as presenting only a "facial" challenge. For this reason, I recommend that the court grant summary judgment in favor of the Attorney General with respect to count III.

C. Merits

Despite my recommendation concerning the Attorney General's challenge to PCMA's standing to sue in a representative capacity, I address the merits of PCMA's presentation of its facial takings claim because PCMA has separately moved for summary judgment in its favor and that motion has been referred for recommended decision. Should the courts choose to grant the Attorney General's motion for summary judgment against this claim, then this discussion will be largely academic.

[11] That evidence may well have come from institutional records or knowledge or other evidence available to the Washington State Apple Advertising Commission as a state agency. In this case, by comparison, PCMA asserts (as it must) that it does not have any first hand information about its members' alleged trade secrets. (See Docket No. 89, ¶ 172; Docket No. 104, ¶ 172: "No employees, officers, or directors of PCMA have had access to its members' contracts and trade secrets in the last three years.")

PCMA argues that it is entitled to summary judgment in its favor on its takings claim and its 42 U.S.C. § 1983 claim based on an analysis of the three takings factors set forth in Penn Central Transportation Company v. New York City, 438 U.S. 104 (1978), as applied to concerns over trade secret protection in Ruckelshaus v. Monsanto Company, 467 U.S. 986 (1984), and Philip Morris, Inc. v. Reilly, 312 F.3d 24 (1st Cir. 2002). According to PCMA, "if PBMs must reveal the information [required by the UPDPA] to their customers, even if to no one else, all value as property is destroyed, resulting in an unconstitutional taking." (Docket No. 85 at 24.) The Attorney General argues that summary judgment should enter against PCMA's takings claim because PCMA cannot meet the heightened burden that applies to a facial challenge. (Docket No. 88 at 32.) According to the Attorney General:

> [I]f a single PBM had a single contract with a covered entity that afforded that covered entity access to the type of information to be disclosed under sections 2(D) and 2(G), with the same or fewer confidentiality protections than those in the statute, the facial challenge fails because . . . there is no "trade secret," no adverse economic impact, and no interference with investment backed expectations.

(Id.) Alternatively, the Attorney General argues that even if the court concludes that the information at issue in this case is entitled to trade secret protection, the UPDPA's confidentiality provisions "'inoculate' the disclosure provisions from constitutional infirmity." (Id. at 33.) Like PCMA, the Attorney General discusses all three of the Penn Central factors in his memorandum. (Id. at 35-42.) Those three factors are the following:

(1) "the extent to which the regulation [would] interfere[] with distinct investment-backed expectations";

(2) "the economic impact of the regulation on the claimant"; and

(3) "the character of the governmental action."

Penn Central, 438 U.S. at 124.[12]

Because PCMA brings only a facial challenge, "the narrow inquiry" before this court is "whether the mere enactment of the [UPDPA] constituted a taking." Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Planning Agency, 535 U.S. 302, 318 (2002). Typically, in the context of a physical taking of property, a facial challenge invites a categorical rule. See id. at 320-21. Although PCMA maintains that a *per se* taking results from the enactment of the UPDPA because it requires the disclosure of trade secrets as a condition of doing business in Maine (Docket No. 85 at 15), I am not persuaded that application of a *per se* rule makes sense in this case because of the need for searching and individualized fact finding in order to evaluate the Penn Central factors. See Tahoe-Sierra, 535 U.S. at 322-23 (describing the distinction between physical takings, which permit a categorical approach, and regulatory takings, which "entail[] complex factual assessments of the purposes and economic effects of government actions"). Indeed, I have concerns that PCMA is not really pressing a facial challenge here. For each of the three Penn Central factors, PCMA presents arguments that are dependent not only upon evidence of its members' internal practices, the economic value of the information at issue, and the impact the UPDPA would have on its members' use of information, but also upon entirely hypothetical projections about what some of its customers might do with the information once it is disclosed to them. (Docket No. 85 at 18-23.) In contrast, in Yee the Supreme Court held that a regulatory takings claim was ripe because the plaintiff argued only that the regulation in question did not "'substantially advance' a 'legitimate state interest,' no matter how it is applied," and did not base the claim on the "extent to which [they were] deprived of the economic use of their [property]." 503 U.S. at 534. My impression is that PCMA's taking claim is really an unripe as-applied claim masquerading as a facial claim.

[12] I have listed these factors in the order they were addressed by Judge Torruella in Philip Morris.

PCMA contends that the constitutional finding it seeks is plainly required by Ruckelshaus v. Monsanto and Philip Morris and that the court only needs to determine that PCMA's members have at least some reasonable investment-backed expectation that their trade secrets will remain secret, to conclude, categorically, that disclosure to PBM's provider customers works a taking. (Docket No. 88 at 17-18.) I disagree because the record does not compel a finding that confidential disclosure to these customers will destroy or extinguish the PBMs' alleged trade secrets. The point is that viewing the record in the light most favorable to the Attorney General, and drawing all reasonable inference in his favor, the court cannot conclude that the confidential disclosures the UPDPA requires will destroy the PBMs' trade secrets or their reasonable investment-backed expectations.

In Ruckelshaus v. Monsanto, the Supreme Court considered whether trade secret data Monsanto submitted to the Environmental Protection Agency under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), could be disclosed publicly by the EPA without effecting a regulatory taking. The Court's answer was that it depended upon which of three evolving statutory schemes applied at the time the data were submitted. Ruckelshaus v. Monsanto, 467 U.S. at 990-97 (describing FIFRA's original purpose and its evolution through two amendments), 998-99 (describing the nature of Monsanto's claims), & 1004-14 (discussing the merits based on which statutory scheme the data were submitted under). The question of whether the data deserved trade secret protection was not before the Court. The EPA stipulated that Monsanto had property rights in the data, and the Court merely paused to consider whether "the intangible nature of a trade secret" deserved protection under the Fifth Amendment. Id. at 1001-1004. The Court concluded that trade secrets are protected by the Takings Clause. Id. at 1003-1004. Turning to the ultimate takings question, the Court observed that the ad hoc,

regulatory takings analysis set the appropriate standard. Id. at 1004-1005. The Court concluded that of the three *ad hoc* factors (the character of the government action, its economic impact, and its interference with reasonable investment-backed expectations), the case could be resolved solely by reference to Monsanto's investment-backed expectations. Id. at 1005. Based on that factor, the Court rejected most of Monsanto's case, holding that public disclosure of data submitted under the latest (post-1978) and the earliest (pre-1972) versions of FIFRA could not effect takings. As for post-1978, a taking could not be found because "Monsanto knew that, for a period of 10 years from the date of submission, EPA would not [disclose] data . . . without Monsanto's permission," because "Monsanto was further aware that it was entitled to an offer of compensation [from the party receiving a disclosure] . . . until the end of the 15th year from the date of submission," and because Monsanto knew that "much of the . . . data . . . could be disclosed to the general public at any time." Id. at 1006. Because Monsanto was aware of all these different avenues for public disclosure and nevertheless submitted its data to the FDA "in exchange for the ability to market pesticides," id. at 1007, the Court reasoned that it could not find that Monsanto had a reasonable, investment-backed expectation that could be "disturbed" by a disclosure made in compliance with the act. Id. at 1006-1007. As for pre-1972, the Court reasoned that a taking could not be found because there was no federal law in effect at that time that could have justified Monsanto in thinking that its data would remain confidential or that the EPA would not conclude that public disclosure was needed. Id. at 1008-1009. In other words, the Court appeared to reason that submission of trade secret data to a federal agency, without an "express promise" of confidentiality, precludes a finding of a reasonable investment-backed expectation that the trade secret would not be publicly divulged. Id. at 1008-1009. Another way of looking at this aspect of the holding is that government disclosure, for public benefit, of trade

secret data submitted to it in exchange for the right to market a regulated product does not amount to a taking unless the government has made an express promise to protect the data's confidentiality. This reading is born out by the Court's analysis of data submitted by Monsanto between 1972 and 1978. During this timeframe, FIFRA afforded a submitter of data the "opportunity to protect its trade secrets from disclosure by designating them as trade secrets at the time of submission." Id. at 1010-11. Thus, because "the Federal Government had explicitly guaranteed to Monsanto and other registration applicants an extensive measure of confidentiality and exclusive use[,]" the Court held that Monsanto had a 'reasonable investment-backed expectation with respect to its control over the use and dissemination of the data it submitted." Id. at 1011.

In all three situations described above, the Court's holding turned entirely on the *past* submission of trade secret data with or without statutory assurances that the data would be protected. Reviewing a historical record of this kind, the task faced by the Court in Ruckelshaus v. Monsanto was much "cleaner" than what is presented in this case. Here, PCMA wants a prospective ruling that any requirement of disclosure, even if subject to confidentiality, works a taking, something that has very little resemblance to what the Supreme Court did in Ruckelshaus v. Monsanto. Also distinct from Ruckelshaus v. Monsanto is PCMA's demand for injunctive relief. With respect to remedy for disclosure of data submitted between 1972 and 1978, the Supreme Court in Ruckelshaus v. Monsanto entered an order that the time had not yet come for imposing any relief because there remained an opportunity for Monsanto to obtain just compensation:

> EPA consideration or disclosure of health, safety, and environmental data will constitute a taking *if* Monsanto submitted the data to EPA between October 22, 1972, and September 30, 1978; the data constituted trade secrets under Missouri law; Monsanto had designated the data as trade secrets at the time of its

> submission; the use or disclosure conflicts with the explicit assurance of confidentiality or exclusive use contained in the statute during that period; *and the operation of the arbitration provision does not adequately compensate* for the loss in market value of the data that Monsanto suffers because of EPA's use or disclosure of the trade secrets.

Id. at 1013-14 (footnote omitted). See also id. at 1016 ("Equitable relief is not available to enjoin an alleged taking of private property for a public use, duly authorized by law, when a suit for compensation can be brought against the sovereign subsequent to the taking. The Fifth Amendment does not require that compensation precede the taking.") (footnote and citation omitted), 1019 ("The District Court erred in enjoining the taking.") & 1020 (noting, in conclusion, that a Tucker Act remedy is available to provide Monsanto with just compensation," and that "[o]nce a taking has occurred, the proper forum . . . is the Claims Court"). In my view, Ruckelshaus v. Monsanto does not provide a good format for analyzing whether PCMA's prospective submission of information under the UPDPA works a taking because we are not concerned here with past submissions of data or information. If Ruckelshaus v. Monsanto dictates anything with respect to the disposition of this suit, it is that declaratory relief might be in order, but injunctive relief is not.

The First Circuit's *en banc* opinion in Philip Morris comes closer to the mark, but is still no cigar. In Philip Morris, the First Circuit reviewed a facial challenge to a Massachusetts tobacco ingredients disclosure act. 312 F.3d at 26. The act required disclosure of all ingredients used in tobacco products, "by relative amount," other than tobacco, water and reconstituted tobacco sheet. Id. The act further provided that the information would be disclosed to the public. Id. at 28. A number of tobacco companies (not an association)[13] brought a facial challenge to the act, before it could be implemented, contending that the act "create[d] an

[13] The panel opinion reveals that a number of separate suits were commenced and subsequently joined by the trial court. Philip Morris, Inc. v. Reilly, 267 F.3d 45, *3, 2001 U.S. App. LEXIS 22348, *11 (1st Cir. 2001) (withdrawn from bound volume).

unconstitutional taking." Id. at 26. The district court agreed, enjoining enforcement of the act; a divided First Circuit panel reversed, concluding that public disclosure . . . is a valid exercise of the police power and, in the absence of explicit guarantees of confidentiality . . ., does not effect an unconstitutional taking"; and after an "en banc" review of the takings issue by three judges, the panel decision was replaced with an opinion affirming the district court. Id. at 26. Like Ruckelshaus v. Monsanto and unlike this case, the key factual findings that the Philip Morris opinion turned on were not disputed. Thus, it was not disputed by the Massachusetts Attorney General "that the tobacco companies' ingredient lists are trade secrets," Philip Morris, 312 F.3d at 31, or that "publication of [the tobacco companies'] ingredient lists, organized by relative amount, on a brand-by-brand basis would likely destroy the secrecy of their formulas," id. at 27. Moreover, unlike the UPDPA, the Massachusetts act allowed for unrestricted public disclosure of the tobacco companies' ingredient lists. The Court found as a fact that Massachusetts "hope[d] to publicize the ingredient list of various brands" in order to "help consumers make more informed choices." Id. at 28. Based on those undisputed facts, the majority of the *en banc* Court concluded that it could dispose of the facial challenge on the merits, having a record that plainly established that the companies had, at least until passage of the act, reasonable expectations in the safety of their trade secrets by virtue of Massachusetts common law, and that public disclosure (and, thus, disclosure to competing manufacturers), would "extinguish," id. at 41, "essentially destroy," id. at 42, or "completely destroy," id. at 43, the companies' trade secrets. See also id. at 41 (finding it "*paradigmatic*" that the tobacco companies' assertion that their trade secrets would lose "all value" was true.) (emphasis added). Finally, the court concluded that the act also imposed an unconstitutional condition because Massachusetts was not offering tobacco companies a "benefit" of corresponding value to offset the taking. Id. at 47. As

for remedy, the Court affirmed the district court's entry of injunctive relief, but only on a technicality: the legality of imposing injunctive relief was not challenged on appeal. Id. at 47 n.22.

The takings claim presented in the instant case is like the takings claim presented in Philip Morris to the extent that PCMA seeks prospective relief and no PBM has yet divulged any of its alleged trade secrets in compliance with the UPDPA. According to Judge Torruella, author of the lead opinion in Phillip Morris, when a trade secret taking claim is raised before disclosure, it is more likely that a taking will be found, because unless a promise of confidentiality is extended or extracted from the government, there is no reasonable basis to expect that the trade secret will not be divulged by the State. Id. at 38. However, this case is also different from Philip Morris in significant ways. The UPDPA does not subject information to unfettered public disclosure, but affords a measure of confidentiality. Furthermore, it is not clear that the information that would be disclosed under the UPDPA deserves trade secret protection and it is established that disclosures of at least some information to at least some PBM customers will not undermine trade secrets protection because those customers have already been granted access to the information. In addition, PCMA's evidence about the likelihood of harm, given the confidentiality provisions now engrafted to the UPDPA, is entirely conjectural and will likely vary according to which PBM is under consideration. On this record, I am not persuaded that PCMA can carry its burden to prove that every disclosure under the UPDPA, if uncompensated, will result in an unconstitutional taking, and I believe that the question ought to be presented in the context of an as-applied challenge. Nevertheless, I follow Judge Torruella's lead and address the Penn Central factors in turn, mindful that PCMA faces "an uphill battle" and "must establish that no set of circumstances exists under which the Act would be valid." Philip

Morris, 312 F.3d at 52 (Lipez, J., dissenting) (quoting Tahoe-Sierra Pres. Council, 535 U.S. at 1477, and Pharm. Research & Mfrs. of Am. v. Concannon, 249 F.3d 66, 77 (1st Cir. 2001)).

According to PCMA, the UPDPA places PBMs' reasonable investment-backed expectations in jeopardy of destruction because the disclosures the UPDPA calls for will divulge trade secrets to customers who, as commercial entities, could derive economic value from the information by entering the PBM industry and eliminating PBMs as middlemen. (Docket No. 85 at 23-24.) Contrary to PCMA's assertions, the record does not clearly establish that any given disclosure under the UPDPA will divulge trade secrets, destroy or extinguish the economic value of the alleged trade secret information, or cause provider customers to enter the PBM market.

1. Reasonable investment backed expectations

From PCMA's perspective, if it can show that any one of its members would have to disclose information under the UPDPA that is otherwise subject to trade secret protection, then not only will the first *and* second prongs of the Penn Central test be established, but also a *per se* taking will be conclusively established. (Id.) PCMA thus fully briefs why the terms of the contracts that PBMs negotiate with drug manufacturers and pharmacies deserve trade secret protection. (Id. at 18-23.) I do not reproduce PCMA's arguments here because, although I agree with PCMA that the terms and conditions set forth in confidential contracts could[14] amount to

[14] I do not mean to suggest that proof of trade secret status is a foregone conclusion. Among the factors generally considered by Maine courts is the relative "ease or difficulty with which others could properly acquire . . . the information." Bernier v. Merrill Air Eng'rs, 2001 ME 17, ¶ 26, 770 A.2d 97, 106 n.6. Although PCMA asserts that every PBM forms a unique contract with any given drug manufacturer, it seems highly likely to me that any two comparably situated PBMs (as far as bargaining power is concerned) could, in any given year, extract the same or comparable rebate terms from a drug manufacturer as any other PBM. In other words, the likelihood that one PBM will negotiate functionally equivalent or even identical rebate terms as another PBM does from a given manufacturer in any one year (all of the contracts supplied by PCMA in the record are annual contracts) seems, to me, likely to occur. Also, I am not entirely sure that the court should simply assume that PCMA's factual assertions about the costs to PBMs of developing "relationships with manufacturers and pharmacy networks" (Docket No. 94, ¶ 8), is an appropriate substitute for the amount invested in, for example, each new year's rebate terms, which appear to be set forth in appendixes to the contracts. These and other concerns, such as those highlighted by the court in its order granting the preliminary injunction, do pose significant conceptual problems for treating the information at issue herein as deserving trade secret status. On another note, I also observe that the Maine Trade Secrets Act expressly

"information . . . that . . . [d]erives independent economic value . . . from not being generally known to and not being readily ascertainable by proper means by other persons who can obtain economic value from its disclosure or use," 10 M.R.S.A. § 1542(4), I also agree with the Attorney General that the question under the first prong of the facial test is not whether such information *could* be a trade secret, but whether the record *proves* that it is reasonable for PBMs to expect that the information at issue could never be subject to a disclosure regulation, including a disclosure regulation with a confidentiality provision restricting further disclosure. On that question, I agree that PCMA cannot establish a facial taking on the existing record. The record clearly establishes that in at least some instances, confidential disclosure under the UPDPA would be in keeping with preexisting PBM practice between some PBMs and some of their customers.[15] I therefore conclude that PCMA fails to carry its burden of demonstrating that the UPDPA could not be valid under any set of circumstances. Tahoe-Sierra Pres. Council, 535 U.S. at 1477; Pharm. Research & Mfrs. of Am., 249 F.3d at 77. Furthermore, it seems striking to me that, although the Attorney General has strived to present evidence of actual situations in which no taking would occur, PCMA has not even attempted to present one concrete situation where the disclosure of information by one of its representative PBMs to an actual, identified, Maine-based benefits provider customer or "covered entity" would compromise trade secret information. Instead it has put forth highly-generalized statements of fact that depend upon the

cautions that the Act "does not affect . . . [t]he duty of any person to disclose information where expressly required by law." See also 10 M.R.S.A. § 1548(1)(D). This express limitation in Maine's Trade Secrets Act may have more significance for the "reasonable investment-backed expectation" factor than did the ancillary common law principles and statutes raised by the Massachusetts Attorney General in Philip Morris. See 312 F.3d at 31-32. Given this express limitation in Maine's Trade Secrets Act, what basis is there for a PBM to expect that contracts and terms negotiated after the UPDPA's effective date will be afforded trade secret protection in Maine?

[15] The Attorney General also asserts in his statement of material facts (Docket No. 88) that PBMs are already subject to extensive regulation, including regulation designed to prevent violation of state and federal anti-kickback legislation. (Docket No. 89, ¶¶ 182-184, citing position paper prepared by AdvancePCS, Caremark Rx and Express Scripts and a report produced by the U.S. Department of Health and Human Services, Office of the Inspector General).

court drawing rather liberal inferences in its favor as the summary judgment movant. Finally, I agree with the Attorney General that the year-to-year nature of these contracts significantly erodes PCMA's position that any diminution in the value of the information contained in the contracts works a taking. (Docket No. 88 at 40.) Unlike classic trade secrets, like the formulas used to produce pesticides or cigarettes, which have an abiding market value, the terms of an annual contract expire annually. The Legislature amended the UPDPA to provide that its terms were only applicable to contracts entered into or renewed after the UPDPA's effective date. 22 M.R.S.A. § 2699(5). Because expectations must be evaluated at the date of disclosure, Ruckelshaus v. Monsanto, 467 U.S. at 1014 n.17, and because the contracts found in the record reflect that drug rebates and other terms are renegotiated annually, the contractual information at issue does not deserve to be treated as categorically untouchable trade secrets but as new data that is subject to health and safety regulations requiring transparency. Stated another way, the PBMs' market "relationships" with drug manufacturers and pharmacy networks are not something that the Takings Clause requires governments to treat as sacrosanct or opaque in perpetuity and expectations in as-yet unexecuted or yet-to-be negotiated contracts are not reasonable if they fail to take into consideration newly enacted regulations.

2. Economic impact

PCMA's economic impact argument is the same argument it presents in support of its members' investment-backed expectations. The primary factual assertion that PCMA advances in support of its economic impact argument is the projection that disclosure will undermine the PBMs' negotiating position with their benefits provider customers, thereby costing them money, and that the PBMs' provider customers will potentially enter the PBM market and cut PBMs out of the loop if PBMs have to make the disclosures called for by the UPDPA. (Docket No. 94, ¶

19.) In support of this assertion, PCMA offers passages from the deposition testimony of numerous individuals currently or formerly retained by PCMA or otherwise within the PBMs' employ. (Id.) Even if the court were to credit these predictions, I conclude that the lack of reasonable investment-backed expectations in new and future contract terms overrides this factor and that the injuries alleged are but part and parcel of the regulatory environment. Philip Morris, 312 F.3d at 36 ("Courts protect only reasonable expectations. Ideally, the relevant inquiry should recognize that not every investment deserves protection and that some investors inevitably will be disappointed."); see also id. at 48 (arguing that the investment-backed expectation factor should have primacy when trade secrets are at issue); Penn Cent., 438 U.S. at 124 ("The economic impact of the regulation on the claimant and, *particularly*, the extent to which the regulation has interfered with distinct investment-backed expectations are, of course, relevant considerations) (emphasis added). In this case there is undisputed confidential evidence in the record demonstrating that with respect to at least one PBM's relationship with one of its provider customers, compliance with the UPDPA's disclosure provisions would have absolutely no economic impact. (Docket No. 89, ¶¶ 140-41.) Thus, PCMA cannot succeed with its facial challenge because it cannot establish that there is no circumstance under which the UPDPA will not effect a taking. Finally, PCMA's allegations that the UPDPA will undermine competition in the market is diluted by the fact that the disclosures called for by the UPDPA are to be made to benefits providers, not to PBMs and, except with respect to drug substitution information, the PBM may impose confidentiality obligations on the recipients of the information.

3. Character of the governmental action

PCMA argues that the character of the governmental action at work in the UPDPA is "a naked transfer of wealth by appropriation of property[,] a classic taking." (Docket No. 85 at 26;

Docket No. 103 at 31.) Thus, PCMA argues that the court must find the UPDPA to be an illegitimate exercise of the police power because the state has not offered any benefit to offset the burden imposed on PBMs (Docket No. 85 at 25-26) and because the stated goal of lowering drug costs will not result (Id. at 27). The problem with the first argument is that it conflates the inquiry of whether the State is pursuing a proper objective with the separate inquiry of whether the UPDPA imposes an unconstitutional condition. (Docket No. 85 at 24-26.) If the court cannot determine in the context of this facial challenge that the UPDPA would necessarily effect a taking, how can it make the finding that preconditioning market access on compliance with the UPDPA would impose an unconstitutional condition? The problem with the second argument is that it assumes that it is the province of this court to judge policy issues already addressed, and more appropriately addressed in our system of government, by the Legislature.

The standards assigned by the Supreme Court teach that violations of the Takings Clause are not so readily to be found when interference with property "arises from some public program adjusting the benefits and burdens of economic life to promote the common good." Penn Cent., 438 U.S. at 124. "Government hardly could go on if to some extent values incident to property could not be diminished without paying for every such change in the general law," Pa. Coal Co. v. Mahon, 260 U.S. 393, 413 (1922), and "recognized economic values" could not be adversely affected through the enactment of new laws or government programs, Penn Cent., 438 U.S. at 124. And where personal property is concerned, "regulation can severely undermine [its] economic value . . . and not rise to the level of a taking." Philip Morris, 312 F.3d at 43 (citing Andrus v. Allard, 444 U.S. 51, 66 (1979)). The purpose of the UPDPA is clearly to serve and protect the public health and welfare, whether its execution was ill-conceived or not. Adjusting the benefits and burdens of the prescription drug trade that transpires in this State to ensure

transparency in the sale and purchase of drugs is an appropriate governmental endeavor.[16] The fact that, going forward, PBMs must abide by certain restrictions within that market in connection with the provision of PBM services to Maine "covered entities" simply influences or informs the PBMs' future (i.e., post enactment) contract negotiations with drug manufacturers, pharmacy networks and their benefits provider customers, for future trades in prescription drugs. It does not serve to take the value of present or past contracts for PBM services. Setting these parameters on the provision of PBM services may or may not best serve the interest of the Maine public, but it is not an illegitimate exercise of the police power to regulate with respect to the public health.

D. Unconstitutional condition

In Philip Morris, Judge Torruella concluded that the tobacco disclosure act was invalid as an unconstitutional condition because Massachusetts sought to impose the burden of unrestricted public disclosure of trade secret information on tobacco companies as a precondition to marketing products in the Commonwealth. 312 F.3d at 47. This finding turned entirely on

[16] In the 96th footnote of its memorandum (Docket No. 85 at 27), PCMA makes reference to the UPDPA's statutory requirement that PBMs pass through to their benefits provider customers (covered entities) all benefit or payment received from drug substitution practices or that are based on volume discounts. See 22 M.R.S.A. § 2699(2)(E)(3) & (2)(F). Although PCMA raises these provisions in this fashion, its briefing of the takings claim has focused entirely on the disclosure provisions rather than on the requirement that any benefits or payments from manufacturers be passed through to the PBMs' customers. I do not separately evaluate the constitutionality of these provisions because I conclude that PCMA has waived its challenge to them by its failure to separately brief them. Furthermore, even if these benefit and payment transfer provisions were independently objectionable under the Takings Clause, it would appear that the court could readily sever them from the remainder of the statute. See R.I. Med. Soc'y v. Whitehouse, 239 F.3d 104, 106 (1st Cir. 2001) ("Severability is a matter of state law."); 1 M.R.S.A. § 71(8) ("If any provision of the statutes or of a session law is invalid, or if the application of either to any person or circumstance is invalid, such invalidity does not affect other provisions or applications which can be given effect without the invalid provision or application."); Kittery Retail Ventures, LLC v. Town of Kittery, 2004 ME 65, ¶ 18, 856 A.2d 1183, 1190 ("An invalid portion of a statute or an ordinance will result in the entire statute or ordinance being void only when it is such an integral portion of the entire statute or ordinance that the enacting body would have only enacted the legislation as a whole."). The severability issue has been joined previously, see Pharm. Care Mgmt. Ass'n v. Rowe, 324 F. Supp. 2d 71 (D. Me. 2004) (Order on Defendant's Motion to Amend the Order of Preliminary Injunction), and left unresolved. At least with respect to the UPDPA's two benefit and payment transfer provisions, I conclude that the Attorney General has taken sufficient steps to preserve the matter (Docket No. 100 at 16), particularly when measured against PCMA's failure to directly challenge in its memoranda the constitutionality of these two provisions.

Judge Torruella's prior finding that the disclosure act effected a taking. Id. In this case PCMA has failed to carry the burden of demonstrating a facial taking and, therefore, I recommend that the court reject PCMA's assertion that the UPDPA imposes unconstitutional conditions on PBMs' access to the Maine market for PBM services.

IV. Due Process

PCMA maintains that the UPDPA violates the Due Process Clause because it deprives PBMs of property rights without providing any notice or opportunity to be heard. (Complaint, Docket No. 1, "Count Four," ¶ 68.) PCMA's memorandum of law makes it apparent that this claim is meant to tag along with its takings claim. (Docket No. 103 at 32-33.) Essentially, PCMA's position is that there must be a "predeprivation hearing" before a PBM can be expected to comply with the UPDPA's disclosure provisions. (Id.) See Zinermon v. Burch, 494 U.S. 113, 132 (1990) ("In situations where the State feasibly can provide a predeprivation hearing before taking property, it generally must do so regardless of the adequacy of a postdeprivation tort remedy to compensate for the taking."). I recommend that the court grant summary judgment in favor of the Attorney General on this claim. Because PCMA fails to demonstrate that the UPDPA facially works a taking of PBM property, I conclude that it likewise fails to demonstrate that the UPDPA is facially deficient for want of a predeprivation hearing provision.

V. Commerce Clause

Article I, Section 8, Clause 3 of the Constitution cedes to Congress the power "to regulate Commerce . . . among the several States." The Supreme Court has recognized as implicit within this affirmative grant of power a "negative" or "dormant" aspect that restricts the ability of state and local governments to burden interstate commerce by impeding private trade in the national marketplace through local regulation or taxation. GMC v. Tracy, 519 U.S. 278, 287 (1997).

According to PCMA, the UPDPA violates the Commerce Clause "because the burden it imposes on interstate commerce 'is clearly excessive in relation to the putative local benefits'" (Docket No. 103 at 33, quoting Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970)), and because it has an impermissible extraterritorial effect (Id. at 38, relying on Edgar v. MITE Corp., 457 U.S. 624 (1982)). I address the extraterritoriality claim first.

A. Extraterritoriality

Among the various ways that state regulation may run afoul of the Commerce Clause is by having the effect of regulating commercial activity occurring wholly outside of the regulating state. Thus, in MITE, the Supreme Court held that an Illinois securities law that sought to regulate tender offers for the stock of Illinois corporations violated the Commerce Clause because of its "nationwide reach which purports to give Illinois the power to determine whether a tender offer may proceed anywhere." 457 U.S. at 643. Similarly, in Brown-Forman Distillers Corporation v. New York State Liquor Authority, the Supreme Court invalidated a New York wholesale liquor price control regulation because it "[f]orc[ed] a merchant to seek regulatory approval in [New York] before undertaking a transaction in another [state]." 476 U.S. 573, 582 (1986). According to PCMA, the UPDPA has an unconstitutional extraterritorial reach because it "could be applied to [PBM-manufacturer contracts] which would not affect a single [Maine resident]." (Docket No. 103 at 39, paraphrasing MITE, 457 U.S. at 642.) I disagree with this characterization. The UPDPA clearly provides: "Compliance with the requirements of this section is required in all contracts for pharmacy benefits management entered into in this State or by a covered entity in this State." 22 M.R.S.A. § 2699(3). Furthermore, the UPDPA defines "pharmacy benefits management" as "the procurement of prescription drugs . . . for dispensation within this State to covered individual" Id., § 2699(1)(E). Only someone engaged in a highly-

abstract theoretical exercise could seriously maintain that the UPDPA is designed to regulate contracts for pharmacy benefits management services that would not affect a single Maine resident. The obvious import of the provisions just quoted is that the UPDPA applies when a PBM enters into a pharmacy benefits management contract with a Maine covered entity for provision of pharmacy benefits management services that benefit Maine covered individuals.

B. Pike balancing test

Non-discriminatory and non-protectionist regulations that have indirect or incidental effects on interstate commerce are valid unless the party challenging the regulations can demonstrate that "the burden imposed on such commerce is clearly excessive in relation to the putative local benefits." Bruce Church, 397 U.S. at 142. According to PCMA, the UPDPA imposes burdens that are excessive because "the costs of disclosure . . . could lead to the total curtailment of any PBM cross-border commerce." (Docket No. 103 at 33.) Other than this threat, PCMA's argument for excessiveness turns entirely on the presupposition that the UPDPA will effect takings of information that would otherwise be given trade secret protection in every other state. (Id. at 33-34.) Because PCMA has failed to support its facial challenge under the Takings Clause, it has likewise failed to provide the court with any great weight to place on the excessive burden side of the scale. This is a failure of proof that warrants an entry of summary judgment against PCMA on this claim. N.H. Motor Transp. Ass'n v. Flynn, 751 F.2d 43, 48 (1st Cir. 1984) ("[T]he burden of proving 'excessiveness' falls upon the [plaintiff], not the state."). As for the "putative local benefits" side of the scale, PCMA argues that the UPDPA will not achieve its purpose of reducing the costs of, and increasing the public's access to, prescription drugs. (Id. at 36.) Even assuming that the likelihood of the UPDPA achieving the State's objectives could be proven in this or any litigation, which I doubt, I do not believe that the

evidence PCMA offers of this likelihood is probative enough, even if all inferences are drawn against the Attorney General as the movant, for the court to presume that it might pass on the wisdom of the healthcare policies adopted by the Legislature in the context of a trial. In any event, the salient point is that the UPDPA is clearly designed to improve public health by increasing access to prescription drugs and, therefore, the *putative* benefit is substantial, quite distinct from the situation in Bruce Church, where the legislation under review involved the "tenuous interest in having . . . cantaloupes identified as originating in Arizona." 397 U.S. at 145. See also Pharm. Research & Mfrs. of Am., 249 F.3d at 84 (finding it a substantial benefit that Maine's Rx Program "will potentially provide prescription drugs to Maine citizens who could not otherwise afford them."). The substantiality of the putative benefit at issue here will support the imposition of some appreciable incidental burdens on interstate commerce. Without the benefit of an established taking on the record, I conclude that the burden of disclosing information to a customer, subject to confidentiality, is not "clearly excessive" in relation to the putative local benefit of "a novel legislative approach to one of the serious problems of our time." Pharm. Research & Mfrs. of Am., 249 F.3d at 80.[17]

VI. Free Speech

The seventh count of PCMA's complaint concerns the First Amendment. According to PCMA, the UPDPA violates the First Amendment because it compels PBMs to engage in commercial speech by mandating disclosure of their confidential business information to those they would not voluntarily communicate the information to. (Docket No. 103 at 41.) The Attorney General argues that the First Amendment has nothing to do with a mandatory

[17] I am also not persuaded that the economic impact faced by PBMs necessarily presents anything more than "possible effects on the profits of the individual [PBMs]," Pharm. Research & Mfrs. of Am., 249 F.3d at 84, something that is distinct from a burden on interstate commerce. See id.

disclosure law and, alternatively, that the disclosures called for in the UPDPA serve an appropriate government interest. (Docket No. 88 at 47.)

"'[C]ommercial speech [enjoys] a limited measure of protection, commensurate with its subordinate position in the scale of First Amendment values,' and is subject to 'modes of regulation that might be impermissible in the realm of noncommercial expression.'" Bd. of Trs. v. Fox, 492 U.S. 469, 477 (1989) (quoting Ohralik v. Ohio State Bar Ass'n, 436 U.S. 447, 456 (1978)). Broadly stated, "commercial speech compelled by government is governed by a . . . set of principles which require a court to balance a number of factors according to its judgment concerning the welfare of buyers and sellers in the market place." United Foods, Inc. v. United States, 197 F.3d 221 (6th Cir. 1999). First Amendment protections are implicated not only by regulations designed to restrict a person's right to speak freely, but also by regulations that would compel speech and thus override a person's "right to refrain from speaking at all." Wooley v. Maynard, 430 U.S. 705, 714 (1977). Because the UPDPA undeniably compels commercial speech, I disagree with the Attorney General's suggestion that the UPDPA is not subject to First Amendment scrutiny. However, there does not appear to be any clear precedent for the situation presented herein; those in the business of selling goods and services do not appear to have often raised First Amendment challenges to statutes forcing disclosures pertaining to the services being sold.

Loosely analogous to this case are those Supreme Court precedents in which the Court has reviewed state and federal regulations that exact monetary contributions from businesses in order to fund government advertising campaigns that are, ostensibly, supposed to benefit the entire industry that is subject to the regulation. See, e.g., United States v. United Foods, Inc., 533 U.S. 405 (2001) (holding unconstitutional a state regulatory scheme that mandated that fresh

mushroom handlers pay assessments to a state "Mushroom Council" to fund generic advertisements promoting mushroom consumption). For such cases, the Supreme Court has developed the rule that compelled contributions are generally constitutional when the industry at issue is characterized by a cooperative or collectivist market (such as the professional bar or a cooperative agricultural market subject to regulation that displaces competition) in which group action is deemed necessary to maintain a stable market, but unconstitutional where the only impetus behind the regulation is to ensure an adequate subsidy for the government's advertising campaign. Id. at 414-15. This line of demarcation appears to reflect the position that the government may not compel commercial speech or subsidization of commercial speech simply because it believes the commercial speech will serve the interest of those supplying the subsidy. In my view, because the UPDPA compels speech in order to advance the public good, those cases involving regulatory restrictions on commercial speech for public purposes are more analogous to the current situation than are the compelled advertising cases such as United Foods.

In Zauderer v. Office of Disciplinary Counsel, the Supreme Court reviewed the constitutionality of reprimands imposed on an attorney for certain newspaper advertisements he ran to attract clients. 471 U.S. 626 (1985). Zauderer illustrates how the constitutionality of restrictions on advertising generally turn on the government's ability to tie the restriction to concern over preventing "the dissemination of commercial speech that is false, deceptive, or misleading." Id. at 638. However, also recognized by the Court is the ability of the states to restrict commercial speech that is not false, deceptive or misleading so long as the restriction is imposed "in the service of a substantial governmental interest" and the means chosen "directly advance that interest." Id. The logical corollary to these rules is that states may also compel the dissemination of commercial speech in order to ensure that other commercial speech is not false,

deceptive or misleading, or in order to serve a substantial government interest, regardless of concerns over deception. Thus, states have broad authority to regulate the content of speech that is designed "to solicit or obtain legal business" in order to advance a substantial governmental interest. Id. at 641. Moreover, where a mere "disclosure requirement" is imposed, rather than a restriction on speech, the Supreme Court has held that the standard is lowered somewhat because a business's "interest in *not* providing any particular factual information in . . . advertising is minimal." Id. at 651. Thus, the Court has emphasized that "disclosure requirements trench much more narrowly on an advertiser's interest than do flat prohibitions on speech" and that disclosure requirements need only be "reasonably related" to advancing the governmental interest at issue. Id.

The Attorney General argues that the UPDPA's disclosure provisions are designed to overcome the potential conflict of interest that PBMs have to collude with drug manufacturers to increase the prescription drug costs imposed on benefits providers and their sponsors and subscribers ("covered entities" and "covered individuals" under the UPDPA), insofar as manufacturers afford monetary incentives for PBMs to manipulate their formularies or use drug switching programs and other practices to ensure a certain volume of purchases for a specific manufacturer's drugs, regardless of the cost effectiveness of such practices for the ultimate consumers. (Docket No. 88 at 47-48.) The Attorney General maintains that there is no doubt as to "the potential for conflicts and deceptive practices by PBMs," citing a handful of cases decided by this court and others and a consent order entered into by Medco and the Attorney General's Office.[18] (See id. at 48.) In the Attorney General's words:

[18] The Attorney General also points to a proclamation issued by Medco that its goal is "to position Medco as the most transparent company in [the] industry." (Docket No. 88 at 49, citing Docket No. 89, ¶¶ 187-188.)

> Maine has chosen to [control costs and increase access] by providing information to the entity that is responsible for paying the cost of those drugs and is in the best position to protect the interests of Maine citizens; with that information, obtained from the PBM with which it contracts, the covered entity will be able to enter negotiations with a full picture of the PBM's arrangements.

(Id.) There is no question in this case but that the UPDPA is designed to serve a substantial governmental interest: increasing public access to prescription drugs. Thus, the only question is whether compelling PBMs to disclose confidential information to their provider customers, subject to confidentiality restrictions on further dissemination, is reasonably related to advancing the governmental interest the UPDPA is designed to achieve. I conclude that requiring PBMs to confidentially disclose to their provider customers: "financial and utilization information" regarding the services they provide, subject to confidentiality, 22 M.R.S.A. § 2699(2)(D); the costs of drugs involved in a drug substitution where the substituted drug is more expensive than the originally prescribed drug, id., § 2699(2)(E)(2); the financial incentive offered by the manufacturer for substituting its drug for another manufacturer's drug, if any, id.; and the "financial terms and arrangements for remuneration" that PBMs negotiate with manufacturers and pharmacies, subject to confidentiality, is reasonably related to controlling the cost of prescription drugs in Maine because it is designed to create incentives within the market for the abandonment of certain practices that are likely to unnecessarily increase cost without providing any corresponding benefit to the individual whose prescription is being filled and that appear to be designed merely to improve a drug manufacturer's market share. As argued by the Attorney General, the UPDPA essentially has the effect of imposing on entities seeking to sell pharmacy benefits management services within the State of Maine, the fiduciary duties of full disclosure and, with respect to drug substitution practices, non-self-dealing. Because the imposition of the duties to disclose financial information, subject to confidentiality, is reasonably related to the

substantial governmental interests that invigorate the UPDPA,[19] I conclude that PCMA cannot sustain its facial free speech challenge and summary judgment should enter in favor of the Attorney General on this claim.

VII. 42 U.S.C. § 1983

Because I have concluded that the UPDPA does not violate any of the federal rights raised by PCMA, I recommend that summary judgment enter in favor of the Attorney General on the 42 U.S.C. § 1983 claim as well. PCMA argues that summary judgment cannot be entered on this claim, even if summary judgment is entered against all of the substantive claims, because there remains the question whether post-injunction amendments to the UPDPA[20] confer "prevailing party" status on PCMA for purposes of its pending motion for attorney's fees under 42 U.S.C. § 1988. (Docket No. 103 at 46.) I fail to see why the motion for fees requires the court to withhold the entry of judgment on this substantive claim and PCMA's memorandum fails to provide me with any rationale why the court should manage its docket in that fashion.

CONCLUSION

For the reasons stated herein, I **RECOMMEND** that the court **GRANT** the Attorney General's motion for summary judgment and **DENY** PCMA's motion for summary judgment.

[19] To the extent that the applicable standard is in question, I also conclude that, for the same reasons, the means put in place by the UPDPA "directly advance" the substantial governmental interest of reducing the cost of, and increasing access to, prescription drugs. In other words, regardless of whether the UPDPA presents the "best" approach that might ever be conceived, there is:

> a "fit" between the legislature's ends and the means chosen to accomplish those ends – a fit that is not necessarily perfect, but reasonable; that represents not necessarily the single best disposition but one whose scope is in proportion to the interest served; that employs not necessarily the least restrictive means but . . . a means narrowly tailored to achieve the desired objective.

Bd. of Trs v. Fox, 492 U.S. at 480 (internal quotation marks and citation omitted).

[20] The State amended the UPDPA in certain respects after the court granted PCMA's motion for preliminary injunction. The parties' cross-motions for summary judgment both address the constitutionality of the statute as amended.

NOTICE

A party may file objections to those specified portions of a magistrate judge's report or proposed findings or recommended decisions entered pursuant to 28 U.S.C. § 636(b)(1)(B) for which *de novo* review by the district court is sought, together with a supporting memorandum, and request for oral argument before the district judge, if any is sought, within ten (10) days of being served with a copy thereof. A responsive memorandum and any request for oral argument before the district judge shall be filed within ten (10) days after the filing of the objection.

Failure to file a timely objection shall constitute a waiver of the right to *de novo* review by the district court and to appeal the district court's order.

/s/ Margaret J. Kravchuk
U.S. Magistrate Judge

Dated February 2, 2005

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION v. ATTORNEY GENERAL, ME
Assigned to: JUDGE D. BROCK HORNBY
Cause: 28:2201 Declaratory Judgement (Insurance)

Date Filed: 09/03/2003
Jury Demand: None
Nature of Suit: 950 Constitutional - State Statute
Jurisdiction: Federal Question

Plaintiff

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UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,	)	
Plaintiff	)	
v.	)	Civ. No. 03-153-B-W
G. STEVEN ROWE, IN HIS OFFICIAL CAPACITY AS ATTORNEY GENERAL OF THE STATE OF MAINE,	)	
Defendant	)	

ORDER GRANTING MOTION FOR PRELIMINARY INJUNCTION

On September 3, 2003, the Plaintiff, Pharmaceutical Care Management Association ("PCMA"), filed a Complaint in this Court against the Defendant, G. Steven Rowe, in his official capacity as Attorney General of the State of Maine ("State"), seeking declaratory and injunctive relief from "An Act To Protect Against Unfair Prescriptive Drug Practices" ("UPDPA"), 22 M.R.S.A. § 2699. With the filing of the Complaint, PCMA filed a Motion for Preliminary Injunction. This Court GRANTS the Motion for Preliminary Injunction.

I. Facts and Procedural History

a. Background

The pharmaceutical industry in the United States lies at the center of a complex public policy controversy about the delivery and cost of health care. This lawsuit is a symptom of a larger debate about access, affordability, and efficacy within the American health care system and tests the limits of state attempts to legislate a response. Located in Washington, D.C., PCMA is a

trade association of pharmaceutical benefits management companies ("PBMs"). PBMs administer prescriptive drug benefit plans for the more than 200 million Americans covered by the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. §§ 1001-1461, and non-ERISA health care plans, self-insured employers, union-sponsored plans, and federal, state, and local government purchasers. They have become a central force in the $175 billion national market for prescription drugs.[1]

PCMA and the State draw strikingly different portraits of the PBM industry. PCMA sees its members as engaging in extraordinarily fierce, industry-wide competition and playing a vital role in the delivery of cost-effective, quality care. PCMA cites studies that indicate its members have saved billions of dollars for their customers and, ultimately, for consumers. PCMA also emphasizes its members' central role in the provision of quality health care: by organizing and rationalizing vast amounts of nationally-based data, the PBMs have been in a unique position to perform drug utilization reviews; avoid dangerous drug combinations, questionable doses, and excessive addictive medications; and engage in medical and pharmacy education.

[1] To describe, even briefly, the role of PBMs in the American health care system takes a moment. After a physician prescribes a drug and the patient presents the prescription to a pharmacy, the insured portion of the bill (after any co-pays or deductibles) is forwarded to a health maintenance organization ("HMO"), an employer, or an insurer for payment. These third-party payors have commonly entered into contracts with PBMs to process prescription drug payments. When PBMs first appeared on the national scene more than thirty years ago, they offered a niche service to third-party payors: computerized processing of prescriptive drug bills. The PBMs, in essence, became efficient financial intermediaries among third-party payors, pharmacies, and drug companies.

This has become no small service. As prescriptive medicine has become more vital to the provision of quality health care, it has assumed an ever-increasing percentage of the overall health care dollar. At the same time, third-party reimbursement mechanisms have become bewilderingly complex. The PBMs' niche has evolved as a consequence of enormous market forces, thaumaturgic scientific breakthroughs, spiraling health care costs, and Byzantine reimbursement formulas.

As time passed, however, PBMs have begun to offer more to their clients than efficient claims handling. By amalgamating the economic weight of their clients, the PBMs began to approach drug companies and pharmacies and negotiate significant volume discounts or rebates. The PBMs now offer a wide range of services, including rebate programs, pharmacy networks, and drug utilization reviews. Instead of remaining on the sidelines as quiet claims processors, the PBMs have themselves emerged as major players in the health care system with their own undeniable economic clout.

By contrast, the State sees the PBMs as a highly-concentrated industry, insulated from competitive pressures and garnering enormous profits in an unregulated and secretive niche. The State minimizes the PBMs' role in assuring quality care. It notes that the PBMs (with the exception of mail order services) do not handle drugs, do not purchase or sell drugs, do not prescribe drugs, do not act as insurers, and do not assume risk. In response to PCMA's point about drug utilization reviews, the State raises concerns about the use of "switching" or "intervention" strategies.[2]

The State contends that unlike virtually every other area of the health care system, PBMs have largely escaped governmental scrutiny. They are not regulated as financial institutions, health care providers, or insurance companies, and have in the past consistently maintained they are not subject to ERISA. This asserted regulatory gap has begun to attract the attention of federal and state government and the State contends the recent Maine legislation is only a harbinger of things to come. The PBMs vigorously deny what they contend are the "scattershot," "inflammatory," and "egregious mischaracterizations" set forth in the State position. *Pl.'s Reply Mem.* at 1-2.

[2] Again, to understand this allegation takes a moment. The State alleges the PBMs and the drug companies have made what amounts to a devil's bargain: in exchange for volume discounts and rebates relinquished by drug manufacturers, the PBMs agree to promote that manufacturer's drugs and, by doing so, receive a financial reward. Thus, when a physician prescribes one drug brand and the pharmacy begins to fill it, the PBM may seek to influence the choice by steering toward the favored drug manufacturer. Although this practice may inure to the benefit of the client and customer, there are instances when the PBMs engage in "low-to-high" switching, whereby the drug manufacturer pays the PBM to switch patients from less expensive to more expensive drugs. The State claims the PBMs employ scores of pharmacists whose sole function is to review computerized records and contact prescribers to persuade them to switch drugs for individual patients.

The State portrays these arrangements between the PBMs and drug companies as an undisclosed conflict of interest. The State claims the size and terms of these undisclosed paybacks are uniformly concealed from the PBMs clients and the lion's share of PBM profits come not from the covered entities, but from drug company payments deliberately concealed from their clients. A report by the Maine Legislature's Health and Human Services Committee estimated the PBMs receive $12.2 billion in undisclosed payments from drug manufacturers each year. Although acknowledging there are many PBMs, the State asserts that the industry as a whole is highly concentrated with four, soon to be three, companies controlling the national market and enjoying unusual levels of profitability.

b. Maine Legislation.

The UPDPA was enacted by the Maine Legislature in 2003 and signed into law by Governor Baldacci on June 13, 2003. The UPDPA itself is succinct, containing only one new statutory section: 22 M.R.S.A. § 2699. The UPDPA consists of a series of definitions and a list of "required practices." A violation of the UPDPA constitutes a violation of the Maine Unfair Trade Practices Act ("UTPA") and subjects the violator to a fine of not more than $10,000. 22 M.R.S.A. § 2699(4).

The UPDPA's dramatic impact on the PBM industry is immediately apparent. It statutorily defines the relationship between a PBM and its clients as a fiduciary relationship, imposing a "fiduciary duty" running from the PBM to each "covered entity." 22 M.R.S.A. §§ 2699(2)(A), (B). The UPDPA imposes extensive duties of disclosure from the PBM to the client, including the duty to disclose: (1) any "conflict of interest"; (2) "all financial and utilization information requested by the covered entity relating to the provision of benefits"; and, (3) "all financial terms and arrangements for remuneration of any kind that apply between the [PBM] and any prescription drug manufacturer or labeler, including, without limitation, formulary management and drug-switch programs, educational support, claims processing and pharmacy network fees. . . ." 22 M.R.S.A. §§ 2699(2)(D)-(E), (G).

While the UPDPA allows a PBM to substitute a lower-priced generic drug for a therapeutically equivalent higher-priced prescriptive drug, 22 M.R.S.A. § 2699(2)(E)(1), it prohibits the PBM from substituting a higher-priced drug for a lower-priced drug unless the substitution is made "for medical reasons that benefit the covered individual" and the "covered entity," 22 M.R.S.A. § 2699(2)(E)(2). The UPDPA also imposes disclosure and approval obligations on the PBM before doing so. *Id.* Finally, the UPDPA mandates that any benefit the

PBM receives from switching to higher-priced drugs or from volume discounting must be passed "in full" to the covered entity. 22 M.R.S.A. §§ 2699(2)(E)(3), (F). The UPDPA contains a limited confidentiality provision, as well: if a covered entity requests financial and utilization information, the PMB may designate the information as confidential and the covered entity is required not to disclose the information except as required by law. 22 M.R.S.A. § 2699(2)(D).

c. Preliminary Injunction Standard.

PCMA's Motion for Preliminary Injunction rests on three theories: (1) preemption under ERISA; (2) unlawful taking of trade secrets in violation of the Takings Clause of the United States Constitution; and (3) a violation of the Commerce Clause of the United States Constitution.

As a plaintiff in a motion for preliminary injunction, PCMA bears the burden of satisfying each element of a familiar four-part test: (1) it must be likely to succeed on the merits; (2) it must suffer from immediate irreparable injury without injunctive relief; (3) the harm to the plaintiff in the absence of an injunction must exceed the harm to the defendant if the injunction is not granted; and, (4) the public interest must be better served by granting the injunction than by denying it. *Pharmaceutical Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66 (1st Cir. 2001) ("*PhRMA I*"), *aff'd, Pharmaceutical Research & Mfrs. of Am. v. Walsh*, 123 S. Ct. 1855 (2003) ("*PhRMA II*"); *New Comm. Wireless Serv., Inc. v. Spintcom, Inc.*, 287 F.3d 1, 8-9 (1st Cir. 2002).

In evaluating a motion for preliminary injunction in which the plaintiff is claiming constitutional infirmity and federal preemption, the court must apply some bedrock interpretive principles. First, this Court is required not only to presume the state legislative act is constitutional, but also to apply this presumption with special force, since the UPDPA seeks to

regulate an area of public health. *See PhRMA II*, 123 S.Ct. at 1867; *Hillsborough County v. Automated Med. Lab., Inc.*, 471 U.S. 707 (1985). Second, this Court is charged with avoiding a declaration of unconstitutionality if there is an alternative interpretation that would render the UPDPA lawful. These general principles apply more particularly to a motion for preliminary injunction. Finally, when addressing federal preemption, if the field Congress is said to have preempted has traditionally been occupied by the States, this Court must start with the assumption that the historic powers of the States are not to be superseded by the federal act unless that was the "clear and manifest purpose of Congress." *Hillsborough*, 421 U.S. at 715; *PhRMA I*, 249 F.3d at 75.

II. Likelihood of Success on Merits.[3]

a. Standing.

As a preliminary matter, this Court must address PCMA's associational standing to pursue this action on behalf of its member.[4] Under certain circumstances, injury to an organization's members will satisfy the Article III requirement of a case or controversy and the organization will be allowed to litigate in federal court on their behalf. *E.g., United Food & Com. Workers Union Local 751 v. Brown Group*, 517 U.S. 544, 551 (1996); *International Union, United Auto, Aerospace and Agric. Implement Workers of Am. v. Brock*, 477 U.S. 274, 281 (1986); *NAACP v. Alabama ex rel. Patterson*, 357 U.S. 449, 459 (1958). There are three

[3] This Court will not consider language not used in the final version of the UPDPA as indicative of legislative intent. *See, e.g., Availl Serv. Inc. v. Cooper Ind., Inc.*, 263 F.3d 134 (5th Cir. 2001) (stating court should limit reliance on legislative history to that part of history that Congress adopts into law); *United States v. Fox*, 845 F.2d 152 (7th Cir. 1988) (holding that deletion of language moots weight otherwise given to legislative history regarding that language); *Cairns v. Franklin Mint Co.*, 120 F.Supp. 2d 880 (C.D. Cal. 2000) (noting state court readings of deleted language as persuasive that such provisions should not be read into law).

[4] In its response, the State has questioned whether PCMA has standing to raise a takings issue for its members. As the absence of associational standing would bar PCMA from bringing any of its claims on behalf of its members, not just the takings clause claim, the Court will address the issue of standing before considering the claims themselves.

elements of associational standing: (1) association members must have standing to sue in their own right; (2) the interests sought to be protected must be germane to the purposes of the association; and (3) neither the relief requested nor the claim asserted requires the individual members' participation. *Hunt v. Washington State Apple Adver. Comm'n,* 432 US. 333, 343 (1977) (quoting *Warth v. Seldin*, 422 U.S. 490, 511 (1975)). The parties agree that the first two criteria are present; the State challenges whether the third is.

If the plaintiff claiming associational standing can ensure that "the remedy, if granted, will inure to the benefit of those members of the association actually injured," the association will be allowed to invoke the remedial powers of the court on behalf of its members. *Brock,* 477 U.S. at 288 (1986) (quoting *Warth,* 422 U.S. at 515 (1975)). Whether an association has standing for its members "depends in substantial measure on the nature of the relief sought." *Hunt,* 432 U.S. at 343. In this case, PCMA is seeing declaratory and injunctive relief and it "can be reasonably supposed that the remedy, if granted, will inure to the benefit of those members of the association actually injured." *Id.*

The First Circuit considered associational standing in the context of a motion for preliminary injunction in *Camel Hair & Cashmere Institute, Inc. v. Associated Dry Goods Corp.,* 799 F.2d 6, 12 (1st Cir. 1986). In *Camel Hair,* the First Circuit noted that "actions for declaratory, injunctive and other forms of prospective relief have generally been held particularly suited to group representation." *Id.* In addition, the *Camel Hair* Court distinguished "between the showing required to establish a right to injunctive relief and that required to establish a right to damages." *Id.* Generally, where, as in this case, the court is addressing only the question of preliminary injunctive relief, the participation of individual members is not necessary.[5] *Id.*

[5] The State contends not all PCMA members have taken the same position on the secrecy of the information the UPDPA mandates they disclose. It cites the "client principles" from PCMA member AdvancePCS, which state it

This Court concludes that PCMA has fulfilled the criteria set forth in *Hunt* and has associational standing to press its members' claims for declaratory and injunctive relief. Although there may be some differences among the PBMs as to their treatment of the financial and rebate information, the Court is persuaded that all PBMs view this information as a highly confidential trade secret. For associational standing purposes, the key is whether there is a nexus between the members' commonality and the remedy their association seeks. *Camel Hair,* 799 F.3d at 12 (finding "no conflict between the needs and interests of the members."). In this case, it is clear there is such a nexus. The members share the view that the information the UPDPA would disclose goes to the heart of their mutual competition and PCMA seeks an injunction against its revelation. Put another way, if there were evidence that the members were sufficiently disparate in their approach to trade secrets to conclude that some would gain a competitive edge by disclosure, then this would undercut PCMA's claim for associational standing. However, the evidence before the Court is exactly to the contrary: all PCMA members support its demand for relief. [6]

views all rebates as the property of its clients and allows the client to audit the rebate amounts down to the transaction level. Similarly, the State points out that PCMA member Express Scripts, Inc., allows full audits by its clients. These differences, the State contends, negate PCMA's claim of associational standing, since enforcement of the UPDPA would affect its members differently. PCMA responded with supplemental declarations from Susan de Mars of AdvancePCS and Edward Ignaczak of Express Script, explaining that their companies require the auditors performing the rebate audits to sign confidentiality agreements and complete the review at their company offices. These auditing procedures are insufficient to convince this Court that the UPDPA disclosures would affect PCMA members differently.

[6] In *Rent Stabilization Association v. Dinkins,* 5 F.3d 591 (2d Cir. 1993), the Second Circuit discussed the *Hunt* criteria in the context of a takings claim. Noting that *Hunt* mandates "*neither the claim asserted* nor the relief requested" require the participation of the individual members (emphasis in *Rent Stabilization*), the Second Circuit concluded that because a takings claim commonly mandates an essentially *ad hoc,* factual inquiry, associational standing could not be granted to an association of 25,000 building owners because the law would necessarily affect each owner differently. *Rent Stabilization,* 5 F.3d at 597 (citing *Kaiser Aetna v. United States,* 444 U.S. 164, 175 (1979)). The *Rent Stabilization* holding does not prohibit the grant of associational standing in this case. Here, PCMA's members are readily identifiable. Further, even though there may be some differences in the exact way the UPDPA's mandated disclosures could affect individual members, this Court concludes that the UPDPA's disclosures would not only injure each member, but that the requested remedy would "inure to the benefit of those members of the association actually injured." *Warth,* 422 U.S. at 515; *see infra* note 17 (discussing facial and as-applied claims).

b. Commerce Clause.

PCMA claims the UPDPA violates the Commerce Clause, by having extraterritorial effect and discriminating against out-of-state companies in favor of in-state companies. This Court disagrees. Under the Commerce Clause, Congress has the power "to regulate commerce with foreign nations, and among the several states, and with the Indian tribes." U.S. Const. art I, § 8. In matters not governed by federal legislation, the Commerce Clause has long been understood to have a "negative" aspect that denies the States the power unjustifiably to discriminate against or burden the interstate flow of articles of commerce. *See Oregon Waste Sys., Inc. v. Dep't of Envtl. Quality,* 511 U.S. 93, 98 (1994); *Wyoming v. Oklahoma,* 502 U.S. 437, 454 (1992); *Welton v. Missouri*, 91 U.S. 275 (1876). This negative command, known as the dormant Commerce Clause, prohibits states from acting in a manner that burdens the flow of interstate commerce. *Id.*; *PhRMA I*, 249 F.3d at 79.

i. *Per Se* Violation: Extraterritorial Reach.

PCMA asserts that § 2699(1)(E) of the UPDPA impermissibly affects commerce outside Maine by requiring the disclosure of trade secrets contained in PCMA members' contracts, even if those contracts do not relate to Maine's "covered entities." As such, PCMA argues the UPDPA projects Maine legislation into other states by mandating disclosure of PBMs' confidential contracts in those states. *Pl.'s Mem.* at 23 (citing *Healy v. Beer Inst.*, 491 U.S. 324, 334 (1989)).

A state statute is a *per se* violation of the Commerce Clause when it has an "extraterritorial reach;" that is, necessarily requiring out-of-state commerce to be conducted according to in-state terms. *PhRMA I,* 249 F.3d at 79; *Healy,* 491 U.S. at 336. PCMA does not appear to argue that the UPDPA constitutes a *per se* violation of the Commerce Clause and, to

the extent the argument is being made, there has been no showing that the UPDPA regulates commerce wholly outside Maine's borders. *See id.*

PCMA argues the UPDPA would impermissibly regulate PBM services outside of Maine, since it requires disclosure of PBM contracts with drug manufacturers even if the contracts do not relate to Maine "covered entities." In this Court's view, the UPDPA clearly ties its reach to Maine. The statute limits PBM obligations to a "covered entity" as:

> . . . [A] nonprofit hospital or medical service organization, insurer, health coverage plan or heath maintenance organization *licensed pursuant to Title 24 or 24-A*; a health program *administered by the department or the State* in the capacity of provider of health coverage; or an employer, labor union or other group of persons *organized in the State* that provides health coverage to covered individuals *who are employed or reside in the State.*

22 M.R.S.A. § 2699(1)(A) (emphasis added).

The disclosure provisions of the UPDPA rely on the statute's definition of "covered entity" and, accordingly, are tied to Maine. For instance, § 2699(2)(D)[7] requires the PBM to provide to the covered entity, upon request, "all financial and utilization information requested by the *covered entity* relating to the provision of benefits to covered individuals through that

[7] 22 M.R.S.A. § 2699(2)(D) provides:

> A pharmacy benefits manager owes a fiduciary duty to a covered entity and shall discharge that duty in accordance with the provisions of state and federal law.
>
> .....
>
> D. A pharmacy benefits manager shall provide to a covered entity all financial and utilization information requested by the covered entity relating to the provision of benefits to covered individuals through that covered entity and all financial and utilization information relating to services to that covered entity. A pharmacy benefits manager providing information under this paragraph may designate that material as confidential. Information designated as confidential by a pharmacy benefits manager and provided to a covered entity under this paragraph may not be disclosed by the covered entity to any person without the consent of the pharmacy benefits manager, except that disclosure may be made in a court filing under the Maine Unfair Trade Practices UPDPA or when authorized by that UPDPA or ordered by a court of this State for good cause shown.

covered entity and all financial and utilization information relating to services to that *covered entity*." (emphasis added). Likewise, § 2699(2)(G)[8] mandates disclosure to the covered entity of "all financial terms and arrangements for remuneration of any kind that apply between the pharmacy benefits manager and any prescription drug manufacturer or labeler. . . ." Though § 2269(2)(G) is not by its express terms limited to disclosure of contracts between PBMs and manufacturers that directly relate to covered entities, the disclosure requirements are set forth as part of the fiduciary duties a PBM owes a "covered entity."

The UPDPA also establishes that compliance is required "in all contracts for pharmacy benefits management entered into in this State or by a covered entity in this State." 22 M.R.S.A. § 2699(3). If the PBM does not contract with Maine covered entities, the law has no application. The Maine UPDPA is not seeking to "project its legislation" into other States.[9] *See Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 521 (1935); *PhRMA*, 123 S.Ct. at 1870-71.

[8] 22 M.R.S.A. § 2699(2)(G) provides:

> A pharmacy benefits manager owes a fiduciary duty to a covered entity and shall discharge that duty in accordance with the provisions of state and federal law.
>
> .....
>
> G. A pharmacy benefits manager shall disclose to the covered entity all financial terms and arrangements for remuneration of any kind that apply between the pharmacy benefits manager and any prescription drug manufacturer or labeler, including, without limitation, formulary management and drug-switch programs, educational support, claims processing and pharmacy network fees that are charged from retail pharmacies and data sales fees.

[9] PCMA argues that disclosure of trade secrets for "covered entities" in Maine could "expose trade secret information relevant to the PBM's commercial relationships in other States–depriving PBMs of the competitive advantages they have in those jurisdictions that derive from their trade secrets." *Pl.'s Reply Mem.* at 23. But, as the First Circuit said in *PhRMA I*, "simply because the manufacturers' profits might be negatively affected by the Maine UPDPA . . . does not necessarily mean that the Maine UPDPA is regulating those profits." 249 F.3d at 82. The fact a law may have a potentially devastating effect on a particular interstate firm is not sufficient to rise to a Commerce Clause burden. *Id.* (citing *Instructional Sys., Inc. v. Computer Curriculum Corp.*, 35 F.3d 813, 827 (3rd Cir. 1994)). Where the burden on out-of-state interests rises no higher than that placed on competing in-state interests, it is a burden on *commerce* rather than a burden on *interstate* commerce. *Id.* The fact the State regulated indiscriminately supports the conclusion that the Commerce Clause has not been violated. *Id.*

ii. Virtually *Per Se* Rule: Discriminatory Against Out-Of-State Commerce.

If a state statute discriminates against interstate commerce, the Court will apply strict scrutiny under what the Supreme Court has termed the "virtually *per se* rule of invalidity." *Oregon Waste,* 511 U.S. at 100; *Brown-Forman Distillers Corp. v. N.Y. State Liquor Authority,* 476 U.S. 573, 579 (1986); *PhRMA I,* 249 F.3d at 80. This level of scrutiny will be applied "if the state statue discriminates against interstate commerce on its face or in practical effect." *PhRMA I,* 249 F.3d at 80. On its face, the UPDPA does not favor in-state economic interests over out-of-state interests; therefore, the line of case law that addresses facially discriminatory state statutes is inapposite.[10]

PCMA argues, however, the UPDPA favors an in-state Maine pharmacy over an out-of-state mail order pharmacy, since it expressly addresses the "mail service pharmacy," § 2699(2)(E)(1), but not the retail pharmacy. Yet, none of the mail order pharmacies affiliated with PCMA members are physically located in Maine and PCMA does not state or imply that no mail order pharmacies are located in Maine.[11] At the very least, PCMA has failed to sustain its burden on this issue. The UPDPA "regulates evenhandedly with only 'incidental' effects on interstate commerce" and does not "discriminate against interstate commerce either on its face or

[10] *See, e.g., Oregon Waste,* 511 U.S. at 93 (Oregon statute imposed higher disposal fee on out-of-state waste); *Wyoming,* 502 U.S. at 437 (Oklahoma statute required Oklahoma electric plants to burn a mixture of coal containing at least 10 percent Oklahoma-mined coal); *New Energy Co. v. Limbach,* 486 U.S. 269 (1988) (Ohio statute awarded tax credit against Ohio fuel sales tax for ethanol produced in Ohio or to out-of-state producers only if the other State granted similar credits); *Lewis v. BT Inv. Managers, Inc.,* 447 U.S. 27 (1980) (Florida statute favored in-state businesses over businesses with principal operations outside Florida).

[11] The State points out in its memorandum that PCMA could not demonstrate there are no mail order pharmacies located in Maine. *Def.'s Mem.* at 39.

in practical effect."[12] *See Oregon Waste,* 511 U.S. at 99; *Hughes v. Oklahoma,* 441 U.S. 322, 336 (1979).

iii. *Pike v. Bruce Church* Analysis.

Although PCMA did not make a *Pike v. Bruce Church* argument in its initial memorandum, it did so in rebuttal. *Pike* explained that where a state statute regulates evenhandedly and has only incidental effects on interstate commerce, the court balances the burden on interstate commerce against the putative local benefit. 397 U.S. 137, 142 (1970); *PhRMA I,* 249 F.3d at 80. In this Court's view, the potential benefit to Maine consumers in reducing the enormous burden of prescriptive medication substantially outweighs the incidental impact the UPDPA may have upon interstate commerce.

c. Takings Clause.

PCMA contends that by requiring revelation of its members' trade secrets, the UPDPA constitutes a "taking" of property for which just compensation is due under the Fifth and Fourteenth Amendments of the United States Constitution. Specifically, PCMA challenges the two provisions of the UPDPA that mandate disclosure of information: § 2699(2)(D) and § 2699(2)(G).[13] The Takings Clause claim requires an analysis of several separate issues.

i. Trade Secret.

First, this Court must determine whether the information required to be disclosed under the UPDPA constitutes a trade secret. The PBMs' trade secrets include the confidential terms of contracts with customers, drug manufacturers, and pharmacies as well as financial and utilization

[12] *See supra* note 9.

[13] *See supra* notes 7, 8.

information. The State contends that the information is simply not a trade secret,[14] arguing that a trade secret is not information "as to a single or ephemeral events in the conduct of the business, as, for example, the amount or other terms of a secret bid for a contract." *Def.'s Mem.* at 27 (citing *Restatement of Torts: Liability For Disclosure or Use of Another's Trade Secret*, § 757 cmt. b (1939)). However, intangible property can constitute a trade secret and a property right protected by the Takings Clause, *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1003-04 (1984), the first question is whether under Maine law, the contract terms disclosed under the UPDPA are trade secrets. *See also Reilly*, 312 F.3d at 33.

Maine has adopted the Uniform Trade Secrets Act ("UTSA"), 10 M.R.S.A. §§ 1541-1548, which defines "trade secret" as:

> [I]nformation, including, but not limited to, a formula, pattern, compilation, program, device, method, technique or process, that:
> a. Derives independent economic value, actual or potential, from not being generally known to and not being readily ascertainable by proper means by other persons who can obtain economic value from its disclosure or use; and
> b. Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

10 M.R.S.A. § 1542(4). In *Spottiswoode v. Levine*, the Maine Supreme Judicial Court listed five factors a court may examine to determine whether the information derives independent economic value from not being generally known or readily ascertainable: (1) the value of the information to the plaintiff and to its competitors; (2) the amount of effort or money the plaintiff expended in developing the information; (3) the extent of measures the plaintiff took to guard the secrecy of

[14] The State contends PCMA's motion should fail because PCMA did not comply with the best evidence rule since it did not introduce the original contracts that form the bases of PCMA's claims. *See* F.R.E. 1002. The State's argument, however, misperceives the issue. For purposes of ruling on this motion, whether the information set forth in a contract constitutes a trade secret does not depend upon the detailed contents of the document itself, but the context and significance of the contract. A description of what was negotiated in the contracts and why the PBMs consider the contents a trade secret is more significant than the specific contract terms. For this purpose, the declarations of the company officials are sufficiently probative. *See R & R Associates, Inc. v. Visual Scene, Inc.* 726 F.2d 36, 38 (1st Cir. 1984). However, this is not to say the actual contents of the contracts may not become fair game later.

the information; (4) the ease or difficulty with which others could properly acquire or duplicate the information; and, (5) the degree to which third parties have placed the information in the public domain or rendered the information "readily ascertainable" through patent applications or unrestricted product marketing. 730 A.2d 166 (Me. 1999).

Applying 10 M.R.S.A. § 1542(4)'s statutory definition, PCMA contends that the PBMs derive "independent economic value" from the specific contract terms each PBM has been able to negotiate with its drug suppliers and pharmacies. Precise information about rebates, if made generally known, would cripple the PBMs' ability to negotiate rebates with drug manufacturers and pharmacies and "destroy the value of this trade secret information."

The Maine statutory definition conveys the same underlying concept as the Restatement's definition of "trade secret": information is a trade secret if it generates "independent economic value" from not being "generally known" nor "readily ascertainable" and the holder of the secret makes an effort to maintain its secrecy. 10 M.R.S.A. § 1542(4). The record indicates that the PBMs consider this information highly-confidential and strive to maintain its secrecy. *See, e.g., supra* note 6. Comparing the *Spottiswoode* criteria to the facts in the record, the Court concludes that PCMA has sustained its burden for purposes of the motion for preliminary injunction to demonstrate that the information the UPDPA mandates disclosed constitutes a trade secret.[15]

ii. **Regulatory Taking.**

1. *Per Se* Taking.

[15] This should not be interpreted as the last word on this issue. The Court is disquieted by the notion that the rebate and secret contractual arrangements in this case can constitute a protected trade secret. Unlike the trade secrets in *Ruckelshaus* (data on pesticide ingredients) and *Reilly* (ingredient lists for tobacco products), information about negotiated contractual terms has no intrinsic economic value. Its true value is derived from the non-competitive impact of its confidentiality. The affidavits and argument submitted by the parties for purposes of a motion for preliminary injunction are insufficient to draw final conclusions on this issue and the consequences of denial of the motion on this ground would be that the information that the Court could ultimately conclude should be protected will be forever released. As Judge Selya stated in *Reilly*, 312 F.3d at 50, "a secret remains secret when not divulged."

In general, the law distinguishes between two types of takings: physical takings and regulatory takings. *Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Planning Agency,* 535 U.S. 302, 323-24 (2002); *Reilly,* 312 F.3d at 33. In the context of tangible property, if the government physically takes possession of the property or a part of the property, then it has "a categorical duty to compensate the former owner." *Tahoe-Sierra,* 535 U.S. at 322. As Justice Stevens stated in *Tahoe-Sierra,* jurisprudence involving condemnations and physical takings is "as old as the Republic itself and, for the most part, involves the straightforward application of *per se* rules." *Id.*

By contrast, regulatory takings jurisprudence is "of more recent vintage and is characterized by "essentially ad hoc, factual inquires." *Id.* (quoting *Penn. Cent. Transp. Co. v. New York City,* 438 U.S. 104, 124 (1978)). To determine how far is too far requires a fact-based inquiry. Yet, the Supreme Court has also applied a *per se* analysis to some regulatory takings. *E.g., Tahoe-Sierra,* 535 U.S. at 325; *Lucas v. South Carolina Coastal Council,* 505 U.S. 1003, 1015 (1992) ("[W]e have found categorical treatment appropriate . . . where regulation denies all economically beneficial or productive use of land").

These distinctions, difficult enough in physical takings, become murky indeed when applied to intellectual property. Although acknowledging PCMA's contention that the disclosure of its members' trade secrets can be construed no other way than a *per se* taking of the secret, this Court has concluded the wiser course is to apply the *Penn Central* analysis.

2. The *Penn Central* Analysis.

Courts have generally applied a three-part *ad hoc,* factual inquiry to evaluate whether a regulatory taking has occurred: (1) the economic impact of the regulation; (2) whether the government action interferes with reasonable investment-backed expectations; and (3) the

character of the government action. *E.g., Reilly,* 312 F.3d at 33; *Penn Central,* 438 U.S. at 124. Applying these factors to the UPDPA, it is apparent that the two disclosure sections are distinct and must be treated separately.

As the Court understands it, § 2269(2)(D) requires the PBM to provide information to an employer, for example, about drug utilization and prescriptive medication payments to or on behalf of its employees. Similarly, it requires the disclosure to the covered entity of "all financial and utilization information relating to services to that covered entity." 22 M.R.S.A. § 2269(2)(D). This language presumably refers to services the PBM provide that do not result in the payment of a benefit. For example, if the PBM performs a drug utilization review untied to a particular payment, then the employer could require the PBM to disclose the information to it. It is true that the breadth of the phrase, "all financial . . . information," may implicate the rebate and remuneration information contemplated by § 2699(2)(G), but if this were the case, § 2699(2)(G) would be redundant.

Assuming § 2699(2)(D) is limited to information about benefits the covered entity has paid for or services the PBM provided to it, this Court cannot conclude that it runs afoul of the *Penn Central* criteria. Moreover, § 2699(2)(D) contains a confidentiality provision that prohibits disclosure of information the PBM has designated as confidential. To the extent this information is in fact a trade secret, the statute's protection from further disclosure inoculates it from constitutional infirmity. [16] *See Reilly,* 312 F.3d at 53 ("[A] more limited disclosure likely would not suffer from the same constitutional infirmities") (Lipez, J., dissenting).

[16] This Court does not credit PCMA's fear that the disclosure protections of § 2699(2)(D) are illusory because the information could be revealed in a subsequent judicial proceeding. A court would have the authority to impose restrictions on dissemination of disclosed information and presumably would do so, unless the information did not warrant such protection.

However, § 2699(2)(G) presents a different problem. It not only mandates disclosure of information that goes to the heart of what the PBMs contend are trade secrets, but it also fails to protect that information from further disclosure. The covered entities would be free to share this information with drug companies or pharmacies and reveal with impunity its PBMs' trade secrets to competitor PBMs. Turning to the first *Penn Central* factor, the record establishes that disclosure of this information would destroy its value. *Reilly,* 312 F.3d at 39 ("[A] trade secret is lost if its holder gives the trade secret to another without extracting a guarantee of confidentiality"). To paraphrase Judge Torruella in *Reilly,* once the competitors obtain this information, they can use it in a fashion that will undermine its value. *Reilly,* 312 F.3d at 41.

Likewise, PCMA has met the second *Penn Central* criterion: reasonable investment-backed expectations that the information would not be disclosed. To determine whether the holder of a trade secret had reasonable investment-backed expectations is, to borrow Judge Toruella's wording again, to "proceed into [a] quagmire." *See Reilly,* 312 F.3d at 37. In this case, the parties agree that the UPDPA is Maine's first foray into PBM regulation. *Def.'s Mem.* at 6. On the other hand, as an unregulated island in a highly regulated sea, the PBMs might well have expected that government regulation was inevitable, since "such restrictions are the burdens we all must bear in exchange for 'the advantage of living and doing business in a civilized community.'" *Ruckelshaus,* 467 U.S. at 1007 (quoting *Andrus v. Allard,* 444 U.S. 51, 67 (1979)). But the PBMs can effectively argue that the prospect of some regulation does not absolve the State from just compensation, especially since the PBMs should not have anticipated untrammeled and unprotected disclosure of their trade secrets. These reasonable investor-backed expectations were further enhanced by Maine's enactment of the UTSA.

Similarly, the third *Penn Central* criterion has been met. In determining the character of the government action—how the UPDPA regulates and the UPDPA's effect on the PBMs' trade secrets, the Court must balance Maine's interest in regulation against the PBMs interest in protecting their trade secrets. *See Reilly,* 312 F.3d at 41. As in *Reilly,* the unprotected disclosure of the PBMs' trade secrets will result in their inability to exclude others, a right that is fundamental to a property interest, *Kaiser Aetna,* 444 U.S. at 179-80, and a destruction of the value of the trade secret. *Reilly,* 312, F.3d at 41. At the same time, the state has a "significant, even compelling" interest in regulation involving public health. *Id.* at 44; *Keystone Bituminous Coal Assoc. v. DeBenedictis,* 480 U.S. 470, 488 (1987).

Where the economic impact of the regulation and effect on reasonable investment-backed expectations is profound, the Court is required to examine whether the regulation bears a reasonable relation to its ends. Of course, the parties disagree on the impact of the regulation: PCMA argues the benefits of disclosure are "speculative" and raises the possibility of serious economic consequences to Maine citizens; the State contends the UPDPA requires only "full and fair disclosure" to enable covered entities to "ensure that their PBMs are not gouging them."

However, the timing of a motion for preliminary injunction places the arguments in a different context. PCMA essentially asks for the maintenance of the *status quo* while the case is litigated. In weighing the respective positions of the parties, this Court concludes that for purposes of the motion for preliminary injunction, the *Penn Central* criteria have been met and the UPDPA to violate the Takings Clause.[17]

[17] In its supplemental brief, the State raises what amounts to a ripeness argument, though characterizes it as one of standing. Citing case law that requires a litigant to exhaust state remedies before seeking relief from a taking, the State claims that the Plaintiff's members do not have standing to contest the UPDPA because they never challenged the law in Maine. Accordingly, the State asserts the claims are not ripe and the Plaintiff does not have associational standing to pursue the claims on their behalf.

While the State is correct that the Plaintiff does not have a claim unless its members have claims, the argument paints existing case law with too broad a brush. In the regulatory takings context, challenges to a law may be facial;

d. Preemption.

PCMA argues ERISA preemption on the following grounds: (1) the UPDPA has a "connection with" employee benefit plans covered by ERISA; (2) the UPDPA has a "reference to" employee benefit plans covered by ERISA; and (3) the UPDPA undermines the exclusivity of ERISA's civil enforcement scheme. The State disputes these grounds and responds that because PBMs are not ERISA fiduciaries and do not otherwise fall into an ERISA entity category, the State is free to regulate them.

i. Background.

Congress enacted ERISA with the express intent to "establish pension plan regulation as exclusively a federal concern." *Alessi v. Raybestos-Manhattan, Inc.*, 451 U.S. 504, 523 (1981). In *Shaw v. Delta Air Lines, Inc.*, the Supreme Court concluded that through ERISA, Congress intended not only to preempt the field, but that the preemptive scope was as broad as ERISA's language. 463 U.S. 85, 98 (1983). ERISA defines "employee welfare benefit plan" to mean:

> [A]ny plan . . . established or maintained by an employer . . . for the purpose of providing for its participants or their beneficiaries, through the purchase or insurance or otherwise, (A) medical, surgical, or hospital care or benefits, or benefits in the event of sickness, accident, disability. . . .

that is, a claim that the law affects a taking by its very terms, and as-applied; that is, a claim that the law affects a taking when applied to the claimant or particular property. It is true an as-applied claim is not ripe until the government entity charged with implementing the law has denied the property owner just compensation, *Williamson Co. Reg'l Planning Comm'n v. Hamilton Bank of Johnson City*, 473 U.S. 172, 186 (1985), because the "taking" depends on the extent to which the entity deprives the claimant of the use of the property without adequate compensation. *Yee v. City of Escondido, Cal.*, 503 U.S. 519, 533 (1992).

In the instant case, the Plaintiff has mounted a facial challenge to the UPDPA, arguing by its terms, the law effects a taking of the Plaintiff's members' trade secrets. The offense is not the State's lack of adequate compensation for the taking, but rather the taking itself. As a facial challenge, the argument ripened when the State enacted the UPDPA. *See Yee*, 503 U.S. at 533.

Further, with facial challenges, where an adequate remedy is not available at law, equitable relief, such as a preliminary injunction, is appropriate. *E.g., Euclid v. Ambler Realty Co.*, 272 U.S. 365, 386 (1926) (stating that equitable relief is clear in instances of facial challenges); *Reilly*, 312 F.3d at 50 (evaluating merits of request for preliminary injunction where claimant had no adequate remedy at law and faced Hobson's choice of forfeiting trade secrets or withdrawing from market). Thus, equitable relief, such as a preliminary injunction, is appropriate to the extent that the UPDPA actually offends the Plaintiff's members' property rights.

29 U.S.C. § 1002(1); *see Pilot Life Ins. Co. v. Dedeaux,* 481 U.S. 41, 44 (1987). Congress "capped off" ERISA with provisions relating to the preemptive effect of the federal legislation, including the following:

> Except as provided in [ERISA's savings clause], the provisions of this subchapter and subchapter III of this chapter shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan. . . .

29 U.S.C. § 1144(a).

Recently, however, the Supreme Court has grown "more guarded" in interpreting the scope of ERISA, *Carpenters Local Union No. 26 v. United States Fiduciary & Guaranty, Co.,* 215 F.3d 136, 139 (2000), and emphasized the starting presumption that "Congress does not intend to supplant state law," *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Insurance Co.,* 514 U.S. 645, 654 (1995); *see California Div. of Lab. Stds. Enf. v. Dillingham Constr.,* 519 U.S. 316, 324 (1997). The Court has been especially careful to note the field of health care is distinctive and "nothing in the language of [ERISA] or the context of its passage indicates that Congress chose to displace general health care regulation, which historically has been a matter of local concern." *Travelers,* 514 U.S. at 661. Indeed, there is no ERISA preemption in health care without clear manifestation of congressional purpose. *E.g., Pegram v. Herdrich,* 530 U.S. 211, 237 (2000).

Within these parameters, this Court must evaluate whether the UPDPA "relates to" any employee benefit plan, for, if it does, it is preempted. *Carpenters Local,* 215 F.3d at 140. A state law "relates to" an employee benefit plan if it either (1) has a connection with or (2) makes reference to such a plan. *Id.*; *Dillingham,* 519 U.S. at 324.

ii. Connection.

In *Travelers* and *Dillingham*, the Supreme Court modified the analysis as to whether a state law has a "connection with" ERISA: the Court "abandoned strict textualism in favor of a more nuanced approach." *Carpenters Local*, 215 F.3d at 140. *Travelers* explained, "For the same reasons that infinite relations cannot be the measure of pre-emption, neither can infinite connections." 514 U.S. at 656. Thus, to determine whether a State law is subject to ERISA pre-emption under the "connection with" portion of the inquiry, courts must consider the objectives of ERISA as a guide to the scope of the state law Congress understood would survive. *Id.*

Cataloguing the objectives of ERISA is a "fairly straightforward exercise." *Carpenters Local,* 215 F.3d at 140. When Congress enacted ERISA, it made manifest its intention to "protect . . . the interests of participants in employee benefit plans and their beneficiaries . . . by establishing standards of conduct, responsibility, and obligation for fiduciaries of employee benefit plans, and by providing for appropriate remedies." *Id.*; 29 U.S.C. § 1001(b). Achieving this end requires the avoidance of "a multiplicity of regulation" and, concomitantly, the creation of a climate that "permits the nationally uniform administration of employee benefit plans." *Travelers,* 514 U.S. at 657; *Carpenters Local,* 215 F.3d at 140. The First Circuit summarized the inquiry as follows: whether the state laws have a "real bearing on the intricate web of relationships among the principal players in the ERISA scenario (e.g., the plan, the administrators, the fiduciaries, the beneficiaries, and the employer)." *Carpenters Local,* 215 F.3d at 141.

Here, there is no dispute that the UPDPA imposes new and broad regulations upon PBMs. It defines them as fiduciaries, requires disclosures of their provision of benefits and utilization reviews, mandates notification of any conflicts of interest, and compels disclosure of

contractual terms with drug companies and pharmacies. The UPDPA also establishes restrictions on the way the PBMs may operate: PBMs are allowed to substitute generic drugs for higher-priced prescription drugs but are forbidden from doing the opposite without obtaining the approval of the "prescribing health professional" and disclosing both the substitution and the cost of both drugs and any benefit derived from the switch to the covered individual and the covered entity. The PBMs are also obligated to transfer in full to the covered entity any financial benefit garnered from either substituting drugs or volume discounts.

This Court concludes that the provisions of the UPDPA are virtually bound to collide with the ERISA goal of a "nationally uniform administration of employee benefit plans." *See Travelers*, 514 U.S. at 657. For example, consider the inherent conflict between the PBM's duties to the covered entity and covered individuals and the entity and individuals' ability to resort to state litigation under the UPDPA.[18] This conflict is codified in 22 M.R.S.A. § 2699(2)(B): "A [PBM] shall discharge its duties with respect to the covered entity for the primary purpose of providing benefits to covered individuals *and* defraying reasonable expenses of administering health plans." The UPDPA assumes the two duties are reconcilable; however, an analysis of § 2699(2)(E)(2)'s implications demonstrates they are not. Section 2699(2)(E)(2) governs the substitution of a more expensive drug for a less expensive generic medication. The law requires the substitution "be made for medical reasons that benefit the covered individual *and* must benefit the covered entity." 22 M.R.S.A. § 2699(2)(E)(2) (emphasis added). If the PBM, even after obtaining doctor approval, were to substitute a drastically more expensive prescriptive medication for a generic drug, the covered entity could well be extremely

[18] The State can well argue that the law only recognizes a conflict that the PBMs already have, regardless of whether it is codified. However, the point for ERISA preemption purposes is whether the UPDPA in its operation is likely to have a real bearing on the intricate web of relationships described in *Carpenters Local* and this example, in the Court's view, demonstrates that it will.

dissatisfied with the increased cost, but the individual could well be fully satisfied—indeed happy—with the switch. Under the UPDPA, though, the PBM does not owe a direct fiduciary duty to the patient; it owes this duty solely to the covered entity. 22 M.R.S.A. § 2699(2) ("A [PBM] owes a fiduciary duty *to a covered entity*. . . . .) (emphasis added). If the PBM acts in the best medical interest of the patient over the best financial interest of the covered entity, the UPDPA virtually invites litigation through its notice and enforcement provisions.

Under § 2699(2(E)(2), before making the switch to a more expensive drug, the PBM must first reveal to both the covered entity and the patient the cost of both drugs and any payments the PBM is receiving directly or indirectly as a result of the substitution. It must then obtain the approval of the person's physician. Armed with information about the cost differential and any rebate, the covered entity is authorized to file suit under the Maine UTPA.

Further, the terms of the UPDPA provide an avenue for legal redress: a violation of the law constitutes a violation of the UTPA. The UTPA contains provisions for action by the Maine Attorney General and the filing of private causes of actions, 5 M.R.S.A. § 213, grants jurisdiction to the Maine Superior Court, and provides the right to trial by jury, 5 M.R.S.A. § 213(1). If a PBM were to switch to a higher-cost drug with the approval of the covered individual and his physician, but over the objection of the covered entity, the UPDPA gives the covered entity a clear cause of action against the PBM for violating its fiduciary obligation. On the other hand, if the PBM refused to substitute the higher priced prescription despite physician approval, the covered individual could presumably initiate a private cause of action under the UTPA for violation of the UPDPA's conflict of interest provision, seeking to enjoin the PBM.

This example is only the first of a host of issues that this Court concludes will find their way to state court as an inevitable consequence of the duties and remedies the UPDPA creates.[19]

The inquiry, then, is twofold: first, whether these potential issues invade the province of ERISA; and second, whether they raise the spectre of an alternative state enforcement mechanism to ERISA's enforcement scheme, triggering preemption. *Rush Prudential*, 536 U.S. at 375; *Ingersoll-Rand*, 408 U.S. at 142-45; *Carpenters Local*, 215 F.3d at 141. The decision as to what drug to prescribe, the price of the drug, the comparative medical efficacy of the drug, and the disclosure requirements to the covered entity and covered individual all seem to fall squarely within the First Circuit's concern: state law interference with the administration of covered employee benefit plans, purporting to regulate plan benefits or impose additional reporting requirements. *Carpenters Local*, 215 F.3d at 141.

Similarly, the prospect of Maine state law suits initiated to enjoin, fine, or obtain monetary damages for the filling of a prescription appear to this Court to conflict with the *Rush Prudential* Court's observation that there is an "overpowering federal policy in the civil

[19] The UPDPA raises the likelihood that the Maine Superior Court will become the forum of choice for the resolution of controversies that are essentially between the covered entity and the covered individual. If the covered entity or covered individual were to challenge a PBM decision under the UTCP, although the pretext of the complaint might be the PBM's role, the nub of the issue could very likely be whether the covered entity's financial interests should take precedence over the covered individual's medical interests. For those health plans covered by ERISA, the issue litigated in Maine State Superior Court under the UTPA should be resolved under 29 U.S.C. § 1132(a)(1). The Supreme Court has not retreated from its view that ERISA enacted a comprehensive enforcement scheme, which preempts state regulation on the same issues. *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355 (2002); *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41 (1987); *Massachusetts Mut. Life Ins. Co. v. Russell*, 473 U.S. 134 (1985).

The Court is also concerned that the UPDPA places the personal physician in the center of the dispute about the cost and effectiveness of medication. Before the physician is asked to render an opinion, the UPDPA requires the PBM first to disclose the cost information to the covered entity and the patient (plus any benefit payment to the PBM), thereby making it a virtual certainty (if the expense is sufficiently great) that the doctor will be lobbied at least by his patient and perhaps by the covered entity, on her decision as to which drug is best and most cost effective for the patient.

Finally, the UPDPA provides that the PBM "shall transfer in full" to the covered entity any benefit or payment it receives as a result of the substitution. 22 M.R.S.A. § 2699(2)(E)(3). The determination of what is "in full" is a potential source of litigation, the extent to which it includes PBM overhead, for example. This portion of the UPDPA can be enforced only if the covered entity has detailed knowledge of the PBM's books, a knowledge consistent with the disclosures contemplated under subsection (2)(D), but for which there is no enforcement mechanism other than state litigation. Similar issues appear with subsection (2)(F).

enforcement provisions" of ERISA. 536 U.S. at 375-76. If the Maine UTPA provides a remedy for covered individuals to the extent they have made a co-pay or deductible payment for a prescriptive medication, this remedy conflicts with the remedy provided in 29 U.S.C. § 1132(a)(1). The UPDPA provides without question the right of covered entities to sue for injunctive relief and monetary damages under the UTPA. The UPDPA's right to injunctive relief would be duplicative of the fiduciary's right to redress under § 1132(a)(3). But the UPDPA also provides for monetary relief not found in § 1132(a)(3). *Massachusetts Mutual Life,* 473 U.S. at 146 (quoting *Nachman Corp. v. Pension Benefit Guaranty Corp.*, 446 U.S. 359, 361 (1980) (noting ERISA is an "interlocking interrelated, and interdependent remedial scheme, which is in turn part of a 'comprehensive and reticulated statute") (internal citation omitted).

Accordingly, this Court concludes that the terms of the UPDPA and its enforcement mechanisms intrude too far into the ambit of federal regulation of health benefits by ERISA plans. Therefore, the UPDPA has an impermissible "connection with" ERISA.

iii. Reference.

The Supreme Court has provided that a State law has a "reference to" an ERISA covered program, if it "acts immediately and exclusively upon ERISA plans . . . or where the existence of ERISA plans is essential to the law's operation." *Dillingham,* 519 U.S. at 325. In *Carpenter's Local,* Judge Selya concluded that *Travelers* and *Dillingham* required a revised approach to the "reference to" analysis:

> The sockdolager is that emergent Supreme Court precedent, by disavowing a strictly textual approach to the interpretation of ERISA's preemption provision, encourages us for the first time to conduct the "reference to" inquiry in light of the actual operation of the challenged state statue.

215 F.3d at 144.

The relevant factors in such an analysis include: (1) whether the State law imposes requirements on ERISA plans; (2) whether the State law exempts such plans from otherwise applicable statutory provisions; (3) whether the State law in its operation, comports with ERISA's objectives; (4) whether the State law dictates the form that a covered plan would take; (5) whether the State law specifies the mode or manner of plan administration; (6) whether the State law otherwise jeopardizes the sort of uniformity Congress aspired to achieve. *Id.* Additionally, the Court is to consider whether the state law applies "to a wide range of situations, including an appreciable number that have no specific linkage to ERISA plans" or "to a sufficiently broad, sufficiently generalized universe of situations." *Id.* at 144-45.

If the State law is one of general application, does not single out ERISA plans for special treatment, does not depend on the ERISA plans' existence as an essential part of its operation, and is indifferent to ERISA coverage, the State law is considered valid and not preempted. Indeed, *Carpenter's Local* reasoned that if the State law is one of the "myriad state laws" of general applicability that impose some burdens on the administration of ERISA plans, but do not "relate to them" within the meaning of the governing statute, preemption will not be triggered. 215 F.3d at 145 (citing *DeBuono v. Medical and Clinical Serv. Fund,* 520 U.S. 806, 815 (1997)).

To apply the *Carpenters Local* analysis, this Court is required to balance the impact of the statute on ERISA plans. The UPDPA imposes no express requirements on ERISA plans, does not exempt ERISA plans from its operation, is one of general applicability, and makes no express reference to ERISA—factors which weigh strongly against preemption. *Carpenters Local*, 215 F.3d at 144-45. On the other hand, for the reasons set forth above, this Court has concluded that the UPDPA substantially interferes with the "mode and manner of plan

administration" and in operation jeopardizes the sort of uniformity that Congress aspired to achieve. *Id.* at 144.

ERISA itself has become such an all-encompassing part of our legal lexicon that it is virtually impossible to wade into health care regulatory waters without referring, intentionally or not, to ERISA terminology. This is particularly true when the State seeks to regulate the administration and provision of a significant slice of health care benefits, as Maine is seeking to do in this case. Even where the State consciously seeks to craft its terms so as to avoid ERISA definitions, the language ultimately ends up bumping into ERISA terminology. Thus, where the UPDPA defines "covered entity" as, "an employer . . . or other group of persons organized in the State that provides health coverage to covered individuals," even though the UPDPA does not use the phrase, "employee welfare benefit plan," it is defining the same concept. ERISA defines "employee welfare benefit plan" as, "any plan . . . maintained by an employer . . . for the purpose of providing . . . medical . . . benefits. . . ." 29 U.S.C. § 1002(1). At oral argument, the State did not disagree with PCMA's contention that the "vast amount" of the covered individuals the PBMs service in Maine are covered under ERISA plans.[20] At least a significant number of "covered individuals," § 2699(1)(B), under "covered entities," § 2699(1)(A), receive prescriptive drug benefits through PBMs pursuant to ERISA-regulated "employee welfare benefit plans" under ERISA.

[20] At oral argument, the Assistant Attorney General stated:

> And the point is—here is that PBMs, they said, the vast amount of plans that they service are ERISA plans. That may be, in fact, true in the sense that they—that they're working on providing pharmaceutical products that ultimately will end up in the hands of ERISA participants. But, the contracts that they have themselves are not necessarily with ERISA fiduciaries, and they could be with a whole host of different entities and certainly could—I dare to say that most of them are not with the particular plans themselves.

Similarly, the ERISA regulatory scheme is premised on defining critical players as fiduciaries, imposing fiduciary obligations on them, and penalizing them for their failure to comply. What Maine has done is mimic ERISA's regulatory scheme on an emerging and important player, one not currently regulated by ERISA. The UPDPA defines the PBMs as fiduciaries, requires disclosures, and then penalizes non-compliance. From this Court's perspective, the very size and significance of the PBM industry—its national scope, its crucial position in the center of the health care delivery system—make it less likely that a comprehensive state regulatory scheme can be enacted against such a major player without reference to the overriding federal law that so permeates the employee health benefit plan landscape. This is especially true since the route the State has chosen tracks the federal regulatory scheme, effectively filling in by state law an ever-expanding hole in federal oversight.

This is not to say the State cannot enact legislation generally to regulate health care. The *Travelers* Court has expressly said otherwise. However, this legislation presents a series of factors that make it problematic in light of ERISA preemption: (1) the national, as opposed to state or even regional, impact of the PBM industry; (2) the significant economic weight of the industry; (3) the centrality of the industry in the delivery and cost of health care benefits; (4) the vital nature of the health care benefits the PBM industry affects; (5) the breadth and detail of State regulation over the PBM industry; (6) the comprehensive scope of its enforcement provisions; and (7) the availability of private causes of actions on benefit issues. In this context, for the Court to ignore ERISA would be to ignore the proverbial elephant in the room.

The final analysis relies on the *Carpenters Local* sockdolager: conducting the "reference to" inquiry in light of the actual operation of the statute. Having concluded that the UPDPA has a "connection with" ERISA plans, this Court is led by a similar process to the conclusion that the

UPDPA has simply too profound an impact on ERISA plans—their administration and benefits—to avoid the reality that, in its operation, the UPDPA has a "reference to" ERISA.

iv. Preemption Conclusion.

This Court does not take lightly its obligation to presume that state statutes, particularly those imposing general health regulations, are not preempted by federal law. However, reviewing the UPDPA in the shadow of *Travelers* and *Dillingham*, this Court concludes that PCMA has demonstrated substantial likelihood of success on the issue of whether the UPDPA relates to ERISA so as to trigger preemption. As Judge Hornby recently wrote, even though *Travelers* represented "a retreat from the broadest reading once given to 'relate to,'" it did not overrule *Shaw*. *Catholic Charities,* 2004 WL 231778 at 1, *8 (D. Me. 2004).

VIII. Other Preliminary Injunction Considerations.

As noted earlier, before this Court can issue a preliminary injunction, PCMA has the burden of satisfying each element of a four-part test: (1) the probability of success on the merits; (2) the likelihood of irreparable harm; (3) a favorable balance of equities; and (4) the impact the injunction will have on the public interest. Based on the record before this Court, PCMA has met the first two requirements: a likelihood of success on the merits and a significant risk of irreparable harm. To balance the equities, this Court notes that PCMA is currently seeking maintenance of the status quo pending final resolution of the case and this Order does not decide the State's ultimate ability to enforce the law. Finally, although the State has argued that a delay in enforcement will affect the public interest, this Court concludes the delay in any public benefit pending final resolution of the litigation is offset by the three other preliminary injunction criteria.

IX. Conclusion.

Considering the factors applicable to the extraordinary relief of a preliminary injunction, this Court concludes that PCMA has made a compelling showing to warrant the grant of a short-term injunction in this case. Accordingly, in order to preserve the status quo during the pendency of this action, the State is PRELIMINARILY ENJOINED from seeking to enforce 22 M.R.S.A. § 2699.

SO ORDERED.

Dated: March 9, 2004

/s/ John A. Woodcock, Jr.
JOHN A. WOODCOCK, JR.
UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,

Plaintiff,

v.

THE DISTRICT OF COLUMBIA and ANTHONY A. WILLIAMS, Mayor of the District of Columbia,

Defendants.

Civil Action No.: 04-1082 (RMU)

Document No.: 3

ORDER

GRANTING THE PLAINTIFF'S MOTION FOR INTERIM INJUNCTIVE RELIEF

For the reasons stated in the accompanying Memorandum Opinion, it is this 21st day of December, 2004,

ORDERED that the plaintiff's motion for interim injunctive relief is **GRANTED**; and it is

FURTHER ORDERED that the defendants are **PRELIMINARILY ENJOINED** from seeking to enforce Title II of the District of Columbia's Access Rx Act of 2004, D.C. Code §§ 48-831 *et seq.*

SO ORDERED.

RICARDO M. URBINA
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,		
Plaintiff,	Civil Action No.:	04-1082 (RMU)
v.	Document No.:	3
THE DISTRICT OF COLUMBIA and ANTHONY A. WILLIAMS, Mayor of the District of Columbia,		
Defendants.		

MEMORANDUM OPINION

GRANTING THE PLAINTIFF'S MOTION FOR INTERIM INJUNCTIVE RELIEF

I. INTRODUCTION

This case comes before the court on the plaintiff's motion for a preliminary injunction. The plaintiff, a national trade association representing pharmaceutical benefit management companies ("PBMs"), seeks to preliminarily enjoin enforcement of Title II of the District of Columbia's Access Rx Act of 2004 ("Access Rx Act" or "the Act"), D.C. Code §§ 48-831 *et seq.* Because the plaintiff demonstrates a substantial likelihood of success on the merits, that it would suffer irreparable injury if the injunction were not granted, that the injunction would not substantially injure other interested parties, and that the public interest would be furthered by the injunction, the court grants the plaintiff's motion and temporarily enjoins the defendant from enforcing Title II of the Access Rx Act.

II. BACKGROUND

At issue in this case is the District of Columbia's attempt to regulate PBMs. PBMs are companies that process claims for pharmaceutical drug benefits for over 200 million Americans. Compl. ¶ 14. A PBM's customers are entities such as Employee Retirement Income Security Act ("ERISA") health plans, government entities and insurance companies, but not individual persons. *Id.* As time passed, PBMs began to expand their services to include, *inter alia*, (1) establishing networks of pharmacies that provide discounted drugs to plan members; (2) negotiating rebate arrangements with drug manufacturers; (3) reviewing drug utilization to decrease prices and enhance safety; (4) creating therapeutic drug interchange programs; and (4) establishing generic drug substitution programs. *Id.* ¶ 15.

In response to rising prescription drug prices, the D.C. Council unanimously passed the Access Rx Act, which, in the Council's estimation, would lower the cost of prescription drugs. Def.'s Opp'n to Pl.'s Mot. for Prelim. Inj. ("Def.'s Opp'n") at 3-6. On May 18, 2004, the Access Rx Act took effect in the District of Columbia. Compl. ¶ 1. Title II of the Act, the only portion of the Act that the plaintiff challenges, seeks to regulate PBMs by imposing fiduciary duties on them, as well as by requiring disclosure of certain financial information. *Id.* ¶ 3; Pl.'s Mot. for Prelim. Inj. ("Pl.'s Mot.") at 5. Specifically, Title II dictates that PBMs owe a fiduciary duty to their customers, which they must discharge in accordance with all applicable laws. Access Rx Act § 201(a). Title II also imposes several disclosure requirements. For instance, PBMs must disclose to their customers "information showing the quantity of drugs purchased by the covered entity and the net cost to the covered entity for the drugs. This information shall include all rebates, discounts and other similar payments." *Id.* § 201(c)(1)(A). Furthermore, PBMs must

also disclose to its customers "all financial terms and arrangements for remuneration of any kind that apply between the [PBM] and prescription drug manufacturer or labeler, including, without limitation, formulary management and drug substitution programs, educational support, claims processing and data sales fees." *Id.* § 201(c)(1)(B).

Section 201(d) provides that when dispensing prescription drugs, a PBM may substitute a lower-priced therapeutically equivalent drug for a higher-priced drug. But, if the substitute drug costs more than the prescribed drug, the prescription of the higher priced substitute drug must be made for medical reasons and the PBM must obtain the approval for the prescribing health professional after disclosing to the individual and the covered entity any benefit or payment accruing to the PBM because of the substitution. *Id.* §§ 201(d)(1)-(2). Additionally, the PBM must "transfer in full to the covered entity any benefit or payment received . . . as a result of a prescription drug substitution." *Id.* § 201(d)(3). Finally, section 203 of Title II provides that any violation of the title is a violation of the District of Columbia Consumer Protection Procedures Act ("DCCPPA"), D.C. Code § 48-832.03. *Id.* § 203. Violations of the DCCPPA are enforceable through administrative proceedings or direct suit in the Superior Court of the District of Columbia. D.C. Code § 28-3905.

III. ANALYSIS

A. Legal Standard for Interim Injunctive Relief

This court may issue interim injunctive relief only when the movant demonstrates:

> (1) a substantial likelihood of success on the merits, (2) that it would suffer irreparable injury if the injunction is not granted, (3) that an injunction would not

substantially injure other interested parties; and (4) that the public interest would be furthered by the injunction.

Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1066 (D.C. Cir. 1998) (quoting *CityFed Fin. Corp. v. Office of Thrift Supervision*, 58 F.3d 738, 746 (D.C. Cir. 1995)); *see also World Duty Free Americas, Inc. v. Summers*, 94 F. Supp. 2d 61, 64 (D.D.C. 2000). It is particularly important for the movant to demonstrate a substantial likelihood of success on the merits. *Cf. Benten v. Kessler*, 505 U.S. 1084, 1085 (1992) (per curiam). Indeed, absent a "substantial indication" of likely success on the merits, "there would be no justification for the court's intrusion into the ordinary processes of administration and judicial review." *Am. Bankers Ass'n v. Nat'l Credit Union Admin.*, 38 F. Supp. 2d 114, 140 (D.D.C. 1999) (internal quotation omitted).

Because interim injunctive relief is an extraordinary form of judicial relief, courts should grant such relief sparingly. *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997). As the Supreme Court has said, "[i]t frequently is observed that a preliminary injunction is an extraordinary and drastic remedy, one that should not be granted unless the movant, by a clear showing, carries the burden of persuasion." *Id.* (citation omitted). Therefore, although the trial court has the discretion to issue or deny a preliminary injunction, it is not a form of relief granted lightly. *Ambach v. Bell*, 686 F.2d 974, 979 (D.C. Cir. 1982).

B. The Court Grants the Plaintiff's Motion for Interim Injunctive Relief

The plaintiff presents three alternative grounds for why the court should declare Title II invalid. The plaintiff asserts that there is a substantial likelihood that each of its arguments will succeed. First, the plaintiff claims that Title II is preempted by ERISA, 29 U.S.C. §§ 1001 *et*

seq., and by the Federal Employees Health Benefits Act, 5 U.S.C. §§ 8901 *et seq.* Pl.'s Mot. at 8-21. Second, the plaintiff argues that Title II violates the Takings Clause of the Fifth Amendment to the United States Constitution. *Id.* at 21-37. Finally, the plaintiff claims that Title II violates the Commerce Clause of the United States Constitution. *Id.* at 37-42. The court concludes that for the purposes of resolving the motion for interim injunctive relief, there is a substantial likelihood of success on the plaintiff's takings argument.

1. Likelihood of Success on the Merits

The Takings Clause of the Fifth Amendment prohibits the taking of private property by the government without just compensation. *Palazzolo v. Rhode Island*, 533 U.S. 606, 617 (2001). As noted, Title II requires PBMs to disclose a host of different financial information and terms of contracts between themselves and pharmaceutical manufacturers. Access Rx Act §§ 201(c)(1); 201(d)(2). The plaintiff argues that Title II's disclosure requirements amount to a taking of trade secrets without just compensation. The defendants disagree, asserting that the plaintiff's feared injuries are speculative.

"The inquiry into whether a taking has occurred is essentially an ad hoc, factual inquiry." *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1005 (1984) (internal quotation omitted). The Supreme Court, however, has directed courts to consider three factors when making this inquiry: (1) the economic impact of the regulation; (2) the regulation's interference with reasonable, investment-backed expectations; and (3) the character of the government action. *Penn Central Transp. Co. v. City of New York*, 438 U.S. 104, 124 (1978).

a. Economic Impact of Regulation

As an initial matter, the defendants do not seriously contest that the terms of contracts between PBMs and drug companies constitute trade secrets. Under the District of Columbia's Uniform Trade Secrets Act ("DCUTSA"), a trade secret is defined as:

> information, including a formula, pattern, compilation, program, device, method, technique, or process, that: (a) derives actual or potential independent economic value, from not being generally known to, and not being readily ascertainable by, proper means by another who can obtain economic value from its disclosure or use; and (b) is the subject of reasonable efforts to maintain secrecy.

D.C. Code § 36-401. The plaintiff's supporting exhibits demonstrate that PBM's indeed derive economic value from keeping contract terms with pharmaceutical companies such as rebate arrangements confidential and that they take reasonable efforts to maintain the secrecy of the arrangements. *See, e.g.*, Pl.'s Mot. Ex. 2 ¶¶ 12-16, Ex. 3 ¶¶ 12-19. Accordingly, the terms of PBM contracts with pharmaceutical companies are trade secrets. *Pharm. Care Mgmt. Ass'n v. Rowe*, 307 F. Supp. 2d 164, 179-80 (D. Me. 2004) (concluding in a nearly identical case that for the purposes of a resolving a motion for a preliminary injunction, rebate and secret contractual arrangements between PBMs and drug manufacturers are trade secrets); *cf. Burlington N. R.R. Co. v. Omaha Pub. Power Dist.*, 888 F.2d 1228, 1232-33 (8th Cir. 1989) (holding that a party's contract terms and pricing formula constituted a trade secret).

The broad scope of §§ 201 (c)(1) and 201(d)(2) leads the court to the conclusion that Title II compels PBMs to disclose trade secrets. Because of the nature of the property, the value of a trade secret may be completely destroyed upon disclosure.[1] *Monsanto*, 467 U.S. at 1002 (stating

[1] A PBM may designate information disclosed under District of Columbia Access Rx Act of 2004 ("Access Rx") Section 201(c)(1) as confidential, which limits disclosure by the covered entity. Access Rx § 201(c)(1)(B). This limitation, however, does not prevent the destruction of the trade

that "[i]f an individual discloses his trade secret to others who are under no obligation to protect the confidentiality of the information, or otherwise publicly discloses the secret, his property right is extinguished"); *accord In re Iowa Freedom of Info. Council*, 724 F.2d 658, 664 (8th Cir. 1983).

b. Interference with Reasonable Investment-Backed Expectations

The next factor for a court to examine is whether or not the regulation interferes with a reasonable investment-backed expectation. This means that the expectation must be "more than a unilateral expectation or an abstract need." *Monsanto*, 467 U.S. at 1005 (internal quotation omitted). In the District of Columbia, however, the DCUTSA provides that actual or threatened misappropriation of trade secrets may be enjoined. D.C. Code § 36-402. Courts have concluded that in states where a statute exists that specifically protects trade secrets from disclosure, parties have a reasonable investment-backed expectation that the trade secret will not be disclosed. *Philip Morris, Inc. v. Reilly*, 312 F.3d 24, 41 (1st Cir. 2002); *accord Rowe*, 307 F. Supp. 2d 164, 179-80 (concluding that where a state statute protected trade secrets from disclosure, legislation requiring PBMs to disclose financial arrangements with pharmaceutical companies interferes with the PBMs' reasonable investment-backed expectations).

c. Character of Government Regulation

To determine which way the character of the government regulation factor leans, the court weighs the District of Columbia's interest in regulating PBMs with the PBMs' interest in

secrets' value because the covered entity could use a PBMs trade secrets to perform pharmaceutical benefits services in house and cut out PBM's entirely. Pl.'s Mot. Ex. 9 ¶¶ 54-58. Moreover, some covered entities are attempting to establish their own PBMs and could use information gained from Title II to obtain a competitive advantage over the plaintiff's members. *Id.*

protecting their trade secrets. *Rowe*, 307 F. Supp. 2d at 180. On one hand, the fact that Title II causes PBMs to suffer economically does not conclusively establish a taking. *Andrus v. Allard*, 444 U.S. 51, 66 (1979). As noted, however, disclosure of a trade secret does not merely reduce the trade secret's value. Rather, disclosure of a trade secret "extinguish[es]" the owner's property right. *Monsanto*, 467 U.S. at 1002.

The defendant argues that the character of the government action weighs in favor of determining that a taking has not occurred because the action has a legitimate public purpose. Pl.'s Opp'n at 30. But, "for a state to be able to completely destroy valuable trade secrets, it should be required to show more than a *possible* beneficial effect." *Reilly*, 312 F.3d at 44 (citing *Keystone Bituminous Coal Ass'n v. DeBenedictis*, 480 U.S. 470, 485-93 (1987) (emphasis in the original). Moreover, the defendant provides evidence that Title II is likely to have the oppositive of its intended effect. That is to say, Title II will actually drive up the cost of prescription drugs for District of Columbia residents. Pl.'s Mot. Ex. 9 at ¶ 51. Of course, at this stage of the litigation, the defendant has not yet had the benefit of discovery or a full opportunity to produce rebuttal evidence. For the purposes of deciding the preliminary injunction, however, the court concludes that the potential benefit to the District of Columbia, if any, does not outweigh the destruction of the plaintiff's trade secrets.

2. Irreparable Injury

The defendant argues that the plaintiffs have not satisfied the irreparable injury prong of the preliminary injunction test because the injuries to the plaintiff would be purely economic. Def.'s Opp'n at 36. It is true that "in the absence of special circumstances . . . recoverable economic losses are not considered irreparable." *Taylor v. Resolution Trust Corp.*, 56 F.3d 1497,

1507 (D.C. Cir. 1995). The instant case, however, presents an atypical economic loss. Because the value of a trade secret is extinguished upon disclosure, disclosure of a trade secret is not a mere recoverable economic loss. *FMC Corp. v. Taiwan Tainan Giant indus. Co.*, 730 F.2d 61, 63 (2d Cir. 1984) (per curiam) (granting a preliminary injunction and concluding that "it is clear that the loss of trade secrets cannot be measured in money damages" because "[a] trade secret one lost is, of course, lost forever"); *Rowe* 307 F. Supp. 2d at 187. Therefore, the court concludes that the plaintiff has demonstrated that it will suffer irreparable injury if the injunction is not granted.

3. Substantially Interested Other Parties and The Public Good

Next, the court must examine the effects of issuance of a preliminary injunction on the public. The court may a issue a preliminary injunction only if the injunction would not substantially injure other interested parties and the public interest would be served by the injunction. Here, other interested parties are the residents of the District of Columbia. The plaintiff argues that the irreparable injury to PBMs outweighs any hardship to the defendants. Pl.'s Mot. at 44. The defendant claims that Title II serves the public interest by allowing the District to attempt to protect its citizens from the increasing costs of health care. Def.'s Opp'n at 38. Based on the record currently before it, the court concludes that issuance of a preliminary injunction would not substantially injure the public and would serve the public interest.

The evidence before the court indicates that the PBM industry is highly competitive, enhances drug safety by alerting pharmacists to dangerous drug interactions and saves customers money by controlling drug costs,. *E.g.*, Pl.'s Mot. Ex. 2 ¶¶ 7-10; Ex. 3 ¶ 7; Ex. 9 ¶¶ 24-28. It is important to note that the plaintiff merely seeks to maintain the status quo until final resolution

of the many issues presented in this litigation. By issuing a preliminary injunction, the public will still retain the benefits of the PBM industry noted above. This is not to say that, if enforced, Title II would not accomplish its stated goals of making prescription drugs more affordable and improving the overall health of District of Columbia residents. Rather, the court simply concludes that enjoining the enforcement of Title II until the ultimate resolution of the case will not substantially injure other interested parties because the residents of the District of Columbia will still retain the benefits of the PBM industry. Conversely, the evidence indicates that if enforced, Title II could have the unintended effect of actually driving the PBM business and its attendant benefits out of the District of Columbia. Pl.'s Mot. Ex. 9 ¶¶ 57-59. Accordingly, the court concludes that the issuance of interim injunctive relief would not substantially injure other interested parties. *Rowe*, 307 F. Supp. 2d at 187.

Finally, for the purposes of deciding the motion for a preliminary injunction, the court concludes that the public interest is served by enjoining enforcement of the statute. As noted, enforcement of Title II may actually have the opposite of its intended effect and drive up the price of healthcare. In addition, the court has already concluded that the plaintiff has demonstrated a substantial likelihood that at least part of Title II may be unconstitutional. Thus, the public interest is served by enjoining enforcement of the statute. *Michigan Bell Tel. Co. v. Engler*, 257 F.3d 587, 600 (6th Cir. 2001) (noting that the public interest is served by enjoining the enforcement of potentially unconstitutional statutes); *accord Steakhouse, Inc. v. City of Raleigh*, 166 F.3d 634, 642 (4th Cir. 1999).

IV. CONCLUSION

For the foregoing reasons, the court grants the plaintiff's motion for interim injunctive relief. An order consistent with this Memorandum Opinion is separately and contemporaneously issued this 21st day of December, 2004.

RICARDO M. URBINA
United States District Judge

Larry Kucker, Director of Employee Benefits for State of South Dakota
(605) 773-4918

Transparency bill in effect July 1, 2004 (HB 1311)

State employees – 24,100

Required compliance with HB 1311 in RFPs last summer. Thirteen PBMs sent in bids (located all over the U.S.)

- **Selected Prescription Connections, serving about 5 million consumers**
- **This PBM did not operate in SD prior to the RFP but happy to comply with transparency**
- **Pay set fee per employee per month (fee for service only)**
- **Saved $800,000 by just switching to new PBM**
- **Project additional savings of $750,000 from receipt of 100% of rebates in first year (biennium savings projected at $1.5 million hard cash!!)**

Once the playing field is level (every one counts everything the same), and you are beyond the issue of transparency the PBMs are more than willing to discuss a variety of strategies to help the plan sponsor save additional money (generics alternatives, etc).

They do not offer any incentives to use mail order… all same costs whether the patient chooses to get medications from local pharmacist or mail order. Mail order typically used in most remote areas of state where access is limited.

Have no expectation of lawsuits at all.

PBM - South Dakota Law

Westlaw.

FOR EDUCATIONAL USE ONLY

SDCL. § 58-29E-1

SOUTH DAKOTA CODIFIED LAWS
TITLE 58. INSURANCE
CHAPTER 58-29E. PHARMACY BENEFITS MANAGEMENT

→58-29E-1. Definition of terms

Terms used in this chapter mean:

(1) "Covered entity," a nonprofit hospital or medical service corporation, health insurer, health benefit plan, or health maintenance organization; a health program administered by a department or the state in the capacity of provider of health coverage; or an employer, labor union, or other group of persons organized in the state that provides health coverage to covered individuals who are employed or reside in the state. The term does not include a self-funded plan that is exempt from state regulation pursuant to ERISA, a plan issued for coverage for federal employees, a health plan that provides coverage only for accidental injury, specified disease, hospital indemnity, medicare supplement, disability income, long- term care, or other limited benefit health insurance policies and contracts;

(2) "Covered individual," a member, participant, enrollee, contract holder, policy holder, or beneficiary of a covered entity who is provided health coverage by the covered entity. The term includes a dependent or other person provided health coverage through a policy, contract, or plan for a covered individual;

(3) "Director," the director of the Division of Insurance;

(4) "Generic drug," a chemically equivalent copy of a brand-name drug with an expired patent;

(5) "Labeler," an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the federal Food and Drug Administration under 21 C.F.R. § 270.20 (1999);

(6) "Pharmacy benefits management," the procurement of prescription drugs at a negotiated rate for dispensation within this state to covered individuals, the administration or management of prescription drug benefits provided by a covered entity for the benefit of covered individuals, or any of the following services provided with regard to the administration of the following pharmacy benefits:

(a) Mail service pharmacy;

(b) Claims processing, retail network management, and payment of claims to pharmacies for prescription drugs dispensed to covered individuals;

(c) Clinical formulary development and management services;

(d) Rebate contracting and administration;

(e) Certain patient compliance, therapeutic intervention, and generic substitution programs; and

(f) Disease management programs involving prescription drug utilization;

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SDCL. § 58-29E-1

(7) "Pharmacy benefits manager," an entity that performs pharmacy benefits management. The term includes a person or entity acting for a pharmacy benefits manager in a contractual or employment relationship in the performance of pharmacy benefits management for a covered entity and includes mail service pharmacy. The term does not include a health carrier licensed pursuant to Title 58 when the health carrier or its subsidiary is providing pharmacy benefits management to its own insureds; or a public self-funded pool or a private single employer self-funded plan that provides such benefits or services directly to its beneficiaries;

(8) "Proprietary information," information on pricing, costs, revenue, taxes, market share, negotiating strategies, customers, and personnel held by private entities and used for that private entity's business purposes;

(9) "Trade secret," information, including a formula, pattern, compilation, program, device, method, technique, or process, that:

(a) Derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use; and

(b) Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

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SDCL. § 58-29E-2

C
SOUTH DAKOTA CODIFIED LAWS
TITLE 58. INSURANCE
CHAPTER 58-29E. PHARMACY BENEFITS MANAGEMENT

→58-29E-2. Pharmacy benefits manager licensed as third party administrator

No person or entity may perform or act as a pharmacy benefits manager in this state without a valid license to operate as a third party administrator pursuant to chapter 58-29D.

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TITLE 58. INSURANCE
CHAPTER 58-29E. PHARMACY BENEFITS MANAGEMENT

➡58-29E-3. Manager to perform duties in good faith

Each pharmacy benefits manager shall perform its duties exercising good faith and fair dealing toward the covered entity.

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TITLE 58. INSURANCE
CHAPTER 58-29E. PHARMACY BENEFITS MANAGEMENT

→58-29E-4. Disclosure by manager of revenues received from pharmaceutical manufacturer or labeler under contract with manager--Content--Fees

A covered entity may request that any pharmacy benefits manager with which it has a pharmacy benefits management services contract disclose to the covered entity, the amount of all rebate revenues and the nature, type, and amounts of all other revenues that the pharmacy benefits manager receives from each pharmaceutical manufacturer or labeler with whom the pharmacy benefits manager has a contract. The pharmacy benefits manager shall disclose in writing:

(1) The aggregate amount, and for a list of drugs to be specified in the contract, the specific amount, of all rebates and other retrospective utilization discounts received by the pharmacy benefits manager directly or indirectly, from each pharmaceutical manufacturer or labeler that are earned in connection with the dispensing of prescription drugs to covered individuals of the health benefit plans issued by the covered entity or for which the covered entity is the designated administrator;

(2) The nature, type, and amount of all other revenue received by the pharmacy benefits manager directly or indirectly from each pharmaceutical manufacturer or labeler for any other products or services provided to the pharmaceutical manufacturer or labeler by the pharmacy benefits manager with respect to programs that the covered entity offers or provides to its enrollees; and

(3) Any prescription drug utilization information requested by the covered entity relating to covered individuals.

A pharmacy benefits manager shall provide such information requested by the covered entity for such disclosure within thirty days of receipt of the request. If requested, the information shall be provided no less than once each year. The contract entered into between the pharmacy benefits manager and the covered entity shall set forth any fees to be charged for drug utilization reports requested by the covered entity.

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CHAPTER 58-29E. PHARMACY BENEFITS MANAGEMENT

→58-29E-5. Permission of entity required to contact covered individual-- Exception

A pharmacy benefits manager, unless authorized pursuant to the terms of its contract with a covered entity, may not contact any covered individual without express written permission of the covered entity.

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TITLE 58. INSURANCE
CHAPTER 58-29E. PHARMACY BENEFITS MANAGEMENT

→58-29E-6. Confidentiality of information--Injunction--Damages

Except for utilization information, a covered entity shall maintain any information disclosed in response to a request pursuant to § 58-29E-4 as confidential and proprietary information, and may not use such information for any other purpose or disclose such information to any other person except as provided in this chapter or in the pharmacy benefits management services contract between the parties. Any covered entity who discloses information in violation of this section is subject to an action for injunctive relief and is liable for any damages which are the direct and proximate result of such disclosure. Nothing in this section prohibits a covered entity from disclosing confidential or proprietary information to the director, upon request. Any such information obtained by the director is confidential and privileged and is not open to public inspection or disclosure.

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TITLE 58. INSURANCE
CHAPTER 58-29E. PHARMACY BENEFITS MANAGEMENT

→58-29E-7. Audits of manager's books and records

The covered entity may have the pharmacy benefits manager's books and records related to the rebates or other information described in subdivisions 58-29E-4(1), (2), and (3), to the extent the information relates directly or indirectly to such covered entity's contract, audited in accordance with the terms of the pharmacy benefits management services contract between the parties. However, if the parties have not expressly provided for audit rights and the pharmacy benefits manager has advised the covered entity that other reasonable options are available and subject to negotiation, the covered entity may have such books and records audited as follows:

(1) Such audits may be conducted no more frequently than once in each twelve-month period upon not less than thirty business days' written notice to the pharmacy benefits manager;

(2) The covered entity may select an independent firm to conduct such audit, and such independent firm shall sign a confidentiality agreement with the covered entity and the pharmacy benefits manager ensuring that all information obtained during such audit will be treated as confidential. The firm may not use, disclose, or otherwise reveal any such information in any manner or form to any person or entity except as otherwise permitted under the confidentiality agreement. The covered entity shall treat all information obtained as a result of the audit as confidential, and may not use or disclose such information except as may be otherwise permitted under the terms of the contract between the covered entity and the pharmacy benefits manager or if ordered by a court of competent jurisdiction for good cause shown;

(3) Any such audit shall be conducted at the pharmacy benefits manager's office where such records are located, during normal business hours, without undue interference with the pharmacy benefits manager's business activities, and in accordance with reasonable audit procedures.

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TITLE 58. INSURANCE
CHAPTER 58-29E. PHARMACY BENEFITS MANAGEMENT

→58-29E-8. Dispensation of substitute prescription drug for prescribed drug

With regard to the dispensation of a substitute prescription drug for a prescribed drug to a covered individual, when the pharmacy benefits manager requests a substitution, the following provisions apply:

(1) The pharmacy benefits manager may request the substitution of a lower-priced generic and therapeutically equivalent drug for a higher-priced prescribed drug;

(2) With regard to substitutions in which the substitute drug's net cost is more for the covered individual or the covered entity than the prescribed drug, the substitution must be made only for medical reasons that benefit the covered individual. If a substitution is being requested pursuant to this subdivision, the pharmacy benefits manager shall obtain the approval of the prescribing health professional.

Nothing in this section permits the substitution of an equivalent drug product contrary to § 36-11-46.2

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TITLE 58. INSURANCE
CHAPTER 58-29E. PHARMACY BENEFITS MANAGEMENT

→58-29E-9. Rules--Content

The Division of Insurance shall promulgate rules, pursuant to chapter 1-26, to carry out the issuance of the license required by § 58-29E-2 and the enforcement provisions of this chapter. The rules may include the following:

(1) Definition of terms;

(2) Use of prescribed forms;

(3) Reporting requirements;

(4) Enforcement procedures; and

(5) Protection of proprietary information and trade secrets.

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SDCL. § 58-29E-10

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TITLE 58. INSURANCE
CHAPTER 58-29E. PHARMACY BENEFITS MANAGEMENT

→58-29E-10. Civil action--Enforcement of chapter--Damages

Any covered entity may bring a civil action to enforce the provisions of this chapter or to seek civil damages for the violation of its provisions.

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SDCL. § 58-29E-11

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TITLE 58. INSURANCE
CHAPTER 58-29E. PHARMACY BENEFITS MANAGEMENT

→58-29E-11. Application of chapter to certain contracts

The provisions of this chapter apply only to pharmacy benefits management services contracts entered into or renewed after June 30, 2004.

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TESTIMONY
BY
CALVIN N. ROLFSON
Legislative Consultant
Pharmaceutical Research & Manufacture's of America

RE:
HOUSE BILL 1332

Mr. Chairman, Members of the Committee:

My name is Cal Rolfson. I am a Legislative Consultant for the Pharmaceutical Research & Manufacturer's of America (PhRMA). Joel Gilbertson would be here to present this testimony, but he had another committee hearing to attend, so he suggested I tell you that he is sending his "Dad" as his substitute on this Bill.

PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies that are devoted to inventing medicines that allow patients to live longer, healthier and productive lives. The industry invests more than 30 billion dollars annually in discovering and developing new medicines. The vast majority (more than 70%) of all scientific research for the development of new drugs comes from private

industry, such as PhRMA companies.

Ordinarily, PhRMA would be opposed to this Bill. However, I appear today to merely propose a clarifying amendment. With the adoption of that amendment PhRMA does not oppose the Bill.

As the Bill is currently written, there may be a conflict between a provision of the North Dakota Food, Drug and Cosmetic Act, found in NDCC Chapter 19-02.1. Attached to my testimony [Exhibit #1] is a highlighted copy of NDCC 19-02.1-02(14) of that Act.

At page 5 of House Bill No. 1332, the Section on "Prohibited Practices" lists what the pharmacy benefits manager ("PBM") may <u>not</u> do regarding substitution of one drug for another. However, there are two exceptions. The exceptions on page 5 of the Bill, allow substitution of generic drugs for brand name drugs in certain cases. The possible conflict is that NDCC 19-02.1-02 (14) likewise conditionally prohibits substitutions, but it permits substitution only if the prescriber or the person ordering the drug expressly allows the substitution.

There is nothing in this Bill at Section 26.1-27.1-06(1)(6) [Page 5] that requires express authorization for substitution. Thus, substitution

presumably may be orally or broadly authorized by the PBM manager. This possible conflict with our state's Food, Drug and Cosmetic Act may create unnecessary confusion.

More importantly this amendment is necessary to avoid confusion that "generic and therapeutic equivalence" is not confused with drugs that are "therapeutically equivalent" but are of a "chemically different entity," thereby permitting therapeutic substitution under the Bill. For example, allowing "therapeutic substitution" is akin to substituting one cholesterol lowering agent for a completely different one, even if there is NO generic version and different active ingredients. This is NOT the same as standard generic substitution, which is the substitution of the same active ingredient, under a generic name.

"Therapeutic substitution" is the substitution of an entirely different chemical entity that is prescribed by a patient's physician or other licensed prescriber without the prior knowledge or consent of the prescriber.

The decision as to what constitutes appropriate therapy requires not only a thorough understanding of pharmacology, but also detailed knowledge of each individual patient's unique condition and medical

history. Such a therapeutic substitution decision can and should be made only by a patient's physician or other licensed prescriber. Allowing pharmacists or others, such as a corporate PBM, to second-guess the patient's physician or override the physician's orders could endanger patients by directing them to take the wrong medicine.

PhRMA opposes state bureaucratic efforts to determine which medications in a therapeutic class are interchangeable - regardless of whether they are different chemical compounds which the FDA has never determined to be equivalent. This type of substitution can lead to unintended health outcomes, which may also result in additional health care expenditures such as added physician visits or hospitalizations.

This Amendment would avoid a potential future dispute and conflict in this important area. With this amendment, PhRMA would be neutral on House Bill 1332.

The State of South Dakota similarly amended a Bill like this to resolve the same potential dispute in that state.

EXHIBIT 1

CHAPTER 19-02.1
NORTH DAKOTA FOOD, DRUG, AND COSMETIC ACT

19-02.1-01. Definitions. For the purpose of this chapter:

1. "Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of food, drugs, devices, or cosmetics.

2. "Color" includes black, white, and intermediate grays.

3. "Color additive" means a material which:

   a. Is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity from a vegetable, animal, mineral, or other source; or

   b. When added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable, alone or through reaction with other substance, of imparting color thereto, except that such term does not include any material which has been or hereafter is exempted under the federal act.

4. "Contaminated with filth" applies to any food, drug, device, or cosmetic not securely protected from dust, dirt, and as far as may be necessary by all reasonable means, from all foreign or injurious contaminations.

5. "Cosmetic" means:

   a. Articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance; or

   b. Articles intended for use as a component of any such articles, except that such term does not include soap.

6. "Department" means the state department of health.

7. "Device", except when used in the first paragraph following subsection 21 of this section and in subsection 10 of section 19-02.1-02, subsection 6 of section 19-02.1-10, subsections 3 and 16 of section 19-02.1-14, and subsection 3 of section 19-02.1-18, means instruments, apparatus and contrivances, including their components, parts, and accessories, intended:

   a. For use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or

   b. To affect the structure or any function of the body of man or other animals.

8. "Drug" means:

   a. Articles recognized in the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States, or official national formulary, or any supplement to any of them;

   b. Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;

be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

The provisions of this chapter regarding the selling of food, drugs, devices, or cosmetics must be considered to include the manufacture, production, processing, packing, exposure, offer, possession, and holding of any such article for sale; and the sale, dispensing, and giving of any such article and the supplying or applying of any such articles in the conduct of any food, drug, or cosmetic establishment.

Nothing in subsection 21 may be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological process of produce of the soil and thereby affecting its color, whether before or after harvest.

19-02.1-02. Prohibited acts. The following acts and the causing thereof within the state of North Dakota are hereby prohibited:

1. The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded.

2. The adulteration or misbranding of any food, drug, device, or cosmetic.

3. The receipt in commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

4. The sale, delivery for sale, holding for sale, or offering for sale of any article in violation of section 19-02.1-11 or 19-02.1-16.

5. The dissemination of any false advertisement.

6. The refusal to permit entry or inspection, or to permit the taking of a sample, as authorized by section 19-02.1-21.

7. The giving of a guaranty or undertaking which guaranty or undertaking is false, except by a person who relied on a guaranty or undertaking to the same effect signed by, and containing the name and address of the person residing in the state of North Dakota from whom the person received in good faith the food, drug, device, or cosmetic.

8. The removal or disposal of a detained or embargoed article in violation of section 19-02.1-05.

9. The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to a food, drug, device, or cosmetic, if such act is done while such article is held for sale and results in such article being adulterated or misbranded.

10. Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of this chapter or of the federal act.

11. The using, on the labeling of any drug or in any advertisement relating to such drug, of any representation or suggestion that an application with respect to such drug is effective under section 19-02.1-16 or that such drug complies with the provisions of such section.

12. In the case of a prescription drug distributed or offered for sale in this state, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal,

or to transmit, to any practitioner licensed by applicable law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved under the federal act. Nothing in this subsection may be construed to exempt any person from any labeling requirement imposed by or under other provisions of this chapter.

13. Placing or causing to be placed upon any drug or device or container thereof, with intent to defraud, the trade name or other identifying mark, or imprint of another or any likeness of any of the foregoing; selling, dispensing, disposing of, or causing to be sold, dispensed, or disposed of, or concealing or keeping in possession, control, or custody, with intent to sell, dispense, or dispose of, any drug, device, or any container thereof, with knowledge that the trade name or other identifying mark or imprint of another or any likeness of any of the foregoing has been placed thereon in a manner prohibited by this subsection; or making, selling, disposing of, or causing to be made, sold, or disposed of, or keeping in possession, control, or custody, or concealing, with intent to defraud, any punch, die, plate, or other thing designed to print, imprint, or reproduce that trade name or other identifying mark or imprint of another or any likeness of any of the foregoing upon any drug, device, or container thereof.

14. Dispensing or causing to be dispensed a different drug or brand of drug in place of the drug or brand of drug ordered or prescribed without the express permission in each case of the person ordering or prescribing.

15. The manufacture of drugs, or the supplying of drugs at wholesale or retail, unless a license or permit to do so has first been obtained from the board of pharmacy after application to the board of pharmacy and the payment of a fee set by the board of pharmacy.

16. The filling or refilling of any prescription in violation of subsection 1 of section 19-02.1-15.

19-02.1-03. Injunction proceedings. In addition to the remedies hereinafter provided, the department is hereby authorized to apply to the district court of Burleigh County for, and such court shall have jurisdiction upon hearing and for cause shown to grant, a temporary or permanent injunction restraining any person from violating any provision of section 19-02.1-02, irrespective of whether or not there exists an adequate remedy at law.

19-02.1-04. Penalties and guaranty.

1. Any person who violates any of the provisions of subsections 1 through 16 of section 19-02.1-02 is guilty of a class B misdemeanor.

2. No person shall be subject to the penalties of subsection 1, for having violated subsection 1 or 3 of section 19-02.1-02 if the person established a guaranty or undertaking signed by, and containing the name and address of, the person residing in the state of North Dakota from whom the person received in good faith the article, to the effect that such article is not adulterated or misbranded within the meaning of this chapter, designating this chapter.

3. No publisher, radio-broadcast licensee, or agency or medium for the dissemination of an advertisement, except the manufacturer, packer, distributor, or seller of the article to which a false advertisement relates, shall be liable under this section by reason of the dissemination by the person of such false advertisement, unless the person has refused, on the request of the department, to furnish the department the name and post-office address of the manufacturer, packer, distributor, seller, or advertising agency residing in the state of North Dakota who caused the person to disseminate such advertisement.

PROPOSED AMENDMENTS TO HOUSE BILL NO. 1332

Page 5, after line 14, insert:

"c. Nothing in this section permits the substitution of an equivalent drug product contrary to section 19-02.2-02."

Renumber accordingly

AARP North Dakota

The power to make it better.™

House Industry Business & Labor Committee
HB 1332
January 25, 2005

Chairman Keiser and members of the committee. I am Linda Wurtz, Associate State Director for Advocacy and Communication for AARP North Dakota. I am here today representing over 73,000 AARP members in North Dakota to support HB 1332.

The cost of prescription drugs is of great concern and hardship to AARP members. The skyrocketing cost of prescription drugs has a significant impact on our Medicaid budget. Our seniors are finding it more difficult to retire and harder to survive with the retirement planning they have done. It is very difficult to predict an illness that could require thousands of dollars a month in prescription medicines.

AARP is approaching the issue of prescription drug costs from several aspects, but one is the issue of transparency. Just having access to information regarding the costs of prescription drugs gives the consumer power in making purchasing decisions. On an individual consumer level, AARP monitors the price of specific drugs and reports those findings to members and the general public.

Pharmaceutical Benefits Managers (PBMs) have become a fixture in the national market for prescription drugs, handling a substantial majority of drug purchases in the U.S. Traditionally, PBMs have played an important role as the middleman between drug manufacturers, retail pharmacies, and health plans. This gives PBMs unique power to influence the market for prescription drugs, including prices, market share, and total benefit costs. At their best, PBMs have negotiated lower costs from manufacturers for consumers and have helped provide better affordability for average citizens.

At worst, PMBs' core business is cloaked in secrecy from state and federal regulators and even from their client health plans.

As a result, the actions of PBMs are coming under increased scrutiny throughout our country. In Maine, South Dakota, and the District of Columbia, legislation has been passed to regulate the practices of PBMs.

Requiring pharmacy benefit managers (PBMs) to be transparent in their pricing practices levels the playing field for consumers, creates a more competitive marketplace, and naturally decreases costs. In this case, one of those consumers is the State of North Dakota. If the purchaser does not have a complete picture of the true costs including all possible rebates and discounts, it cannot make an informed decision. HB 1332 will help purchasers know if they are really saving money by using a PBM, avoids any conflict of interest, and ensures that everyone is doing the right thing for the patients they serve.

The proposal before you is modeled on legislation from the above-named states and helps take a step forward to restore the obligation that a PBM should have to its clients. We heartily endorse it.

Thank you. I'd be happy an answer any questions.

AARP North Dakota

The power to make it better.™

Senate Industry Business & Labor Committee
HB 1332
March 21, 2005

Chairman Mutch and members of the committee. I am Linda Wurtz, Associate State Director for Advocacy and Communication for AARP North Dakota. I am here today representing over 73,000 AARP members in North Dakota.

I must emphasize that I am not here to advocate for AARP Services, Inc., which is the branch of AARP that provides services to our members, including prescription drug services. My job is to advocate on issues and inform you of our position on issues important to our members as determined by member surveys and input, and defined by our National Legislative Council and National Board, both of which are volunteer.

The cost of prescription drugs is of great concern and hardship to AARP members. The skyrocketing cost of prescription drugs has a significant impact on our Medicaid budget. Our seniors are finding it more difficult to retire and harder to survive with the retirement planning they have done. It is very difficult to predict an illness that could require thousands of dollars a month in prescription medicines.

AARP is approaching the issue of prescription drug costs from several aspects, but one is the issue of transparency.

Pharmaceutical Benefits Managers (PBMs) have become a fixture in the national market for prescription drugs, handling a substantial majority of drug purchases in the U.S. As the middleman between drug manufacturers, retail pharmacies, and health plans, PBMs have unique power to influence the market for prescription drugs, including prices, market share, and total benefit costs. At their best, PBMs have negotiated lower costs from manufacturers for consumers and have helped provide better affordability for average citizens.

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Requiring pharmacy benefit managers (PBMs) to be transparent in their pricing practices levels the playing field for consumers, creates a more competitive marketplace, and naturally decreases costs. In this case, one of those consumers is the State of North Dakota. If the purchaser does not have a complete picture of the true costs including all possible rebates and discounts, it cannot make an informed decision.

To that end, I supported HB 1332 when it came before House IB&L in its original form. HB 1332 as first written was a nice combination of legislation that has passed, with AARP support, in Maine and South Dakota. It provided clear disclosure and regulation of PBMs.

Since that time, HB 1332 has gone through such a complete metamorphosis that I see nothing left in it for consumers, and I no longer believed that it warranted our support. However, since some of the parties that continue to be involved with HB 1332 have asked about the lack of consumer input, I will explain what AARP, as a consumer advocate, would prefer to see in a bill designed for promote PBM transparency.

Basic Components of Model State PBM Legislation

1. Imposing a Duty on the PBM toward its Client Health Plans

Optimum – "Fiduciary Duty." (Maine and DC) This approach means that the PBM must always act in the best interests of its health plans and cannot enter into any relationships creating a conflict of interests, even if fully disclosed.

Minimum – "Duty of Good Faith and Fair Dealing." (South Dakota) This is generally a more lenient and malleable standard, prohibiting only bad faith conduct but not requiring affirmative disclosure or prohibiting conflicts of interest.

2. Transparency/Disclosure Obligations

Optimum – Comprehensive Disclosure. Mandatory and automatic disclosure of all relevant information about the PBMs' financial relationships with manufacturers and

pharmacy providers. The most logical recipient of such information would be the client health plan.

Minimum – Limited Disclosure. Substantial disclosure upon request. Laws simply requiring the disclosure to a health plan of utilization data relevant to that health plan would do nothing to address the PBMs' financial incentives that may conflict with their obligations to their client health plans.

Issue

⇒ Laws that require disclosure of all rebates and similar payments will reveal the full magnitude of manufacturer price concessions, and thus may enable the client to bargain for lower costs. Some proponents would argue that disclosure of other (i.e. non-rebate) payments from drug manufacturers to PBMs is also necessary to prevent re-naming a rebate to conceal it.

3. Licensing Requirements

Licensing would be an effective means of regulating PBMs when coupled with effective transparency obligations.

4. Regulation of Intervention or "Switching"

PBMs have the greatest direct impact on patients when they conduct intervention or "switching" programs. Switching is therefore of great concern to patient advocates. Concern may be heightened when the switch is for the financial benefit and not the patient's benefit. But, without sufficient transparency, even the health plans may not be able to determine whether there is a benefit from individual switches.

State regulation of switching practices is more vulnerable to an ERISA challenge, however HB 1332 in its original form did try to address that issue.

5. Enforcement

Optimum – Enforcement by the State (Maine and DC) -- The state has the authority to oversee the compliance of the PBMs and challenge violations of the statute.

Minimum - Enforcement by the purchaser (South Dakota) -- Enforceable only by the plans themselves.

Those are the five elements that we feel would be of the most benefit and protection to consumers in relation to PBM transparency. I do not believe that any of them are adequately addressed in the most recent enrollment of HB 1332.

Thank you. I'd be happy an answer any questions.

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HB 1332

Industry, Business and Labor Committee
ND Senate
State Capitol
Bismarck, North Dakota

Mr. Chairman and members of the Committee, my name is Robert Harms and I am here this morning to speak against HB 1332 on behalf of Caremark, Inc., which provides pharmacy benefits management (PBM) services across the US and in North Dakota. Caremark is very concerned about the direction, affect and technical deficiencies of HB 1332 and believes the bill will not attain its purported goals, but will have unintended consequences that will hurt consumers and businesses in our state.

Our concerns include:

- HB 1332 is likely to **reduce competition** in the pharmaceutical arena
- HB 1332 **reduces consumer choice** in making drug purchases by limiting mail service pharmacy and savings offered from such services.
- Likely to increase costs to North Dakota consumers by $112 million
- As a result of increased drug prices, HB 1332 may increase costs of pharmaceutical health insurance benefits, thereby reducing availability of that insurance benefit among North Dakota residents or otherwise increasing health insurance costs to other North Dakota businesses.

ND Pharmacists Assoc
See Patricia Kells testimony on Jan 27, 2005 for GAO report

Much of my testimony is in concert with a Federal Trade Commission letter of September 3, 2004 (relating to California AB 1960- a bill similar to HB 1332), and a GAO report to Senator Dorgan dated January 2003 relating to PBMs. I urge committee members to look at both documents which provide an object assessment of the issue now

under consideration in the form of HB 1332. The FTC letter and GAO report conclude that the affect of such a bill:

- is likely to be anti-competitive and may reduce competition among PBMs, and pharmaceutical companies.
- may drive up drug costs
- may increase costs of insurance and reduce its availability
- And conclude that competition among pharmaceuticals and PBMs is vigorous, resulting in significant cost savings to consumers. In fact the GAO report includes a study that found the **lowest** price for drugs paid by the consumer was through PBM mail service, and the **highest** price was a cash paying customer at a retail pharmacy.

I mentioned a concern that HB 1332 will cost North Dakota pharmacy customers $112 million annually. That figure is based upon a Price-Waterhouse-Coopers study of June 2004 conducted for the Pharmaceutical Care Management Association that assessed the value of PBM services and potential costs of proposed PBM legislation in the US. The Price-Waterhouse study concluded that PBM services in North Dakota effect 456,000 people and save them $112 million annually in drug costs.

Let me leave you with these closing thoughts. All of us want North Dakota businesses to flourish, including our neighborhood pharmacy. Likewise, we want our consumers to have choices for high value goods and services at reasonable prices. As policy makers we should take the long view and set policy that allows both of these goals to come to

fruition, through competition, open markets and freedom of choice. **Those** principles will best serve the people of North Dakota. HB 1332 is a step away from those principles and will hurt the public interest, North Dakota businesses and North Dakota consumers. We are also concerned about the detailed regulatory regime that the bill imposes that invades private sector relationships and impinges upon the right of contract. For these reasons, we urge the Committee to recommend a DO NOT PASS to the full Senate.

Dorgan Says GAO Study on PBM's Fails to Gather Key Data—Senator Who Requested It Says Study Falls Short—"Virtually every week, I read in the papers about PBMs being sued or being fired by states or large employers because of allegations that they aren't passing along savings that they should be and are actually pushing higher-cost medicines to the detriment of their payor clients," Dorgan said. "Clearly, these payors are coming to understand that the questionable arrangements between PBMs and drug manufacturers have an adverse impact on overall drug spending. I'm very disappointed that the GAO did not obtain information from the PBMs that would have allowed us to get to the bottom of this issue with respect to the FEHB program." Dorgan said that the GAO's report does provide one very important lesson for policymakers: "If even GAO, the investigatory arm of Congress, is unable to get this type of information about the financial arrangements of PBMs with respect to the Federal Employees Health Benefits program, then it is more important than ever that any legislation that would use PBMs to manage a prescription drug benefit through Medicare provide for strict oversight of PBMs and shine some sunshine on their use." (Sen. Byron Dorgan (D-N.D.), 1/10/03

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- ✓ Commonly Asked Questions
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- ✓ Mail Service Order Form
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- ✓ Have More Questions?
- ✓ Your Prescription Drug ID Cards†

* Keep this booklet as a reference for Drug List medications when you see a doctor.

† Please note that your ID Cards are attached to the back cover of this booklet.

Note: In this booklet we talk about co-payment. Co-payment or co-pay means the amount a participant is required to pay for a prescription in accordance with a Plan, which may be a deductible, a percentage of the prescription price, a fixed amount or other charge, with the balance, if any, paid by a Plan.

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AT-A-GLANCE

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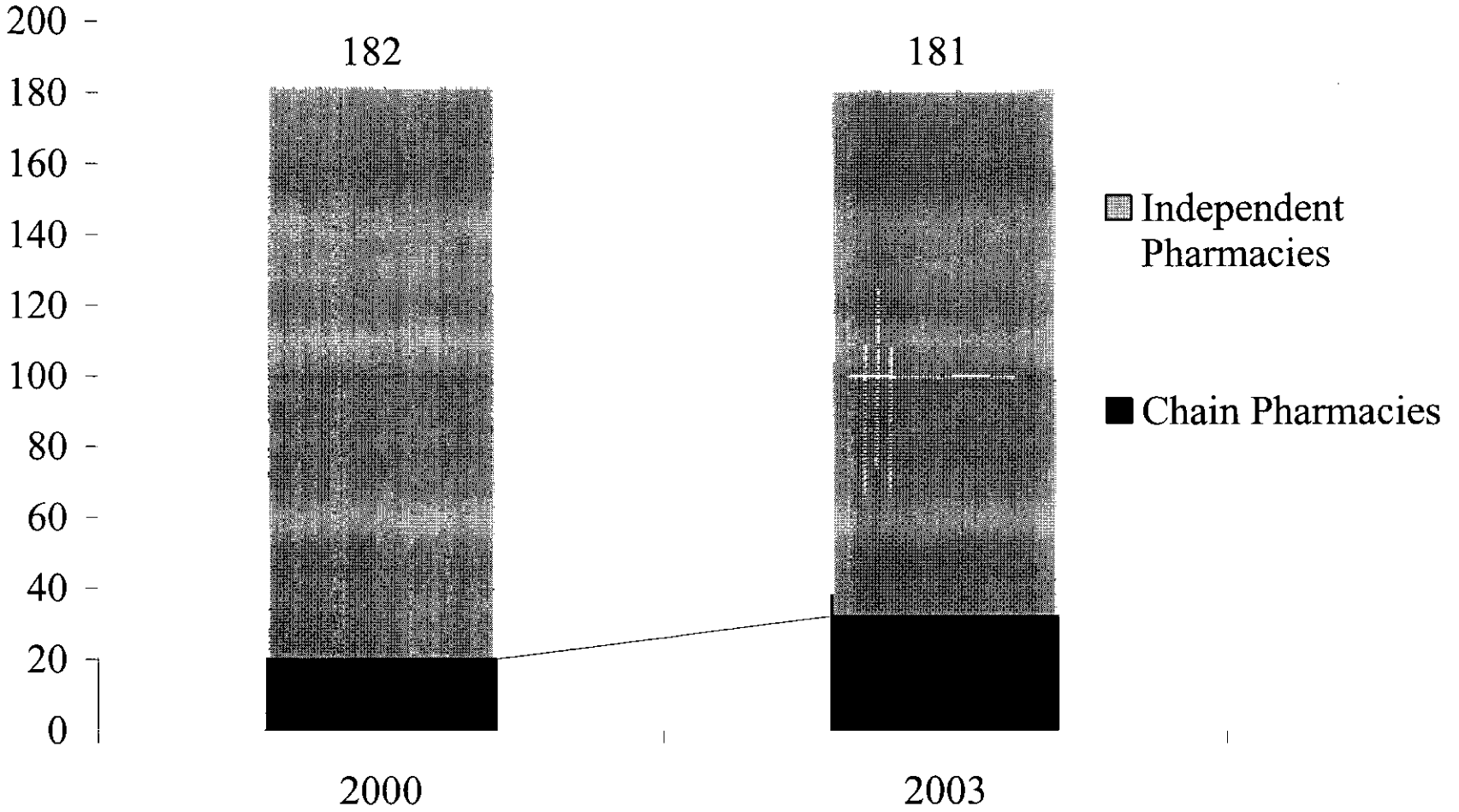
DEDUCTIBLE	$200 per person per year	None
YOU PAY	• 30% of the discounted price for each prescription	• $8 for each generic prescription • $15 for each brand name prescription on the Primary Drug List • $30 for each brand name prescription not on the Primary Drug List
DAYS SUPPLY LIMIT	34-day supply	90-day supply
REFILL LIMIT	One initial fill plus two refills on maintenance medications	None
FOR QUESTIONS CONTACT CAREMARK CUSTOMER CARE	Toll-Free 1-800-831-4440 or www.caremark.com	

HB 1332

Number of Licensed Pharmacies in North Dakota



Source: National Assocation of Boards of Pharmacy

Testimony on HB 1332
House Industry Business and Labor Committee
January 25, 2004

Mister Chairman and Committee Members, for the record I am Rod St. Aubyn, representing Blue Cross Blue Shield of North Dakota. I appear before your committee today to voice our strong opposition to this bill.

This bill should be defeated based on several reasons.

The first and most disconcerting issue is the attempt to allow the state to interfere with contracting between two private companies. In short, this is bad public policy. I cannot think of any other area where this is happening. A health plan, such as ours, enters into many hundreds of contracts. Yet in this one contract area, this bill stipulates what the terms of that contract must include. In addition, it requires that proprietary and confidential information be shared with all of our customers. Where does this lead to next? Will our computer services contract be the next to be mandated to require specific requirements? Should medical providers be required to give all contract terms for all their equipment and services to each patient? Should a bank customer who has a mortgage agreement with a bank be entitled to all other mortgage contracts to ensure that he/she is receiving the same or better deal than other bank customers?

The worst part of this is that no one has been able to prove that a problem exists in ND. Instead, this is a national attempt by the pharmacists to try to get this type of legislation passed around the country. I secured information on this type of legislation through the National Conference of State Legislatures (NCSL).

In 2003, there were attempts to pass this legislation in 18 different states. It passed in one state (Maine), but has since has been stopped by a US District Court through an injunction because of serious legal issues. I list those states below:

Arkansas	Connecticut	Florida	Hawaii	Illinois
Iowa	Kansas	Louisiana	Maine	Maryland
New Jersey	New Mexico	Oregon	Tennessee	Texas
Vermont	Washington	Wyoming		

In 2004, this same type of legislation was introduced in 13 states including the District of Columbia. Those states are listed below:

California	Connecticut	D.C.	Florida	Illinois
Iowa	Maryland	Michigan	Minnesota	Mississippi
New York	South Dakota	Vermont		

Of these states, only 2 passed it (D.C. and South Dakota). A federal district court ruled the D.C. law was invalid and unconstitutional to impose misguided fiduciary and

disclosure requirements on Pharmacy Benefit Managers (PBM's). In granting the Interim Injunctive Relief, I want to quote part of that order:

"Title II dictates that PBM's owe a fiduciary duty to their customers, which they must discharge in accordance with all applicable laws. Title II also imposes several disclosure requirements. For instance, PBM's must disclose to their customers "information showing the quantity of drugs purchased by the covered entity and the net cost to the covered entity for the drugs. This information shall include all rebates, discounts, and other similar payments." Furthermore, PBM's must also disclose to its customers "all financial terms and arrangements for remuneration of any kind that apply between the [PBM] and prescription drug manufacture or labeler, including, without limitation, formulary management drug substitution programs, educational support, claims processing and data sales fees."

Now I want to draw your attention to Sections 2, page 4, lines 1 – 22, of HB 1332. The language is peculiarly similar to the language in the law from District of Columbia that has now been suspended by the court on December 21, 2004. It is also similar to the requirement in the Maine law that has also been suspended. The S.D. law also has similar language, but the fiduciary statement was amended out of the bill and they applied the new law to only new contracts, unlike HB 1332, which is applied to existing contracts as well as new contracts. However, the fiduciary provision remains in this bill. In the Court Order for the D.C., an argument was made regarding the Takings Clause of the Fifth Amendment. The court stated, "The Court concludes that for the purposes of resolving the motion for interim injunctive relief, there is a substantial likelihood of success on the plaintiff's takings argument." The Court goes on to say in the order. "As noted, enforcement of Title II may actually have the opposite of its intended effect and drive up the price of healthcare. In addition, the court has already concluded that the plaintiff has demonstrated a substantial likelihood that at least part of Title II may be unconstitutional." Whether the S.D. law will be challenged on the same grounds is yet to be seen. The fact is that the 3 states have passed this law out of 25 and there have been two successful challenges for injunctions. Passage of HB 1332 could result in successful challenges by PBM's and unnecessary legal costs to the state of ND.

In visiting with the Insurance Commissioner on this bill, he had indicated that employers should have the right to the information, required to be disclosed by this bill. However, I would argue that this bill does not allow the employer access to that information. In Section 1 the definition of "covered entity", it includes employer. However, on page 4, beginning on line 1, the disclosure seems to be limited to the health plan because it states "... a pharmacy benefits manager **with which the covered entity has a pharmacy benefits management services contract** shall disclose to **the** covered entity...." (Emphasis added by me) This contract is between the health plan and the PBM, so the disclosure would be simply between those two entities. That is normally negotiated in the contract anyway. So there does **not** appear to be a requirement to share this with each employer group.

On page 2, line 21, it is important to note that other companies other than the traditional PBM offer disease management programs. This definition could preclude a health insurer from doing its own disease management program or contract with another company without first registering as a PBM. There is no definition for a disease management program.

On page 2, line26, exactly what is a "public self-funded pool". It is not defined and I am not sure if one even exists in ND.

On page 3, lines 9-11, if our company should decide to self administer its own pharmacy program, not unlike our other work with other providers, it appears that we would be required to register as a PBM and follow all of the same requirements, even if there is no contract between the PBM (ourselves) and us. The insurance commissioner already has the authority to review the PBM contract during the financial audits.

On page 3, lines 19-20, just what is "affiliation". It is not defined. If an out of state PBM has contracts with other out-of-state insurers, must that be reported, and for what purpose, if it does?

On page 4, line 3, it states that the PBM shall disclose "all financial and utilization information related to services under the contract." This is extremely broad. Does this mean that the amount and types of drugs for every employee and dependents for an employer group must be disclosed? And if the intent of this law is to disclose this information to the employer, I would question if this could be a HIPAA violation. If HIPAA would allow such a disclosure, I'm sure the employees and dependents would be concerned about this disclosure to their employer. Does this also mean that since the PBM has established the pharmacy network, participating agreements with each pharmacists, and processes claims to these network pharmacists, that the requirement to disclose "all financial information" would require the PBM to share with each employer group the quantity and the dollar amount reimbursed to each pharmacy doing business with that employer group, and the contractual arrangements between the PBM and the individual pharmacist?

On page 4, line 31, and page 5, line 1, how is "drug utilization reports" defined.

On page 5, lines 1-3, it refers to the annual report and indicates that the PBM "may not charge fees for the annual report under subdivision a of subsection 2." If the annual report is part of the contract between the PBM and the health plan, are the administrative fees or contract terms in violation of this?

There are some health plans that handle their pharmacy benefits in-house. Our company could definitely do this as well. However, we have determined it is more cost efficient to contract this service. If we were to handle this ourselves, page 5, lines 5-14, seems to prohibit our ability to change our own formulary. Often we may add new drugs to our formulary or possibly remove drugs that have been determined to be unsafe. I must stress to you that the network contract is at the option of the pharmacist. They are not

forced to enter into the contract, however, state law requires that the network must be made available to all pharmacists by the health plan.

On page 5, lines 25-27, number 4 infringes on the PBM's right to contract. For example, the PBM may require a signature log be maintained for audit reasons. However, if state or federal laws or regulations do not mandate this requirement, this law would prohibit that contracted requirement.

On page 5, line 28, it states that "Except for **utilization information**, a covered entity shall maintain as confidential and proprietary all information..." Why is this **not** confidential? This seems to be totally contrary to HIPAA rules. So as an employer, I can share info about the utilization of drugs by my employees and their dependents. If a particular employee is a high user of medication, can this be a tacit reason to terminate an employee because it is costing their health plan too much? They may not use that as a reason, but could it be a driving force in finding cause?

In the Confidentiality Section beginning on page 5, lines 28-31 and continuing on page 6, lines 1-5, **if** the intent is to share all this information with every employer group, the whole concept of confidentiality is rather contradictory. Even if there is a penalty as defined, how likely will a health plan or PBM pursue some employer group, when they know this will result in the loss of the health contract?

On page 6, lines 6-26, who is responsible for the PBM's extra cost in assisting with these audits if every employer group has the right to audit the PBM's books and records, and who is responsible for the actual audit costs?

On page 6, lines 24 – 25, it states that the audit must be done "without undue interference with the" PBM business activities. If interference does occur, who intervenes? The insurance commissioner would have no authority over an employer group. The PBM would be required to register with the Insurance Commissioner's office, but no such requirement exists for each employer group. And what is the penalty for interfering?

Beginning on line 27, on page 6, it states, "rules adopted by the commissioner to implement this chapter **may** include..." The legislature is giving the Commissioner broad authority to write law that could have a significant impact in this controversial area. If this bill were to be significantly amended, the entire bill could be adopted by rule.

On page 7, lines 6-7, it establishes the effective date for this bill, but goes one step further by basically amending all existing contracts between PBM's and health plans. Once again this exemplifies how this bill interferes with private companies' contracting rights. The bill in SD only applied to new contracts. That has already had a negative impact. At least one PBM announced that they would no longer contract with any new members.

This bill is what I call a "solution in search of a problem". No one can identify specific problems that this will correct in ND. Instead, it creates a dangerous precedent of allowing government intervention between contracted parties. The end result of this bill

will be higher costs, which will simply be passed on to the ND citizen and/or lower reimbursements for pharmacists because of lowered amount of rebates.

Another detriment to this bill is that it could actually create a hostile business environment in our state, thus discouraging PBM's from operating in our state. In a small state like ours, why would we want to discourage businesses to operate in North Dakota? Congress recently passed the new Medicare law (MMA) that provides for prescription drug coverage for seniors. Prescription drug plans (PDP's) will be developed in a multi-state region. Our region includes ND, SD, IA, MN, NE, MT, and WY. The success of these PDP's will be dependent upon competition of PBM's. Because all the rules have not yet been determined and the federal Prescription Drug Plans go into effect on January 1, 2006, additional PBM regulations could have a significant impact on getting appropriate savings for ND's seniors. Now is not the time to create obstacles for these PDP's.

This bill has been heard in almost half of the states and either the legislators have defeated it or the courts have intervened preventing it from being implemented. If the Courts ultimately rule that the law is unconstitutional in Maine or DC, it could have a significant impact on the application of the law in South Dakota. Because PBM's work in numerous states, if there is a need for regulation, it should be a federal issue. State regulation will only hurt our residents by limiting competition.

As I have pointed out, this bill is greatly flawed. **If disclosure is what this Legislature wants, why is this bill only limited to one area of prescription drugs? Why are the pharmacists not required to disclose their rebates, what their acquisition costs are, and what they are reimbursed for the drugs for an employer plan?** If a pharmacist does not like the terms of the contract offered by the PBM, they can simply not sign it. The free market will work if you let it. It is in the health plan's best interest to maintain an adequate network for its members.

Because of all the issues I noted, I strongly urge you to defeat this bill. As has been spelled out by the Department of Justice, the Federal Trace Commission, and the DC District Court, this type of legislation will only hurt your constituents and increase their costs.

Testimony on Proposed Amendments for HB 1332
As Proposed by the Insurance Department on 2/11/05
House Industry Business and Labor Committee
February 14, 2004

Mr. Chairman and Committee Members, for the record, I am Rod St. Aubyn, representing Blue Cross Blue Shield of North Dakota. Thank you for the opportunity to offer our comments on the recently proposed amendments offered by the Insurance Commissioner's Office. We did not have a lot of time to have an in-depth analysis of these amendments, since we didn't get them until late Friday afternoon and I was unable to contact some key personnel. However, based on our initial review, I would offer the following comments.

Page 1, line 23 & 24. The amendments propose to eliminate the term "covered individual", yet this term is used elsewhere in the bill. (page 1, line 16; page 2, line 10, line 12, line 16; Page 5, line 10, line 12) However, if the current definition is used, questions are raised about HIPAA rules as it relates to notification requirements in the bill (ex. Page 5, lines 10-14).

Page 2, line 14. Why is a mail service pharmacy considered a PBM?

Page 2, line 19, seems to require many others such as physicians, physician assistants, nurse practitioners, diabetes educators and others to register as PBMs. If the bill would not have this immediate effect, it would most certainly have that effect in 2006 when the Medicare Modernization Act Amendments take effect. (See Subpart D - Cost and Quality Improvement Requirements for Part D Plans Sections 423.156 through 423.171 of the Medicare Part D Final Rule.)

Page 2, line 21. We have done several programs, such as our own wellness program in-house. This is a form of "disease management program". We have also done some diabetic specific incentives for both the provider and the member. This is definitely what we would consider disease management. However, this is not defined and appears to require us to register and become licensed as a PBM. This just does not seem to make sense. There are many, many programs, which would probably be considered disease management and not done by companies typically considered to be PBM's. If we create bureaucratic roadblocks for these types of programs, how is this going to be a benefit to our citizens and how can we hold down healthcare costs.

Page 3, line 1. I think they inadvertently forgot to change "8" to "6".

Page 3, lines 9-11, this appears to require if a health plan handles their own PBM services in-house, they would be required to register and become licensed. The S.D. law exempted health plans in that circumstance.

Page 3, line 20. How is affiliation defined? Will this require a PBM to disclose all contracts for services they have with other insurance companies in other states?

Page 5, lines 5 – 14. How do you define "drug substitution". If a health plan changes its formulary, do these restrictions apply?

Page 5, line 12, we would suggest that you remove "after disclosing to the covered individual and covered entity the cost of both drugs and any benefit or payment directly or indirectly accruing to the pharmacy benefits manager as a result of the substitution." Compliance with this requirement could not be accomplished accurately. Discounts are often unknown at the time of sale; they are retrospective and dynamic reflecting total volume and demonstrated shifts in market share. This type of disclosure is precisely what the Federal Trade Commission has identified as onerous (see page 9 second paragraph of the September 3, 2004 FTC letter to California Assembly Member Greg Aghazarian). The disclosure is not protected by confidentiality and allows free flowing price information to be circulated among competitors. The Takings Clause of the United States Constitution prohibits the unprotected disclosure of this type of information (See District of Columbia injunction).

Page 5, we would suggest that you remove line 21 through 24. Benefit design items such as coinsurance, co-payments and deductibles are not part of the PBM-pharmacy contract. Furthermore, the ability to vary benefit design is essential to health insurance product offerings. Preventing this type of variation would be the same as requiring all car insurance policies to carry the same deductible.

Requiring uniformity of benefit designs among all providers is in direct conflict to the new Medicare Part D regulations Sections 423.120 (a)(9) and 423.120 (a)(10).

(9) *Differential cost-sharing for preferred pharmacies.* A Part D sponsor offering a Part D plan that provides coverage other than defined standard coverage may reduce copayments or coinsurance for covered Part D drugs obtained through a preferred pharmacy relative to the copayments or coinsurance applicable for such drugs when obtained through a non-preferred pharmacy. Such differentials are taken into account in determining whether the requirements under § 423.104(d)(2) and (d)(5) and § 423.104(e) are met. Any cost-sharing reduction under this section must not increase CMS payments to the Part D plan under § 423.329.

(10) *Level playing field between mailorder and network pharmacies.* A Part D sponsor must permit its Part D plan enrollees to receive benefits, which may include a 90-day supply of covered Part D drugs, at any of its network pharmacies that are retail pharmacies. A Part D plan may require an enrollee obtaining a covered Part D drug at a network pharmacy that is a retail pharmacy to pay any higher cost-sharing applicable to that covered Part D drug at the network pharmacy that is a retail pharmacy instead of the cost-sharing applicable to that covered Part D drug at the network pharmacy that is a mailorder pharmacy.

Page 5, we would suggest that you remove lines 25 through 27. This requirement would severely hamper the ability of a PBM to conduct a pharmacy audit. For example, PBM's often require pharmacies to maintain prescription logs to assure that prescriptions billed were actually received by a patient. This type of requirement is essential and beyond any "state or federal laws or regulations."

The new Section 26.1-27.1-05, providing three contract options, is an oversimplification of the pharmacy benefit management process and severely limits the ability of health plan and employers to negotiate service contracts with PBMs. It is almost certain to increase the cost of pharmacy benefit management services and decrease overall welfare of North Dakota citizens.

We only assume that the establishment of the new Section 26.1-27.1-07. Rulemaking authority., would not give the department authority to adopt rules that have been deleted in these amendments.

While the proposed amendments greatly improve this bill, there are still many unanswered questions. We would strongly suggest that you study this issue during the interim. An amendment to hoghouse this bill into a study resolution was previously offered and should be considered. That way, you will not feel rushed to pass a law, which could have just the opposite result – increasing costs for ND citizens.

PDP regions that are not the same as MA regions if CMS determines that the establishment of these regions improves access to prescription drug plan benefits for Part D eligible individuals.

(c) *Authority for territories.* CMS establishes a PDP region or regions for States that are not within the 50 States and the District of Columbia.

(d) *Revision of PDP regions.* CMS may revise the PDP regions established under paragraphs (b) and (c) of this section.

(e) *Regional or national plan.* Nothing in this section prevents a prescription drug plan from being offered in two or more PDP regions in their entirety or in all PDP regions in their entirety.

§ 423.120 Access to covered Part D drugs.

(a) *Assuring pharmacy access.* (1) *Standards for convenient access to network pharmacies.* Except as provided in paragraph (a)(7) of this section, a Part D plan must have a contracted pharmacy network consisting of retail pharmacies sufficient to ensure that for beneficiaries residing in each State in a prescription drug plan's service area(as defined in § 423.112(a)), each State in a regional MA-PD plan's service area (as defined in § 422.2 and § 422.455(a) of this chapter), a local MA-PD plan's service area (as defined in § 422.2 of this chapter), or a cost plan's geographic area (as defined in § 417.401 of this chapter), the following requirements are satisfied:

(i) At least 90 percent of Medicare beneficiaries, on average, in urban areas served by the Part D plan live within 2 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section;

(ii) At least 90 percent of Medicare beneficiaries, on average, in suburban areas served by the Part D plan live within 5 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section; and

(iii) At least 70 percent of Medicare beneficiaries, on average, in rural areas served by the Part D plan live within 15 miles of a network pharmacy that is a retail pharmacy or a pharmacy described under paragraph (a)(2) of this section.

(2) *Applicability of some non-retail pharmacies to standards for convenient access.* Part D plans may count I/T/U pharmacies and pharmacies operated by Federally Qualified Health Centers and Rural Health Centers toward the standards for convenient access to network pharmacies in paragraph (a)(1) of this section.

(3) *Access to non-retail pharmacies.* A Part D plan's contracted pharmacy network may be supplemented by non-retail pharmacies, including pharmacies offering home delivery via mail-order and institutional pharmacies, provided the requirements of paragraph (a)(1) of this section are met.

(4) *Access to home infusion pharmacies.* A Part D plan's contracted pharmacy network must provide adequate access to home infusion pharmacies consistent with written policy guidelines and other CMS instructions.

(5) *Access to long-term care pharmacies.* A Part D plan must offer standard contracting terms and conditions, including performance and service criteria for long-term care pharmacies that CMS specifies, to all long-term care pharmacies in its service area. The plan must provide convenient access to long-term care pharmacies consistent with written policy guidelines and other CMS instructions.

(6) *Access to I/T/U pharmacies.* A Part D plan must offer standard contracting terms and conditions conforming to the model addendum that CMS develops, to all I/T/U pharmacies in its service area. The plan must provide convenient access to I/T/U pharmacies consistent with written policy guidelines and other CMS instructions.

(7) *Waiver of pharmacy access requirements.* CMS waives the requirements under paragraph (a)(1) of this section in the case of—

(i) An MA-PD plan or cost plan (as described in section 1876(h) of the Act) that provides its enrollees with access to covered Part D drugs through pharmacies owned and operated by the MA organization or cost plan, provided the organization's or plan's pharmacy network meets the access standard set forth under § 422.112 of this chapter for an MA plan, or § 417.416(e) of this chapter for a cost plan.

(ii) An MA private fee-for-service plan described in § 422.4 of this chapter that—

(A) Offers qualified prescription drug coverage; and

(B) Provides plan enrollees with access to covered Part D drugs dispensed at all pharmacies, without regard to whether they are contracted network pharmacies and without charging cost-sharing in excess of that described in § 423.104(d)(2) and (d)(5).

(8) *Pharmacy network contracting requirements.* In establishing its contracted pharmacy network, a Part D sponsor offering qualified prescription drug coverage—

(i) Must contract with any pharmacy that meets the Part D plan's standard terms and conditions; and

(ii) May not require a pharmacy to accept insurance risk as a condition of participation in the Part D plan's contracted pharmacy network.

(9) *Differential cost-sharing for preferred pharmacies.* A Part D sponsor offering a Part D plan that provides coverage other than defined standard coverage may reduce copayments or coinsurance for covered Part D drugs obtained through a preferred pharmacy relative to the copayments or coinsurance applicable for such drugs when obtained through a non-preferred pharmacy. Such differentials are taken into account in determining whether the requirements under § 423.104(d)(2) and (d)(5) and § 423.104(e) are met. Any cost-sharing reduction under this section must not increase CMS payments to the Part D plan under § 423.329.

(10) *Level playing field between mail-order and network pharmacies.* A Part D sponsor must permit its Part D plan enrollees to receive benefits, which may include a 90-day supply of covered Part D drugs, at any of its network pharmacies that are retail pharmacies. A Part D plan may require an enrollee obtaining a covered Part D drug at a network pharmacy that is a retail pharmacy to pay any higher cost-sharing applicable to that covered Part D drug at the network pharmacy that is a retail pharmacy instead of the cost-sharing applicable to that covered Part D drug at the network pharmacy that is a mail-order pharmacy.

(b) *Formulary requirements.* A Part D sponsor that uses a formulary under its qualified prescription drug coverage must meet the following requirements—

(1) *Development and revision by a pharmacy and therapeutic committee.* A Part D sponsor's formulary must be developed and reviewed by a pharmacy and therapeutic committee that—

(i) Includes a majority of members who are practicing physicians and/or practicing pharmacists.

(ii) Includes at least one practicing physician and at least one practicing pharmacist who are independent and free of conflict relative to-

(A) The Part D sponsor and Part D plan; and

(B) Pharmaceutical manufacturers.

(iii) Includes at least one practicing physician and one practicing pharmacist who are experts regarding care of elderly or disabled individuals.

(iv) Bases clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other such

(4) Internal medication error identification and reduction systems.

(5) Provision of information to CMS regarding its quality assurance measures and systems, according to guidelines specified by CMS.

(d) *Medication therapy management program (MTMP).*

(1) *General rule.* A Part D sponsor must have established a MTMP that—

(i) Is designed to ensure that covered Part D drugs prescribed to targeted beneficiaries described in paragraph (d)(2) of this section are appropriately used to optimize therapeutic outcomes through improved medication use;

(ii) Is designed to reduce the risk of adverse events, including adverse drug interactions, for targeted beneficiaries described in paragraph (d)(2) of this section;

(iii) May be furnished by a pharmacist or other qualified provider; and

(iv) May distinguish between services in ambulatory and institutional settings.

(2) *Targeted beneficiaries.* Targeted beneficiaries for the MTMP described in paragraph (d)(1) of this section are enrollees in the sponsor's Part D plan who —

(i) Have multiple chronic diseases;

(ii) Are taking multiple Part D drugs; and

(iii) Are likely to incur annual costs for covered Part D drugs that exceed a predetermined level as specified by the Secretary.

(3) *Use of experts.* The MTMP must be developed in cooperation with licensed and practicing pharmacists and physicians.

(4) *Coordination with care management plans.* The MTMP must be coordinated with any care management plan established for a targeted individual under a chronic care improvement program (CCIP) under section 1807 of the Act. A Part D sponsor must provide drug claims data to CCIPs for those beneficiaries that are enrolled in CCIPs in a manner specified by CMS.

(5) *Considerations in pharmacy fees.* An applicant to become a Part D sponsor must—

(i) Describe in its application how it takes into account the resources used and time required to implement the MTMP it chooses to adopt in establishing fees for pharmacists or others providing MTMP services for covered Part D drugs under a Part D plan.

(ii) Disclose to CMS upon request the amount of the management and dispensing fees and the portion paid for MTMP services to pharmacists and others upon request. Reports of these amounts are protected under the provisions of section 1927(b)(3)(D) of the Act.

(6) *MTMP reporting.* A Part D sponsor must provide CMS with information regarding the procedures and performance of its MTMP, according to guidelines specified by CMS.

(e) *Exception for private fee-for-service MA plans offering qualified prescription drug coverage.* In the case of an MA plan described in § 422.4(a)(3) of this chapter providing qualified prescription drug coverage, the requirements under paragraphs (b) and (d) of this section do not apply.

§ 423.156 Consumer satisfaction surveys.

CMS conducts consumer satisfaction surveys of Part D plan enrollees similar to the surveys it conducts of MA enrollees under § 422.152 (b) of this chapter.

§ 423.159 Electronic prescription program.

(a) [Reserved]

(b) [Reserved]

(c) *Requirement.* Part D sponsors must support and comply with electronic prescription standards relating to covered Part D drugs for Part D enrollees developed by CMS once final standards are effective.

(d) *Promotion of electronic prescribing by MA-PD plans.* An MA organization offering an MA-PD plan may provide for a separate or differential payment to a participating physician that prescribes covered Part D drugs in accordance with electronic prescription standards, including initial standards and final standards established by CMS once final standards are effective. Any payments must be in compliance with applicable Federal and State laws related to fraud and abuse, including the physician self-referral prohibition (section 1877 of the Act) and the Federal anti kickback statute (section 1128B(b) of the Act).

§ 423.162 Quality improvement organization activities.

(a) *General rule.* Quality improvement organizations (QIOs) are required to offer providers, practitioners, and Part D sponsors quality improvement assistance pertaining to health care services, including those related to prescription drug therapy, in accordance with contracts established with the Secretary.

(b) *Collection of information.* Information collected, acquired, or generated by a QIO in the performance of its responsibilities under this section is subject to the confidentiality provisions of part 480 of this chapter. Part D sponsors are required to provide specified information to CMS for distribution to the QIOs as well as directly to QIOs.

(c) *Applicability of QIO confidentiality provisions.* The provisions of part 480 of this chapter apply to Part D sponsors in the same manner as such provisions apply to institutions under part 480 of this chapter.

§ 423.165 Compliance deemed on the basis of accreditation.

(a) *General rule.* A Part D sponsor is deemed to meet all of the requirements of any of the areas described in paragraph (b) of this section if—

(1) The Part D sponsor is fully accredited (and periodically reaccredited) for the standards related to the applicable area under paragraph (b) of this section by a private, national accreditation organization approved by CMS; and

(2) The accreditation organization uses the standards approved by CMS for the purposes of assessing the Part D sponsor's compliance with Medicare requirements.

(b) Deemable requirements. The requirements relating to the following areas are deemable:

(1) Access to covered drugs, as provided under § 423.120 and § 423.124.

(2) Drug utilization management programs, quality assurance measures and systems, and MTMPs as provided under § 423.153.

(3) Privacy, confidentiality, and accuracy of enrollee records, as provided under § 423.136.

(4) A program to protect against fraud, waste and abuse, as described in § 423.504(b)(4)(vi)(H).

(c) *Effective date of deemed status.* The date the Part D sponsor is deemed to meet the applicable requirements is the later of the following:

(1) The date the accreditation organization is approved by CMS.

(2) The date the Part D sponsor is accredited by the accreditation organization.

(d) *Obligations of deemed Part D sponsors.* A Part D sponsor deemed to meet Medicare requirements must—

(1) Submit to surveys by CMS to validate its accreditation organization's accreditation process; and

(2) Authorize its accreditation organization to release to CMS a copy of its most recent accreditation survey, together with any survey-related information that CMS may require (including corrective action plans and summaries of unmet CMS requirements).

(e) *Removal of deemed status.* CMS removes part or all of a Part D sponsor's deemed status for any of the following reasons—

(1) CMS determines, on the basis of its own investigation, that the Part D sponsor does not meet the Medicare requirements for which deemed status was granted.

(2) CMS withdraws its approval of the accreditation organization that accredited the Part D sponsor.

(3) The Part D sponsor fails to meet the requirements of paragraph (d) of this section.

(f) *Enforcement authority.* CMS retains the authority to initiate enforcement action against any Part D sponsor that it determines, on the basis of its own survey or the results of an accreditation survey, no longer meets the Medicare requirements for which deemed status was granted.

§ 423.168 Accreditation organizations.

(a) *Conditions for approval.* CMS may approve an accreditation organization for a given standard under this part if the organization meets the following conditions:

(1) In accrediting Part D sponsors and Part D plans, it applies and enforces standards that are at least as stringent as Medicare requirements for the standard or standards in question.

(2) It complies with the application and reapplication procedures set forth in § 423.171.

(3) It ensures that—

(i) Any individual associated with it, who is also associated with an entity it accredits, does not influence the accreditation decision concerning that entity;

(ii) The majority of the membership of its governing body is not comprised of managed care organizations, Part D sponsors or their representatives; and

(iii) Its governing body has a broad and balanced representation of interests and acts without bias.

(b) *Notice and comment.* (1) *Proposed notice.* CMS publishes a notice in the **Federal Register** whenever it is considering granting an accreditation organization's application for approval. The notice-

(i) Announces CMS's receipt of the accreditation organization's application for approval;

(ii) Describes the criteria CMS uses in evaluating the application; and

(iii) Provides at least a 30-day comment period.

(2) *Final notice.* (i) After reviewing public comments, CMS publishes a final notice in the **Federal Register** indicating whether it has granted the accreditation organization's request for approval.

(ii) If CMS grants the request, the final notice specifies the effective date and the term of the approval that may not exceed 6 years.

(c) *Ongoing responsibilities of an approved accreditation organization.* An accreditation organization approved by CMS must undertake the following activities on an ongoing basis:

(1) Provide to CMS in written form and on a monthly basis all of the following:

(i) Copies of all accreditation surveys, together with any survey-related information that CMS may require including corrective action plans and summaries of unmet CMS requirements).

(ii) Notice of all accreditation decisions.

(iii) Notice of all complaints related to deemed Part D sponsors.

(iv) Information about any Part D sponsor against which the accrediting organization has taken remedial or adverse action, including revocation, withdrawal, or revision of the Part D sponsor's accreditation. (The accreditation organization must provide this information within 30 days of taking the remedial or adverse action.)

(v) Notice of any proposed changes in its accreditation standards or requirements or survey process. If the organization implements the changes before or without CMS approval, CMS may withdraw its approval of the accreditation organization.

(2) Within 30 days of a change in CMS requirements, submit the following to CMS—

(i) An acknowledgment of CMS's notification of the change.

(ii) A revised crosswalk reflecting the new requirements.

(iii) An explanation of how the accreditation organization plans to alter its standards to conform to CMS's new requirements, within the timeframes specified in the notification of change it receives from CMS.

(3) Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(4) Within 3 days of identifying, in an accredited Part D sponsor, a deficiency that as determined by the accrediting organization poses immediate jeopardy to the plan's enrollees or to the general public, give CMS written notice of the deficiency.

(5) Within 10 days of CMS's notice of withdrawal of approval, give written notice of the withdrawal to all accredited Part D sponsors.

(6) On an annual basis, provide summary data specified by CMS that relate to the past year's accreditation activities and trends.

(d) *Continuing Federal oversight of approved accreditation organizations.* Specific criteria and procedures for continuing oversight and for withdrawing approval of an accreditation organization include the following:

(1) *Equivalency review.* CMS compares the accreditation organization's standards and its application and enforcement of those standards to the comparable CMS requirements and processes when—

(i) CMS imposes new requirements or changes its survey process;

(ii) An accreditation organization proposes to adopt new standards or changes in its survey process; or

(iii) The term of an accreditation organization's approval expires.

(2) *Validation review.* CMS or its agent may conduct a survey of an accredited organization, examine the results of the accreditation organization's own survey, or attend the accreditation organization's survey to validate the organization's accreditation process. At the conclusion of the review, CMS identifies any accreditation programs for which validation survey results indicate—

(i) A 20 percent rate of disparity between certification by the accreditation organization and certification by CMS or its agent on standards that do not constitute immediate jeopardy to patient health and safety if unmet;

(ii) Any disparity between certification by the accreditation organization and certification by CMS or its agent on standards that constitute immediate jeopardy to patient health and safety if unmet; or

(iii) That, regardless of the rate of disparity, there are widespread or systematic problems in an organization's accreditation process that accreditation no longer provides assurance that the Medicare requirements are met or exceeded.

(3) *Onsite observation.* CMS may conduct an onsite inspection of the accreditation organization's operations and offices to verify the organization's representations and assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to the following:

(i) Reviewing documents.

(ii) Auditing meetings concerning the accreditation process.

(iii) Evaluating survey results or the accreditation status decision-making process.

(iv) Interviewing the organization's staff.

(4) *Notice of intent to withdraw approval.* If an equivalency review, validation review, onsite observation, or CMS's daily experience with the accreditation organization suggests that

BCBS

2-9-05

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July 6, 2004

Chad Schulz
Accountant Analyst
Blue Cross Blue Shield
4510 13th Ave SW
Fargo, ND 58121-0001

Dear Chad,

During our review of the July 2001 through June 2003 biennium and the July 2003 through June 2005 biennium Calculation of Interest on State Group reports we found we have several questions and discrepancies. There were also several items missing that we will need to complete our review.

1. Questions on the reports:

   Does NDPERS receive documentation for the perform rebate? If not, is it possible to get a report or some type of support documentation for the perform rebate for both bienniums?

   What are the adjustments, both additions and subtractions, in the 2003-2005 biennium under additions to wellness & reserve on the Calculation of Interest on State Group report?

   On the 2003-2005 report, a claim paid was posted on 11/30/03 for $400,000 and reversed on 12/2/03 with a note stating "$400,000 drug claims net of refunds that were paid in November due to a programming problem were not posted until December." Could you explain this further?

2. Missing Information:

   Copy of the Capitation Summary Report for October 2001 and March 2003

   Copies of year end settlement for the NDPERS EPO agreement with MeritCare, Medcenter One, and Mercy Medical for the 2001-2003 biennium.

   Copy of nursing home claims reversed that were charged to NDPERS the fall of 2003 in the amount of $114,288.69 for the 2001-2003 biennium.

   Copy of the premium adjustments posted on the Calculation of Interest on State Group on 10/14/02 for $150.38.

3. Discrepancies on premium adjustment on the Calculation of Interest on State Group Report for the following dates and amounts:

   2003-2005 biennium

   September 2003 BCBS owes NDPERS $465.86 is not recorded.

   February 13, 2004 BCBS owes NDPERS $2411.97 is recorded as NDPERS owes BCBS.

BCB2

2905
SPARB
Collins

Pharmacy Rebates - NDPERS
4th Quarter 2002 - Actual

Title	TotalCnt	GrossAmt	AdminFee	NetAmt	
Total NDPERS	53,540	336,996.45	26,863.49	310,132.96	
				291,382.96	Cash Received PTI
				18,750.00	Clinical Fee

c. Are prescription drug expenses integrated into the management reporting? If not, provide a sample of the standard pharmaceutical reports.

Yes.

d. Who is responsible for providing account management and customer service to PERS? If provided by a pharmaceutical vendor, provide information regarding the staff responsible for overall servicing of the PERS account.

If a pharmacist encounters a problem situation they contact the HELP desk at Prime Therapeutics and resolve the problem. If a member has questions they contact the service unit.

e. What percent of the formulary drugs have generic substitutes available?

BCBSND's formulary consists of 55% generic products and 45% branded products. Of the branded products, approximately 40% have generic substitutes.

f. Describe how drug rebates will be returned to PERS as part of the accounting process.

Drug rebates for the NDPERS account are identified for us by Prime Therapeutics and are netted against NDPERS claims expense.

g. Explain the appeal process if an enrollee is dissatisfied with a prescription drug.

When a member wishes to receive a non-formulary drug when a formulary drug is available, the member's physician must complete a form outlining the trials of two formulary agents deemed therapeutically equivalent and/or generic equivalent alternative and documentation stating length of trial and failure/intolerance to the formulary products.

SPARB PERS
Letter
2-9-05

BCBS

54-52-04 Board authority.

10. The board may audit any books, papers, accounts, bills, vouchers, and other documents or property of any and all departments, boards, commissions, political subdivisions, financial institutions, contractors, health care organizations, and consultants relating to their participation in services provided to programs administered by the board.

All testimony from BCBS

SPARB Collins 2-9-05

FORMULARIES & REBATES

24. How is your prescription formulary developed and administered?

The BCBSND P&T Committee, a diverse group of physicians and pharmacists within the State of North Dakota, meets quarterly to review therapeutic drug classes and new drug monographs. Drug monographs are prepared by Prime based on their clinical expertise, complete literature review, and complete product dossiers submitted in Academy of Managed Care Pharmacy (AMCP) format by drug manufacturers. The P&T Committee conducts reviews of all therapeutic classes annually with the reviews distributed equally between the four meetings. New drugs are evaluated in conjunction with their therapy area review unless there are compelling clinical or financial reasons to review the agent out of cycle.

Formulary additions and deletions are made on the basis of stepwise consideration of the following criteria spelled out by the P&T Committee:

- **Safety**
- **Efficacy**
- **Uniqueness**
- **Cost**

The overriding consideration of the P&T Committee is to preserve the clinical integrity of the formulary. Decisions are made based on the information gathered through the combined efforts of Prime's clinical staff and the local expertise of the P&T Committee. All parties work together to ensure that safety, efficacy and uniqueness considerations are met. Where those three criteria are similar among drug products, minimization of cost is pursued.

25. Describe in detail the financial arrangements of your formulary program as it relates to clients.
    - For how long is this arrangement guaranteed?

Prime performs custom formulary services as part of its overall program administrative agreement fee with BCBSND. Services under this agreement include pharmaceutical administration, clinical services, custom formulary development, client management services and sales and marketing support. These services and their associated fees are guaranteed for the duration of Prime's contract with BCBSND.

26. Can specific formularies be developed for clients?

BCBSND and Prime have collaborated to develop a formulary specific to the North Dakota marketplace. BCBSND formulary decisions are made with local demographics, population characteristics and regional clinical considerations in mind. While we do not develop custom formularies for specific employer groups, the advantages of the region-specific formulary developed in cooperation with BCBSND are passed on to NDPERS and your members.

27. Do all drug manufacturers whose products are included in your formulary provide your network with rebates?
    - If so, how are the rebates shared with the plan sponsor?
    - If so, are the rebate dollars paid to the plan sponsor or are credits given prospectively?

    Prime currently has rebate agreements with 55 manufacturers, including over 300 individual drugs. Not every manufacturer with drugs on the formulary provides rebates. Rebate payment arrangements are described under question 30 of this section.

28. How often does your Pharmacy & Therapy (P&T) committee conduct formulary reviews?

    BCBSND's P&T Committee meets on a quarterly basis to conduct formulary reviews.

29. How often is the formulary printed and distributed to clients?
    - How often do the drugs on the formulary change?
    - Is your formulary available on the Internet?

    The BCBSND formulary is updated on a quarterly basis and is available via the BCBSND web site. A printed copy is available to members by request.

30. Will you agree to remit or credit back to premium 100% of manufacturers' rebate to the employer?
    - If not, what percentage?
    - How often?
    - Will you include amounts owed to the employer if not yet paid when preparing renewal rates?

    BCBSND will not agree to forward one hundred percent of the payments received from pharmacy manufacturers and from its pharmacy benefits manager for retrospective pharmacy discount services to the group. BCBSND has established a system of Member reimbursement accounts (MRAs) through its pharmacy benefits manager in order to credit a portion of such retrospective pharmacy discounts as a representative percentage of the cost-share paid by the Member for certain prescription medications. The portion credited to the Member's MRA is based on utilization of certain "discounted" prescription medications and the cost-share applied through the Member's benefit plan. However, one hundred percent of the remainder of the retrospective discount payments after appropriate dollars are credited to Member's MRAs may be remitted to the group, less any administrative costs or fees that apply pursuant to the administrative services agreement in place with the group.

31. How long after plan inception is the first rebate share paid and in what intervals thereafter?

    For NDPERS, Prime pays the initial estimated rebates, less the applicable program management fee, approximately 90 days following the end of the respective calendar year quarter. An account reconciliation is performed approximately 12 months following the end of the respective quarter. This is generally the final settlement but there is the possibility of a subsequent settlement at a later date.

32. Do you guarantee that ingredient cost charges made by network pharmacies will be based on the lesser of the discount offered, actual retail paid, MAC price or your actual acquision costs?

Prime's network is contracted on a "lower of" formula. The "lower of" formula bases a drug's price on the lowest of the following:

- **Average Wholesale Price (AWP) discount**
- **Usual and Customary (U&C) price**
- **MAC for generic products**

To ensure members receive the benefit of "lower of" pricing, Prime contractually require all pharmacies in the networks to submit the U&C price on the electronic claim from the participating pharmacy. If the field is not populated, the claim will be rejected at the point of sale.

33. Does the PBM receive rebates or other forms of reimbursement from the manufacturers that is not disclosed or shared with the client?

Prime collects administration fees from manufacturers for services rendered in connection with rebate contracts, such as performing market share analysis required to calculate rebates, consolidating billing for clients, etc. Manufacturer administration fees do not exceed three percent of sales for any manufacturer. Prime receives no other revenue from manufacturers.

34. How does the PBM incent higher formulary utilization?
    - How is that coordinated with incentives for higher generic utilization?

Prime has several programs in place to promote formulary compliance and encourage formulary and generic drug prescribing. These include:

- **PrimeImpact[SM] disease management clinical program**
- **Win With Generics[SM] program**
- **PrimeCompliance[SM] formulary program**

Currently, NDPERS is utilizing the PrimeImpact disease management program, which was described in our response to question 8, as well as several components of the Win With Generics program. The PrimeCompliance program and an additional component of the Win With Generics program are also available for your use in the future, if desired. These programs are described below.

Win With Generics[SM]
BCBSND and Prime offer a comprehensive program to manage generic utilization, called Win With Generics[SM]. The program has several components including physician, pharmacist and member-directed initiatives. This multi-faceted program is designed to:

- **Educate providers and members about the value of generic drugs**
- **Increase member satisfaction**
- **Increase overall generic drug utilization**

PrimeCompliance Formulary Program
The PrimeCompliance Formulary Program encourages physician and member compliance to clients' formularies through a variety of intervention methods. Compliance to the drug formulary can improve quality of care, enhance member satisfaction and generate cost-savings in the form of greater manufacturer discounts (rebates). The program prepares clients to increase their level of interaction with targeted stakeholders who are critical to achieving a plan's pharmaceutical goals. These stakeholders include physicians and members.

35. Complete the chart below, answering the following questions. What dollar rebate per prescription will you offer the plan sponsor? What percentage of the total expected rebate does this amount represent? How much can the plan sponsor expect to save in ingredient costs if a voluntary, incentive-based and mandatory formulary is imposed?

In 2003 (first through third quarters), NDPERS earned an average rebate of $2.78 to $2.95 per claim ($7.03 to $7.94 per rebateable claim). This equates to 7.22% of plan paid amounts in 2003. Estimates for 2004 show potential rebates of $3.38 per claim. These numbers are based on rebates from the current NDPERS incentive-based Formulary benefit.

BCBSND and Prime do not typically provide rebate guarantees. We prefer a low net cost strategy of which rebates are only one cost-saving component. A rebate guarantee may conflict with the goal of a low net cost model, as it can encourage rebate maximization at the expense of lowest overall cost to the employer. For example, when the use of high-cost brand-name drugs over the use of lower cost, therapeutically equivalent alternatives is encouraged simply to obtain a higher rebate, the result is often higher overall cost to the employer.

BCBSND and Prime are unique in using this model, as many PBMs tie rebates to other pharmaceutical-funded programs, which are typically not disclosed. We believe that this approach increases costs overall to the employer. It is also the reason why Prime does not seek or accept revenue sources from pharmaceutical manufacturers except for rebates or rebate administration. Prime's mission is to always operate in a manner that is in its clients' best interests in every situation.

Guaranteed Minimum Rebate	Not applicable	Not applicable	Not applicable
Indicate Years:	**Rebate per Prescription ***	**% of Total**	**% Savings ****
Voluntary (open) Formulary			
Incentive-Based Formulary			

* Express rebates as a % of all Rx's dispensed.
** Express savings as a % of total plan costs (without a formulary).

North Dakota Century Code

CHAPTER 26.1-36-12.2
FREEDOM OF CHOICE FOR PHARMACY SERVICES

1. No third party payor including a health care insurer as defined in section 26.1-47-01, providing pharmacy services and prescription drugs to any beneficiary may;

   a. Prevent a beneficiary from selecting the pharmacy or pharmacist of the beneficiary's choice to provide pharmaceutical goods and services, provided that pharmacist or pharmacy is licensed in this state;

   b. Impose upon any beneficiary selecting a participating or contracting provider a co-payment, fee, or other condition not equally imposed upon all beneficiaries in the plan selecting a participating or contracting provider; or

   c. Deny any pharmacy or pharmacist the right to participate as a preferred provider under chapter 26.1-47 or as a contracting provider for any policy or plan, provided the pharmacist or pharmacy is licensed in this state, and accepts the terms of the third-party payor's contract.

2. Notwithstanding the provisions of subsection 1, the department of human services may exclude, from participation in the medical assistance program administered under chapter 50-24.1 and title XIX of the Social Security Act [Pub. L 89-97; 79 Stat.343; 42 U.S.C. 1396, et seq.], as amended, any provider of pharmacy services who does not agree to comply with state and federal requirements governing the program, or who, after so agreeing, fails to comply with those requirements.

3. Any provision in a health insurance policy in this state which violates the provisions in subsection 1 is void.

4. Any person who violates this section is guilty of a class A misdemeanor and each violation is a separate offense. The commissioner may levy an administrative penalty not to exceed ten thousand dollars for violation of this section.

5. The commissioner of insurance shall enforce the provisions of this section.

Source: S.L. 1989, ch. 370,1

State [redacted]ployee Health Benefits - Monthly premium costs

Compiled by NCSL Health Program - Richard Cauchi - Revised June 2004

	1999 Family		2000 Family		2002 Family		2003 Family				2004 Family					
State cost	$ 361.24		$ 399.75		$ 512.60		$ 608.62				$ 674.31					
Employee	$ 106.84		$ 115.56		$ 149.86		$ 166.13				$ 161.13	(40 states)				
Ave. Total	$ 465.78		$ 512.55		$ 662.46		$ 774.75				$ 835.44					
	State	Empl.	State	Empl.	State	Empl.	State	Employee	Premium Total	Note	State	Employee	Premium Total	period		notes
AL	$ 320.00	$ 164.00	$ 320.00	$ 164.00	$ 445.00	$ 164.00	$ 490.00	$ 164.00	$ 654.00		$ 550.00	$ 164.00	$ 714.00		AL	
AK	$ 488.50	$ 84.50	$ 488.50	$ 84.50	$ 575.00	$ 82.00	$ 630.00	$ 72.00	$ 792.00		$ 705.00	$ 162.00	$ 867.00	7/1-6/30	AK	
AZ	$ 359.86	$ 75.00	$ 387.92	$ 75.00	$ 461.88	$ 125.00	$ 549.92	$ 125.00	$ 674.92		$ 620.78	$ 125.00	$ 745.78		AZ	
AR	$ 261.00	$ 198.00	$ 261.00	$ 198.00	$ 261.00	$ 221.86	$ 581.60	$ 218.90	$ 800.50		$ 493.13	v			AR	
CA	$ 410.00	v	$ 452.00	v	$ 473.00	v	$ 589.00	$ 84.95	$ 673.95		$ 756.00	$ 38.00	$ 794.00		CA	
CO	$ 240.88	$ 245.12	$ 240.62	$ 108.78	$ 310.00	$ 365.93	$ 310.62	$ 386.16	$ 580.06	[1]	$ 310.62	v			CO	
CT	$ 461.42	$ 79.42	$ 549.60	$ 97.24	$ 631.52	$ 111.71	$ 723.10	$ 127.90	$ 851.00		$ 828.87	$ 146.61	$ 975.48		CT	
DE	$ 550.54	$ 0.00	$ 553.78	$ 0.00	$ 697.38	$ 0.00	$ 753.00	$ 0.00	$ 753.00		$ 825.52	v			DE	
FL	$ 362.62	$ 107.61	$ 391.60	$ 116.20	$ 450.34	$ 133.62	$ 508.88	$ 150.98	$ 659.86	[2]	$ 590.30	$ 175.14	$ 765.44		FL	
GA	$ 368.46	$ 121.96	$ 374.34	$ 131.72	$ 415.65	$ 147.10	$ 566.45	$ 173.70	$ 740.15	[3]	$ 646.58	$ 180.28	$ 826.86		GA	
HI	$ 243.36	$ 162.26	$ 229.40	$ 159.60	$ 284.44	$ 189.64	*$ 465.08*	*$ 186.62*	$ 651.70	[4]	v	v			HI	
ID	$ 258.51	$ 38.80	$ 283.33	$ 43.00	$ 369.96	$ 56.11	$ 389.42	$ 56.11	$ 445.53		$ 457.58	$ 81.00	$ 538.58		ID	
IL	$ 456.60	$ 145.00	$ 600.56	$ 145.00	$ 703.50	$ 196.50	$ 889.40	$ 207.00	$ 1,096.40	[6]	$ 887.28	$ 223.50	$ 1,110.78		IL	
IN	$ 454.55	$ 87.49	$ 649.70	$ 45.18	$ 742.26	$ 51.61	$ 826.83	$ 57.49	$ 884.32		$ 834.17	$ 131.15	$ 965.32		IN	
IA	$ 325.73	$ 145.66	$ 352.18	$ 185.60	$ 619.57	$ 211.28	$ 693.79	$ 242.90	$ 936.69		$ 777.90	$ 229.98	$ 1,007.88		IA	
KS	$ 317.37	v	$ 363.42	$ 284.53	$ 487.36	$ 319.44	$ 466.02	$ 363.08	$ 831.10	[13	$ 513.58	$ 402.36	$ 915.94		KS	updated 9/28/04-KS Ins
KY	$ 203.00	$ 200.00	$ 214.00	$ 300.00	$ 245.00	v	$ 287.00	$ 540.80	$ 827.80	[5]	$ 286.16	v			KY	
LA	$ 203.28	$ 203.28	$ 223.62	$ 223.64	$ 344.74	$ 249.62	$ 412.38	$ 313.40	$ 725.78		$ 492.86	$ 298.82	$ 791.68	7/1-6/30	LA	
ME	$ 443.32	$ 110.84	$ 469.92	$ 117.49	$ 509.04	$ 151.00	$ 762.00	$ 190.00	$ 952.00		v	v			ME	
MD	$ 475.20	$ 118.80	$ 428.16	$ 86.50	$ 565.41	$ 141.36	$ 632.86	$ 158.22	$ 791.08		$ 591.93	$ 121.17	$ 713.10		MD	
MA	$ 678.23	$ 156.09	$ 688.60	$ 121.52	$ 769.40	$ 131.33	$ 895.10	$ 157.96	$ 1,053.06	[9]	$ 1,083.74	$ 270.94	$ 1,354.68	7/1-6/30	MA	
MI	$ 517.92	$ 27.26	$ 605.97	$ 31.89	$ 752.61	$ 39.61	$ 752.62	$ 39.61	$ 792.23		$ 903.13	$ 47.53	$ 950.66		MI	
MN	$ 245.20	$ 27.24	$ 301.45	$ 33.49	$ 456.63	$ 50.74	$ 590.28	$ 59.03	$ 649.31		$ 848.39	$ 93.21	$ 941.60		MN	
MS	$ 162.00	$ 221.00	$ 172.00	$ 243.00	$ 205.00	$ 325.00	$ 356.00	$ 325.00	$ 681.00		$ 228.00	$ 356.00	$ 584.00		MS	
MO	$ 228.00	$ 152.00	$ 335.00	$ 190.00	$ 682.00	$ 240.00	$ 735.00	$ 246.00	$ 981.00		$ 829.00	$ 272.00	$ 1,101.00		MO	
MT	$ 245.00	$ 75.36	$ 258.64	$ 91.00	$ 293.64	$ 145.00	$ 334.60	$ 191.00	$ 525.00		$ 410.00	v			MT	
NE	$ 467.50	$ 94.82	$ 464.02	$ 171.73	$ 742.19	$ 197.29	$ 827.27	$ 219.91	$ 1,047.18		$ 856.98	$ 227.80	$ 1,084.78		NE	
NV	$ 264.51	$ 211.95	$ 327.20	$ 227.85	$ 357.50	$ 256.35	$ 465.78	$ 256.59	$ 722.37		$ 495.68	$ 270.95	$ 766.63		NV	
NH	$ 495.42	$ 0.00	$ 689.10	$ 0.00	$ 895.53	$ 0.00	$ 1,027.71	$ 0.00	$ 1,027.71		$ 1,304.40	$ 0.00	$ 1,304.40		NH	
NJ	v	$ 0.00	$ 299.00	$ 0.00	$ 558.51	$ 0.00	$ 875.58	$ 0.00	$ 875.58	[10	$ 742.27	$ 0.00	$ 742.27		NJ	
NM	$ 251.11	$ 167.42	$ 261.04	$ 174.00	$ 330.98	$ 220.65	$ 483.60	$ 161.20	$ 644.80		v	v			NM	
NY	$ 305.84	$ 70.02	$ 414.90	$ 92.56	$ 538.72	$ 84.08	$ 575.02	$ 129.36	$ 704.38		$ 707.60	$ 158.57	$ 866.17		NY	
NC	$ 144.60	$ 216.18	$ 187.98	$ 281.04	$ 244.38	$ 365.36	$ 244.38	$ 365.36	$ 609.74		$ 285.92	$ 427.48	$ 778.94		NC	
ND	$ 301.00	$ 0.00	$ 349.72	$ 0.00	$ 409.09	$ 0.00	$ 409.09	$ 0.00	$ 409.09		$ 488.70	$ 0.00	$ 488.70		ND	
OH	$ 406.03	$ 45.12	$ 464.68	$ 46.47	$ 669.77	$ 66.98	$ 707.54	$ 78.61	$ 786.15		$ 807.92	$ 81.37	$ 889.29		OH	
OK	$ 172.77	$ 172.78	$ 379.46	$ 100.00	$ 625.95	v	$ 735.15	$ 0.00	$ 735.15		v	v			OK	
OR	$ 430.31	$ 0.00	$ 531.97	$ 0.00	$ 571.01	$ 0.00	$ 654.07	$ 0.00	$ 654.07		$ 721.62	$ 0.00	$ 721.62		OR	updated 8/5/04-PEBB
PA	$ 403.89	$ 0.00	$ 410.91	$ 0.00	$ 410.91	$ 0.00	$ 410.91	$ 0.00	$ 410.91		$ 509.17	$ 22.44	$ 531.61		PA	
RI	$ 468.30	$ 0.00	$ 579.94	$ 0.00	*$ 770.00*	$ 0.00	$ 904.96	$ 0.00	$ 904.96		$ 904.56	$ 0.00	$ 904.56		RI	
SC	$ 253.75	$ 142.12	$ 337.37	$ 142.12	$ 466.72	$ 159.12	$ 466.72	$ 196.60	$ 683.32		$ 466.72	$ 234.68	$ 701.40		SC	
SD	$ 225.37	$ 218.39	$ 247.69	$ 218.39	$ 298.50	$ 254.33	$ 336.36	$ 267.26	$ 603.62		$ 399.33	$ 280.62	$ 679.95		SD	
TN	$ 462.54	$ 102.90	$ 410.27	$ 102.90	$ 589.77	$ 147.44	$ 737.21	$ 184.30	$ 921.51		$ 788.82	$ 197.20	$ 986.02		TN	
TX	$ 371.65	v	$ 371.65	v	$ 588.86	$ 262.84	$ 600.96	$ 294.34	$ 895.24		$ 586.39	$ 286.12	$ 872.50		TX	
UT	$ 457.15	$ 0.00	$ 489.62	$ 0.00	$ 615.90	$ 46.37	$ 689.82	$ 51.91	$ 741.73		$ 748.45	$ 56.33	$ 804.78		UT	
VT	$ 671.83	$ 134.37	$ 581.54	$ 145.38	$ 859.11	$ 214.78	$ 1,022.34	$ 255.59	$ 1,277.93		$ 1,055.62	$ 263.91	$ 1,319.53		VT	
VA	$ 397.00	$ 170.00	$ 406.00	$ 185.00	$ 462.00	$ 218.00	$ 557.00	$ 240.00	$ 797.00		$ 690.00	$ 99.00	$ 789.00		VA	
WA	$ 341.75	$ 36.00	$ 391.15	$ 10.00	$ 457.29	$ 146.00	$ 710.00	$ 109.00	$ 819.03		$ 518.00	$ 90.00	$ 608.00		WA	
WV	$ 441.10	$ 48.00	$ 452.10	$ 48.00	$ 486.00	$ 72.00	$ 544.00	$ 109.00	$ 653.00	[11	$ 620.00	v		7/1-6/30	WV	
WI	$ 511.92	$ 14.95	$ 544.90	$ 15.09	$ 705.00	$ 70.00	$ 902.57	$ 31.02	$ 933.59	[12	$ 1,021.21	$ 89.67	$ 1,110.88		WI	
WY	$ 175.00	$ 229.82	$ 200.00	$ 268.16	$ 225.00	$ 412.23	$ 352.00	$ 518.58	$ 870.58		$ 828.29	$ 140.39	$ 968.68		WY	

Data based on family coverage "standard benefit package", using lowest cost full-service HMO as example.
Most states offer multiple plans and options, so individual employees often pay a different rate.
Base figures were compiled annually by Workplace Economics (c), Washington, D.C., editions 1999-2004.
Supplemented with state research and NCSL telephone interviews with state agencies, 2001-2003.
Acknowledgment to Segal Co. and AFSCME for providing comparative data for individual cases.

v = $ varies [1] CO: Kaiser HMO - the widest available lower-cost plan

[2] FL:

[3] GA: figure is the average of 10 different managed care plans; lowest cost basic is $117.33 in '03

[4] HI varies by union bargaining unit. State contribution varies from $419 to $465 in '03. [6] IL tiered by income; figures for $26-40k

[5] KY varies by county, up to $397 for state share; $287 is the average in '03. For '04-'05, employee share varies by salary brackets.

[9] MA has ten plan offerings, including 5 HMOs, which average $62.55

[10] NJ includes a separate prescription drug plan, covered by the state.

[11] WV employee share varies by income- example is for $30-$36k annual income.

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[12] WI varies by county.

[13] KS: premiums listed include both HMO policy premiums plus the separate Rx benefit package.

Testimony on HB 1332
Senate Industry Business and Labor Committee
March 7, 2005

Mister Chairman and Committee Members, for the record I am Rod St. Aubyn, representing Blue Cross Blue Shield of North Dakota and Prime Therapeutics, our PBM, which is owned by several Blue Cross Blue Shield companies. We are able to secure more rebates for our members through this arrangement than by operating alone. I appear before your committee today to voice our opposition to this bill.

This bill is what I call a "solution in search of a problem". No one can identify specific problems that this will correct in ND. Instead, it creates a dangerous precedent of allowing government intervention between contracted parties. The end result of this bill will be higher costs, which will simply be passed on to the ND citizen and/or lower reimbursements for pharmacists because of lowered amount of rebates.

This bill should be defeated based on several reasons.

The first and most disconcerting issue is the attempt to allow the state to interfere with contracting between two private companies. In short, this is bad public policy. I cannot think of any other area where this is happening. A health plan, such as ours, enters into many thousands of contracts. Yet in this **one** contract area, this bill stipulates what the terms of that contract must include. Where does this lead to next? Will our computer services contract be the next to be mandated to require specific requirements? Should medical providers be required to report all contract terms for all their equipment and services?

The worst part of this is that no one has been able to prove that a problem exists in ND. Instead, this is a national attempt by the pharmacists to try to get this type of legislation passed around the country. I secured information on this type of legislation through the National Conference of State Legislatures (NCSL). Even though the bill was significantly amended in the House, this is strictly a national move by pharmacists.

In 2003, there were attempts to pass this legislation as originally introduced in 18 different states. It passed in one state (Maine), but has since has been stopped by a US District Court through an injunction because of serious legal issues. I list those states below:

Arkansas	Connecticut	Florida	Hawaii	Illinois
Iowa	Kansas	Louisiana	Maine	Maryland
New Jersey	New Mexico	Oregon	Tennessee	Texas
Vermont	Washington	Wyoming		

In 2004, this same type of legislation was introduced in 13 states including the District of Columbia. Those states are listed below:

California	Connecticut	D.C.	Florida	Illinois
Iowa	Maryland	Michigan	Minnesota	Mississippi
New York	South Dakota	Vermont		

Of these states, only 2 passed it (D.C. and South Dakota). A federal district court ruled the D.C. law was invalid and unconstitutional to impose misguided fiduciary and disclosure requirements on Pharmacy Benefit Managers (PBM's). In granting the Interim Injunctive Relief, I want to quote part of that order:

"Title II dictates that PBM's owe a fiduciary duty to their customers, which they must discharge in accordance with all applicable laws. Title II also imposes several disclosure requirements. For instance, PBM's must disclose to their customers "information showing the quantity of drugs purchased by the covered entity and the net cost to the covered entity for the drugs. This information shall include all rebates, discounts, and other similar payments." Furthermore, PBM's must also disclose to its customers "all financial terms and arrangements for remuneration of any kind that apply between the [PBM] and prescription drug manufacture or labeler, including, without limitation, formulary management drug substitution programs, educational support, claims processing and data sales fees."

In the Court Order for the D.C., an argument was made regarding the Takings Clause of the Fifth Amendment. The court stated, "The Court concludes that for the purposes of resolving the motion for interim injunctive relief, there is a substantial likelihood of success on the plaintiff's takings argument." The Court goes on to say in the order. "As noted, enforcement of Title II may actually have the opposite of its intended effect and drive up the price of healthcare. In addition, the court has already concluded that the plaintiff has demonstrated a substantial likelihood that at least part of Title II may be unconstitutional." The original bill included much of what was questioned by the courts. Those issues have now been amended out of this engrossed bill. However, what is left in this bill interferes with the private rights of contracting. I often hear legislators comment that North Dakota needs more competition in the health insurance market. If this bill passes, it actually could create obstacles which would hinder other insurers or PBM's from wanting to do business in ND.

Even though the bill is much better than originally introduced, I would like to identify several problems with the current engrossed version (Engrossed HB 1332).

Please note on Page 1, lines 16 – 19, and Page 2, line 27-28, that this bill does not apply to self-funded plans, federal employee plans, a public self-funded pool (whatever that is – it's not defined), nor a private single-employer self-funded plan. In addition, the new Medicare prescription drug benefit, called Part D, preempts many state laws, including the "any willing provider" laws affecting pharmacies, such as that found in Section 26.1-36-12.1 (copy of regulations attached). In effect, at least parts of this law would not apply to the new Part D plans. So what is left? Basically this will only affect the fully insured group plans. Of all the plans that BCBSND administers, only 47.6 of our market is comprised of fully insured plans.

Let's look at the total picture in ND.

Current Census data for ND	633,837
Less uninsured (Families USA, 2003)	- 65,300
Less age 65 and older eligible for Part D (Census)	- 93174
Less BCBSND self-fund participants	-234,091
Balance	241,272

Keep in mind this number is actually lower because you would need to deduct those under Medicaid, SCHIP, and federal employee plans and other self funded participants administered by other insurers.

On page 2, lines 13 & 14, please look at the definition of pharmacy benefit management. It states, in part, that pharmacy benefits management "means the procurement of prescription drugs at a negotiated rate for dispensation within this state to covered individuals;..." I would argue that this would include every retail pharmacists within ND. So in effect, this law would require every pharmacist to register as a PBM as well.

On page 2, lines 18 and 26, the bill includes "mail service pharmacy" in the definition for a PBM. While there are some traditional PBM's that offer a mail service pharmacy, there are several mail service pharmacies that are definitely not what is considered a PBM. For example, AARP offers a mail pharmacy services to its members. I included a page from their web page for your information. This bill would require these entities to register as a PBM. The purpose of this language and language on page 4, lines 13-14, is to limit mail service pharmacies to the citizens of ND in favor of ND pharmacies. And the worst part of this, this limitation will only apply to a small part of our citizens – the fully insured plans.

On page 3, lines 3-9, makes a broad definition of a rebate which we would dispute is **not** the traditional definition of a drug rebate.

On page 4, lines 7-12, appear to interfere with the private right of contracting. However, if you find this appropriate, we would like to offer the following change in the engrossed bill:

2. A pharmacy benefits manager may not require a pharmacist or pharmacy to participate in one contract in order to participate in another contract. The pharmacy benefits manager may not exclude an otherwise qualified pharmacist or pharmacy from participation in a particular network solely because the pharmacist or pharmacy declined to participate in another plan or network managed by the pharmacy benefits ~~*manager.*~~*provided the pharmacist or pharmacy accepts the terms, conditions, and reimbursement rates of the pharmacy benefits manager's contract.*

We would also suggest that you delete lines 13-16 on Page 4, based on previous comments and also note that this is duplicative of Section 26.1-36-12.2, but also contradictory (26.1-36-12.2 (1.) (c.)). This appears to prevent an insurer from establishing a preferred provider organization, which is specifically allowed in 26.1-47. Also this is totally contradictory to what has been established in federal rules for Part D in their final rules adopted on January 28, 2005. That can be found in the Federal Register Section 423.120 (9). I have included a copy of that section for your use. Please note the differential allowed in 423.120 (10) for mail order pharmacy. Also the language is confusing. The PBM does not set co-payments or days of supply. These are set by the health insurer.

On page 5, lines 4-10, the term "company" and "company's" should be replaced with "covered entity" and "covered entity's", since the term "company" is not defined.

And finally on page 5, lines 17-18, the legislature is giving the Commissioner broad authority to write law that could have a significant impact in this controversial area. Even though the original bill has been significantly amended, this language would give the commissioner authority to re-establish the original bill by rule.

As I indicated before, this bill is a "solution in search of a problem". It could actually create a hostile business environment in our state, thus discouraging PBM's from operating in our state. In a small state like ours, why would we want to discourage businesses to operate in North Dakota? Congress recently passed the new Medicare law (MMA) that provides for prescription drug coverage for seniors. Prescription drug plans (PDP's) will be developed in a multi-state region. Our region includes ND, SD, IA, MN, NE, MT, and WY. The success of these PDP's will be dependent upon competition of PBM's. Because all the rules have not yet been determined and the federal Prescription Drug Plans go into effect on January 1, 2006, additional PBM regulations could have a significant impact on getting appropriate savings for ND's seniors. Now is not the time to create obstacles for these PDP's.

Senator Brown recently requested that the Federal Trade Commission review this legislation. They began that process while the bill was in the House. A call was received from a representative of the FTC last week, indicating that they have reviewed the revised bill, and will probably submit their analysis very shortly. We will get you a copy of that analysis as soon as it arrives.

I urge you to defeat this legislation. Should it pass, it will only result in higher administrative costs, the potential of fewer PBM's willing to operate in ND, and will hurt one segment of our citizens – those that are part of a fully insured health plan. As I noted before, everyone else has been exempted from the application of this bill. Employers are already struggling to maintain health coverage as a benefit. Why would the legislature want to add even more administrative costs to those employers? We would urge you to defeat this legislation. Mr. Chairman, I would be willing to answer any questions the committee may have.

standard terms and conditions for network participation. We do not intend to define "reasonable and relevant" in order to provide Part D plans with maximum flexibility to structure their standard terms and conditions.

However, it is unreasonable to assume—the any willing pharmacist requirement notwithstanding—that a Part D plan could establish a network using a uniform set of terms and conditions throughout a service area because it will likely need to modify contracting terms and conditions to ensure access to certain pharmacies (for example, rural and long-term care pharmacies). We clarify that standard terms and conditions particularly for payment terms may vary to accommodate geographic areas or types of pharmacies) and that this is acceptable, provided that all similarly situated pharmacies are offered the same standard terms and conditions. Thus, for example, provided Part D plans offer all mail-order pharmacies in a particular area with the same standard terms and conditions, they may offer separate standard terms and conditions to mail-order pharmacies. With standard terms and conditions as a "floor" of minimum requirements that all similarly situated pharmacies must abide by, Part D plans may modify some of their standard terms and conditions to encourage participation by particular pharmacies.

Comment: Many commenters disagreed with our interpretation of the "any willing pharmacy" provision, specifically with allowing Part D plans to construct networks of preferred and non-preferred pharmacies that have different requirements for beneficiary cost sharing. These commenters argued that allowing preferred networks undermines the any willing pharmacy rule and runs counter to Congressional intent. Many said that allowing Part D plans to steer beneficiaries to preferred pharmacies would impede pharmacy access and disrupt existing relationships between pharmacists and patients. Some argued that our interpretation would disadvantage small, independent, and rural pharmacies. Others said that a designation of "non-preferred" would carry a negative connotation about the pharmacy's quality of service.

Several other commenters concurred with the any willing pharmacy policy in our proposed rule. One commenter said that State any willing pharmacy laws should be expressly preempted, while another commenter said we should clarify that State any willing provider laws continue to apply to Part D plans' non-Medicare business. One commenter asked us to clarify the extent to which we will allow Part D plans to vary their cost sharing for preferred networks.

Response: We believe that we have correctly interpreted the two related provisions in sections 1860D–4(b)(1)(A) and (B) of the Act, which require Part D plans to allow any willing pharmacy to participate in their pharmacy networks, while also allowing Part D plans to reduce cost-sharing differentially for network pharmacies. General principles of statutory interpretation require us to reconcile two seemingly conflicting statutory provisions whenever possible, rather than allowing one provision to effectively nullify the other provision. Consequently, when a statutory provision may reasonably be interpreted in two ways, we have an obligation to adopt the interpretation that gives full effect to competing provisions of the statute. We believe that our policy of permitting cost-sharing discounts for preferred pharmacies, as codified in § 423.120(a)(9), strikes an appropriate balance between the need for broad pharmacy access and the need for Part D plans to have appropriate contracting tools to lower costs.

We note, however, that while these within network distinctions are allowed, the statute also requires that such tiered cost-sharing arrangements in no way increase our payments to Part D sponsors. Therefore, tiered cost-sharing arrangements based on within-network distinctions could be included in Part D plans' benefits subject to the same actuarial tests that apply to formulary-based tiered cost-sharing structures. Thus, a reduction in cost sharing for preferred pharmacies in a Part D plan network could be offered through higher cost sharing for non-preferred pharmacies (or as alternative prescription drug coverage). We also note that differential cost-sharing in the context of preferred and non-preferred pharmacies does not raise the cost-sharing obligation of low-income subsidy eligible enrollees above the levels specified in sections 1860D–14(a)(1) and (2) of the Act.

We recognize the possibility that Part D plans could effectively limit access in portions of their service areas by using the flexibility provided in § 423.120(a)(9) of our final rule to create a within-network subset of preferred pharmacies. In other words, in designing its network, a Part D plan could establish a differential between cost-sharing at preferred versus non-preferred pharmacies—while still meeting the access standards in § 423.120(a)(1) of our proposed rule—that is so significant as to discourage enrollees in certain areas (rural areas or inner cities, for example) from enrolling in that Part D plan. We emphasize that such a network design has the potential to substantially discourage enrollment by certain Part D enrollees, and that we have the authority under section 1860D–11(e)(2)(D) of the Act to disallow benefit designs that are discriminatory. We clarify that State any willing pharmacist laws would be preempted as applicable to plans' Part D business. This is consistent with section 1860D–12(g) of the Act, which extends the State preemption provisions under section 1856(b)(3) of the Act to Part D plans.

Comment: Several commenters thought that Part D plans should only be allowed to have differential cost sharing for preferred pharmacies if they exceed the TRICARE access standard.

Response: We see no statutory basis for such a rule. Moreover, it would be difficult to construct and operationalize such a policy.

Comment: Several commenters wrote that special needs enrollees should be exempted from higher cost sharing at non-preferred pharmacies.

Response: We see no statutory basis for such a rule, and we believe that Part D plans will provide sufficient access for all Part D enrollees under our access standards in § 423.120(a)(1). As noted in our proposed rule, we will use the authority provided under section 1860D–11(e)(2)(D) of the Act to review, as part of the bid negotiation process, how Part D plan networks make preferred and non-preferred distinctions among their network pharmacies and disallow them if such proposed network designs would substantially discourage enrollment by certain beneficiaries in any part of a Part D plan's service area. We believe that special needs enrollees will be sufficiently protected by this review. To the extent that special needs enrollees are also eligible for low-income subsidies, as indicated above, differential cost-sharing based on preferred pharmacy status does not raise the cost-sharing obligation of low-income subsidy eligible enrollees above the levels specified in the Act.

Comment: Several commenters suggested that the TRICARE access standards be applied to Part D plans' "preferred" networks rather than its general network. Several other commenters concurred with the regulation as drafted in the proposed rule.

Response: Section 1860D–4(b)(1)(B) of the Act clarifies that a Part D sponsor has the option of reducing cost-sharing for covered Part D drugs dispensed through network pharmacies below the level that would have otherwise applied. Because the statute provides

that such distinctions can be made within a network, we do not believe that only preferred pharmacies constitute a Part D plan's network for the purposes of meeting the access standards in § 423.120(a)(1) of our final rule. Rather, both preferred and non-preferred pharmacies form part of a Part D plan network, and plans may count both of these types of network pharmacies toward their access standards.

Comment: Several commenters recommended that beneficiaries be able to get an extended supply of drugs, greater than a 30-day supply, from network retail pharmacies and mail-order pharmacies.

Response: We clarify that section 1860D–4(b)(1)(D) of the Act, and § 423.120(a)(10) of our final rule, require Part D plans to permit enrollees to receive extended supplies (for example, 90-day supplies) of covered Part D drugs through a network retail pharmacy.

Comment: Some commenters noted that our proposed regulations would unfairly allow Part D plans to charge beneficiaries more when they obtain their prescriptions at a community pharmacy than when they use mail order. One commenter notes that seniors benefit from face-to-face interaction with a pharmacist more than other age groups, which would be precluded under mail order and would limit enrollees' ability to use the pharmacy and pharmacist of their choice.

Many commenters recommended that we specifically prohibit Part D plans from using economic incentives for beneficiaries to use mail order that could create significant differences in cost sharing for mail order versus retail pharmacy prescription, or that plans make such difference minimal. One commenter recommended that Part D plans use the same average wholesale price (AWP) basis to determine the reimbursement rate for mail order and retail pharmacies. Another commenter noted that there is substantial evidence that seniors, particularly low-income seniors, are victims of theft from their mailboxes, undermining the financial incentive of mail order. This commenter recommended that we allow beneficiaries to pay the mail order price at a retail pharmacy when they can demonstrate their mailbox is not secure.

Response: As provided in section 1860D–11(i) of the Act, we have no authority to interfere with the negotiations between Part D plans and pharmacies and therefore cannot mandate that Part D plans negotiate the same, or similar, reimbursement rates with all pharmacies. Provided Part D plans offer all pharmacies standard terms and conditions, they may modify their contracting terms—including payment provisions as necessary, as long as all similarly situated pharmacies are subject to the same minimum terms and conditions. Moreover, section 1860D–4(b)(1)(B) of the Act provides Part D plans with the authority to designate some network pharmacies, including mail-order pharmacies, as preferred pharmacies offering plan enrollees lower cost sharing.

Comment: One commenter noted that MA organizations that own and operate their own pharmacies usually have internal systems for providing prescription services by mail that are fully integrated with the overall pharmacy operation. As a result, it is difficult to provide an incentive to beneficiaries to use less costly mail services. The commenter said we should permit these organizations to establish differential benefit levels for mail delivery as opposed to in-facility pickup.

Response: As noted above, Part D plans have the flexibility to establish different cost-sharing requirements for the pharmacies in their networks consistent with section 1860D–4(b)(1)(B) of the Act. Accordingly, Part D plans have the flexibility to establish differential cost-sharing requirements for mail delivery and in-facility pickup.

Comment: One commenter recommended that we require Part D plans to contract with pharmacies that offer home delivery service, noting that same-day or next day need for medications makes mail-order an impracticable option.

Response: We do not believe there is a compelling rationale to require Part D plans to contract with pharmacies that offer home delivery service. As discussed elsewhere in this preamble, we have defined the term "dispensing fees" in § 423.100 of our final rule to include reasonable pharmacy costs, including delivery costs, associated with ensuring that possession of the appropriate covered Part D drug is transferred to a Part D enrollee. We clarify that reasonable delivery costs include only those costs appropriate for the typical beneficiary in a particular pharmacy setting. Thus, while it would be appropriate for Part D plans to reimburse long-term care, mail-order, and home infusion pharmacies for home delivery costs via the dispensing fee, this would not be the case for retail pharmacies (where the term "delivery" would be limited to the transfer of a covered Part D drug from the pharmacist to the patient at the point of sale) because the typical retail customer does not require home delivery. While retail pharmacies may offer home delivery services, Part D plans may not reimburse those pharmacies for these costs, and the delivery cost must be borne by the beneficiary.

Comment: Two commenters expressed their support for our interpretation of the term "insurance risk" and asked that we include in our regulations a statement that the prohibition against the assumption of risk by Part D plans' network pharmacies not preclude performance-based measures of activities within the control of a pharmacy (for example, formulary compliance and generic drug substitution).

Response: We clarify that our definition of the term "insurance risk" in § 423.4 of the final rule specifically excludes "payment variations designed to reflect performance-based measures of activities within the control of a pharmacy, such as formulary compliance and generic drug substitutions."

b. Formulary Requirements

1. P&T Committee Requirements

To the extent that a Part D sponsor uses a formulary to provide qualified prescription drug coverage to Part D enrollees, it will be required to meet the requirements of section 1860D–4(b)(3)(A) of the Act to use a pharmaceutical and therapeutic (P&T) committee to develop and review that formulary.

The majority of members comprising the P&T committee will be required to be practicing physicians or practicing pharmacists. In addition, at least one practicing pharmacist and one practicing physician member will have to be experts in the care of elderly and disabled individuals. Section § 423.120(b)(1)(ii) of the proposed rule also provided that at least one practicing pharmacist and one practicing physician members on a Part D plan's P&T committee be independent experts.

When developing and reviewing the formulary, the P&T committee will be required, in accordance with section 1860D–4(b)(3)(B) of the Act, to base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature. Section § 423.120(b)(1)(viii) of our proposed rule required that any decisions made by the P&T committee regarding development or revision of a Part D plan's formulary be documented in writing.

Except as otherwise provided below, the final rule adopts the requirements related to P&T committees set forth in § 423.120(b)(1) of our proposed rule.

Comment: Many commenters thought that P&T committee decisions regarding

HB 1332
Senate Industry Business and Labor Committee
March 21, 2005

Chairman Mutch and Committee Members, for the record I am Rod St. Aubyn, representing Blue Cross Blue Shield of North Dakota. We appear before you today once again opposing HB 1332. This bill is bad for several reasons:

- The regulatory requirements and additional cost associated with this bill will only apply to a small minority of citizens, while all others are exempted by this bill.
- An FTC analysis concludes that the ND Legislature should not adopt HB 1332.
- Passage of this bill could actually reduce network access, especially in the rural areas by restricting differential dispensing fees.
- This bill will be bad for business by limiting pharmaceutical benefit choices.

To refresh my past testimony, this bill will only apply to the fully insured health plans - less than 1/3 of ND citizens. I would estimate that over 80% of the prescriptions in ND would be exempt from these new regulations since senior citizens utilize a large majority of prescriptions. Passage of this bill will discriminately pass on additional regulatory costs to the small businesses of ND, those that don't have the resources to self-insure.

An analysis of this engrossed bill by the Federal Trade Commission, Office of Planning, Bureau of Economics, and Bureau of Competition indicates that it "may have the unintended consequences of increasing the price of pharmaceuticals and ultimately to decrease the number of North Dakotans with insurance coverage for pharmaceuticals. Specifically, we believe that HB 1332 may limit a PBM's ability to guide consumers to lower-cost pharmacies and would prohibit switching consumers to certain lower-priced drugs.

With permission from one of our legislators, I will illustrate a real life example. Legislator X recently came down with the nasty bug that has been invading the legislative chambers. He went to the Doctor of the Day. He was diagnosed with acute bronchitis, which he was told if left untreated could lead to bacterial pneumonia. The doctor prescribed two medicines – Allegra and Biaxin XL. As per the PERS benefit plan, all non-sedating antihistamines are non-covered drugs. Many of these (Claritin and many generic alternatives) can be purchased over-the-counter. Legislator X paid over $36 for ten pills of the prescribed Allegra.

Biaxin XL 500 mg (14 pills- 2 pills per day for 7 days) was also prescribed. This drug was a non-formulary drug. The total cost for this drug was $69.45. Because it was non-formulary, Legislator X's cost share ended up being $47.23. The formulary drug for this classification was Zithromax, which would have cost $45.45, of which Legislator X's cost share would have been $22.61. Except as provided in 19-02.1-02, it appears that

there was no reason that a drug switch couldn't have occurred saving Legislator X about $25.00 in addition to more savings if the non-sedating antihistamine had been switched to an over-the-counter medication. As indicated in the FTC analysis, *"HB 1332 would allow the PBM to request the substitution of a "lower-priced generic or therapeutically equivalent drug" for a prescribed drug. It is unclear in the Bill whether the term "therapeutic equivalent" drug refers to those drugs that are pharmaceutically equivalent or those that are pharmaceutically distinct, but are within the same therapeutic class. To the extent that the Bill adopts the former narrower definition, HB 1332 would prohibit a PBM from requesting that the drug referred to in a patient's prescription be substituted for another drug that is designed to have similar therapeutic effects – but that is pharmaceutically distinct – unless the substitution is "for medical reasons that benefits the covered individual" and the prescribing physician approves the substitution."*

The FTC summarizes their analysis as follows:

"HB 1332 is likely to limit a PBM's ability to reduce the cost of prescription drugs without providing consumers any additional protections. Any such cost increases are likely to undermine the ability of some consumers to obtain pharmaceuticals and health insurance they need at a price they can afford. Accordingly, we would urge the North Dakota legislature not to adopt HB 1332."

I am aware that you have received information from the pharmacists that quotes a paid counsel of theirs who disputes the report. Keep in mind; their "expert" is a paid lawyer and not an economist. In fact, based on a deposition in another case in which Mr. Balto is purported to be an expert witness, he acknowledges in a deposition that he has never taken any college economics courses and his training in the FTC did not involve economics. His background has been in the legal field.

The FTC believes "that HB 1332, if enacted, may have the unintended consequence of increasing the price of pharmaceuticals and ultimately to decrease the number of North Dakotans with insurance coverage for pharmaceuticals." This threat is real. According to the 2004 Employer Health Benefits Survey conducted by the Kaiser Family Foundation and Health Research and Educational Trust:

- Between spring of 2003 and spring of 2004, premiums for employer-sponsored health insurance rose 11.2%, lower than the 13.9% increase in 2003, but still the fourth consecutive year of double-digit growth.
- Since 2000, premiums for family coverage have increased by 59 percent.
- Almost 80% of covered workers with single coverage, and over 90% of covered workers with family coverage made a contribution toward premiums in 2004.
- Approximately 41% of employers offering health benefits say that they are "very likely" or "somewhat likely" to increase the percentage of the family premium that employees must pay in the next two years.

- Firms offering health benefits declined from 68% in 2001 to 63% in 2004.

- Approximately 5% of all employers say that they are "very likely" or "somewhat likely to drop coverage entirely in the next year.

It is likely that the situation in North Dakota is direr given the economic realities of our rural state. Furthermore, according to the FTC, the restrictions proposed in HB 1332 inhibit the ability to manage drug costs "without providing consumers any additional protections."

Although we disagree with Mr. Balto's conclusions, criticism does provide opportunity for common ground. It has been BCBSND's position from the beginning that the issues raised by HB 1332 are complex and should be carefully studied. Questions remain on whether the alleged problems actually exist in North Dakota, whether the proposed remedies make sense for North Dakota and whether North Dakota already has adequate protections in place?

For example, with regard to pharmacy contracting Mr. Balto mentions several times the protections offered by North Dakota's statute guaranteeing freedom of choice for pharmacy participation in managed care plans. *See* N.D. Cent. Code 26.1-36-12.2. North Dakota also has protections in place for the quality of mail service pharmacy operations. *See* N.D. Cent. Code 43-15-34.1 and N.D. Admin. Code 61-08-01 et seq.

While we would prefer that this bill be defeated, we have prepared amendments to address the issues identified by the FTC.

The most significant amendment for our company is located on page 4, the later part of line 14 through line 16. Our company offers many health plans, including the PERS Plan, which all utilize one primary network called RxDakota. In these health plans, there are different outpatient pharmaceutical copays and coinsurance arrangements. The language in this bill would preclude our company from offering different pharmaceutical plans within our different health plans. As a result, **all** our health plans would be required to have the same copays and coinsurances for pharmaceuticals. This will take away choices for our businesses. Some employers may elect to offer their employees a plan with a larger copay and a higher cost share to buy down the rates so they can still offer a health plan for their employees. In addition, we often allow a different coinsurance for a formulary drug than a nonformulary drug. If this bill passes without our amendments, these options will no longer be available for the fully insured company. Keep in mind, we would still be able to do this in the self-funded market. **This bill will discriminate against the small employer and limit their choices.**

In addition, this bill may actually hurt the rural pharmacist. The bill does not define the term "coinsurance". Currently we reimburse the pharmacist an ingredient cost based on a

fee schedule plus a dispensing fee less a copay and the members share of coinsurance. For example, let's assume a member has a plan with a $15 copay, and they are responsible for 20% of the coinsurance. In this example the allowed cost of a drug is $110 plus a $5 dispensing fee. The member would pay the copay ($15) plus 20% of the balance ($20 in this example - 20% of $100). We would define the member's coinsurance as the (Allowed Ingredient cost + the dispensing fee – copay) X member's share of coinsurance percentage.

I included some charts showing these dispensing fees. We currently reimburse the rural pharmacists a higher dispensing fee to ensure network access. This is recognized as well in the Federal Regulations for the new prescription drug program called Medicare Part D. Those rules state:

However, it is unreasonable to assume – the any willing pharmacist requirement notwithstanding – that a Part D plan could establish a network using a uniform set of terms and conditions throughout a service area because it will likely need to modify contracting terms and conditions to ensure access to certain pharmacies (for example, rural and long-term care pharmacies).

....

We believer that we have correctly interpreted the two related provisions in sections 1860D-4(b)(1)(A) and (B) of the Act, which require Part D plans to allow any willing pharmacy to participate in their pharmacy networks, while also allowing Part D plans to reduce cost-sharing differentially for network pharmacies.

....

We clarify that State any willing pharmacist laws would be preempted as applicable to plans' Part D business. This is consistent with section 1860D-12(g) of the Act which extends the State preemption provisions under section 1856(b)(3) of the Act to Part D plans. [Federal Register/Vol. 70, No. 18/ Friday, January 28, 2005, Page 4254]

The language in this bill seems to prevent paying different dispensing fees to ensure network access in rural areas. The section also seems to be contrary to the language in section 26.1-36-12.2, which allows for the option of a PPO option within a drug network. How could you derive any PPO benefit if you would have to have the same copays, coinsurances, and deductibles within a network? Once again, the small employer would not get the same options as the self funded plans. The same applies to what the pharmacists are probably really trying to address – that is mail service pharmacy. You will note what the Federal regulations for Part D say about these in the following:

As noted above, Part D plans have the flexibility to establish different cost-sharing requirements for the pharmacies in their networks consistent with section 1860D-4(b)(1)(B) of the Act. Accordingly, Part D plans have the flexibility to establish differential cost-sharing requirements for mail delivery and in-facility pickup. [Federal Register/Vol. 70, No. 18/ Friday, January 28, 2005, Page 4255]

(9) Differential cost-sharing for preferred pharmacies. A Part D sponsor offering a Part D plan that provides coverage other than defined standard coverage may reduce copayments or coinsurance for covered Part D drugs obtained through a preferred pharmacy relative to the copayments or coinsurance applicable for such drugs when obtained through a non-preferred pharmacy. [Federal Register/Vol. 70, No. 18/ Friday, January 28, 2005, Page 4537]

(10) .... A Part D plan may require an enrollee obtaining a covered Part D drug at a network pharmacy that is a retail pharmacy to pay any higher cost-sharing applicable to that covered Part D drug at the network pharmacy that is a retail pharmacy instead of the cost-sharing applicable to that covered Part D drug at the network pharmacy that is a mail-order pharmacy. [Federal Register/Vol. 70, No. 18/ Friday, January 28, 2005, Page 4537]

Explanation of Amendents –

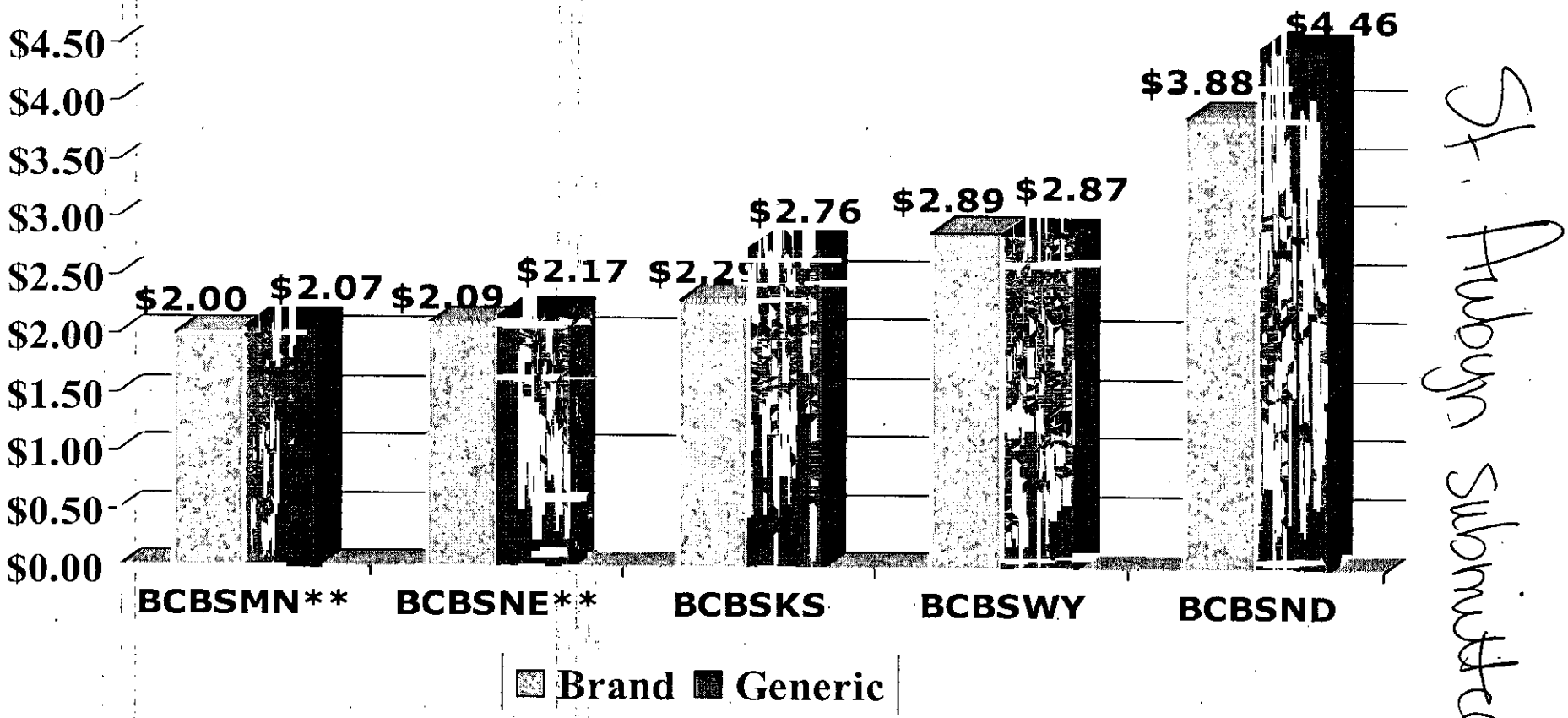
In summary, this is a very complex issue to be deciding during 6 hours of testimony. While we would prefer that this bill be defeated, we have offered amendments that would allow the Insurance Commissioner to regulate PBM's and have the ability to ensure that rebates and other discounts are adequately accounted for. Another option you have is to study this issue. Mr. Pat Ward offered an amendment to study all these issues in the House and I assume he will make the same suggestion to you today.

As I indicated in my testimony this bill should be defeated for several reasons:

- It discriminates a small segment of the insured market – the fully insured groups.
- Based on the FTC analysis it could "undermine the ability of some consumers to obtain pharmaceuticals and health insurance they need at a price they can afford."
- The bill could actually reduce network access if differential dispensing rates are not allowed.
- This bill is bad for businesses by limiting pharmaceutical benefit choices.

We urge the defeat of this bill or at least the adoption of the amendments. Mr. Chairman, I would be willing to answer questions the committee may have.

Figure 1. Dispensing Fee Comparisons Among Prime Clients*



*In-state claims only

**Prime Networks

St. Aubyn submitted

Medicaid Reimbursement Rates

Medicaid Rx Reimbursement by State – 4th Quarter 2003

State	Ingredient Cost	Dispensing Fee
Minnesota	AWP-14%	$3.65
Montana	AWP-15%	$4.70
North Dakota	AWP-10%	$5.60 (G) $4.60 (B)
South Dakota	AWP-10.5%	$4.75
Wyoming	AWP-11%	$5.00

Source: Center for Medicare & Medicaid Services

Existing Networks

RxDakota Instate Network - North Dakota

Area	Pricing	Dispensing Fees			
		Brand	Generic	Brand Maintenance	Generic Maintenance
Rural Independent	AWP - 10%	$5.00	$5.75	$6.00	$6.75
Urban Independent	AWP - 10%	$4.25	$5.00	$5.25	$6.00
National Chain	AWP - 12%	$2.50	$2.50	$3.50	$3.50
Regional Chain	AWP - 10%	$3.75	$4.25	$4.75	$5.25

Retail Pharmacy Density

Number of Retail Pharmacies per 100,000 persons - 2003

State	Pharmacies per 100,000
Minnesota	14.0
Montana	15.5
North Dakota	26.0
South Dakota	16.5
Wyoming	15.4

Source: RTI International

Covered Services	After the Deductible Amount has been met the benefit amount will be the following percentage of Allowed Charge: Basic Plan	PPO Plan	EPO Plan	Self-Referral
Medical Supplies and Equipment Maximum Benefit Allowance of $6,000 per Member per Benefit Period.	75%	80%	85%	85% Subject to the EPO Deductible Amount
▪ Home Medical Equipment ▪ Prosthetic Appliances ▪ Orthotic Devices ▪ Supplies for Administration of Prescription Medications or Drugs ▪ Oxygen Equipment and Supplies ▪ Ostomy Supplies				
▪ Hearing aids for Members to age 18	Subject to a $3,000 Maximum Benefit Allowance per Member every 3 years. Prior Approval is required. This benefit is also subject to the Medical Supplies and Equipment Maximum Benefit Allowance.			
▪ Prosthetic Limbs	Subject to a Maximum Benefit Allowance every 5 years of $6,000 per limb above or below the elbow and $16,000 per limb above or below the knee. This benefit is not subject to the Medical Supplies and Equipment Maximum Benefit Allowance.			
Eyeglasses or Contact Lenses (following a covered cataract surgery)	Maximum Benefit Allowance of 1 pair of eyeglasses or contact lenses per Member when purchased within 6 months following the surgery.			
	75%	80%	85%	75%

Outpatient Prescription Medications or Drugs
Deductible Amount does not apply

- Formulary Drug per Prescription Order or refill

Generic	$5 Copayment then 85% of Allowed Charge.
Brand Name	$15 Copayment then 75% of Allowed Charge.

- Nonformulary Drug per Prescription Order or refill (Generic and Brand Name)

$25 Copayment then 50% of Allowed Charge.

If a Generic Prescription Medication or Drug is the therapeutic equivalent for a Brand Name Prescription Medication or Drug, and is authorized by a Member's Professional Health Care Provider benefits will be based on the Allowance for the Generic equivalent. If the Member does not accept the Generic equivalent the Member is responsible for the cost difference between the Generic and the Brand Name Prescription Medication or Drug and applicable Cost Sharing Amounts.

Prescription Medication or Drug Cost Sharing Amounts do not apply toward the Out-of-Pocket Maximum Amount.

The Copayment Amounts are waived for prenatal vitamins when the Member is enrolled under the Prenatal Plus Program.

Benefits include the following nonprescription diabetes supplies: syringes, lancets and test strips. These items will be paid subject to the Outpatient Prescription Medications or Drugs Generic Formulary Drug Coinsurance Amount. The Copayment Amount is waived.

SelectChoice

BlueCross BlueShield of North Dakota

An independent licensee of the Blue Cross & Blue Shield Association

SelectChoice allows the option to choose any provider — but by selecting and staying within your chosen SelectChoice network you'll gain several advantages. This plan includes a $200 annual benefit for preventive services, a generous 90% benefit payment amount for most covered services and no deductible for office visits.

The benefits of selecting a health care network.

SelectChoice promotes teamwork between all participants in the health care process — the employee, the employer, the doctor or medical group and Blue Cross Blue Shield of North Dakota — all working together to accomplish one common goal: a higher level of health care benefits at a lower premium rate.

Choosing your health care partner.

When you enroll, you will select a specific network. You must choose one network for family and single plus dependent coverage. The network list for your area is provided by Blue Cross Blue Shield of North Dakota.

To maximize coverage, all your family members must obtain medical services from the network you've selected. You and your family may switch to another network on your group's anniversary date. Contact Blue Cross Blue Shield of North Dakota or your employer for the appropriate form.

Getting the most from your benefits.

By receiving health care services within your network, you'll take advantage of the highest level of benefits provided by this plan. For health care outside your network, without an authorized referral, this benefit plan will still pay on most covered services. However, you will pay a higher coinsurance and deductible.

If services are received in North Dakota from a nonparticipating Blue Cross Blue Shield of North Dakota provider, your benefit payments will be reduced an additional 20%.

Using the network.

In SelectChoice, there are two terms you should understand, in-network and out-of-network. In-network is the network you select as your specific SelectChoice health care provider. An out-of-network provider is any provider outside your chosen SelectChoice network.

No deductible for office visits and other certain services.

Unlike many other health plans that require you to meet your deductible before you can receive benefits, this plan's deductible does not apply to the following services when received in-network:

- Home and office visits
- Pre and postnatal maternity care
- Well child care
- Outpatient prescription drugs
- Preventive screening services

Putting the emphasis on preventive health care.

Preventive care is essential in maintaining good health. It helps doctors discover such conditions as heart disease, diabetes, cancer and high blood pressure in early, more treatable stages.

To give you this healthy advantage, mammograms, pap smears and prostate cancer screenings are covered. This plan also provides a preventive screening program for members 6 and older, subject to a maximum benefit allowance of $200 per benefit period when preventive services are received from your network provider. This includes physical exams, immunizations and routine diagnostic services such as:

- Cholesterol screening
- Fecal occult blood testing
- Blood sugar testing
- Urinalysis testing
- Hemoglobin testing

Well child care helps keep your child healthy.

When your child receives covered services from your network provider, this plan pays 100% of the allowed charge after you pay the copayment per office visit. The deductible amount does not apply.

Well child care benefits:

Birth through 12 months:	5 visits
13 months through 24 months:	3 visits
25 months through 72 months:	1 visit per benefit period

Covered immunizations:

This plan covers immunizations approved and recommended by the *Advisory Committee on Immunization Practices*, the *American Academy of Family Practice* and the *American Academy of Pediatrics*. This includes:

- DPT (Diphtheria/Pertussis/Tetanus)
- MMR (Measles/Mumps/Rubella)
- Hemophilus Influenza B
- Chicken Pox (Varicella)
- Pneumococcal Disease
- Hepatitis B
- Polio

Outpatient prescription drug benefits.

To help offset the cost of today's prescription medications and drugs, this plan offers a benefit-rich prescription drug program. By following the guidelines of the program, a significant portion of your prescription drug cost is covered by this plan. The program provides a number of advantages and benefits including:

Automatic claims filing

Participating pharmacies submit your claim for you.

Network benefits

Get the most from your benefits by using the preferred pharmacy network with participating pharmacies nationwide.

All-in-one ID card

Your BCBSND identification card is also your prescription drug card.

And to help members gain additional savings, the program also identifies ways to reduce your out-of-pocket prescription drug costs through the use of generic alternatives.

For further details and coverage amounts of the prescription drug program, refer to the plan's overview of benefits.

SelectChoice

An overview of benefits and services provided by this plan.

BSPRW03 SC PROPOSAL

BlueCross BlueShield of North Dakota
An independent licensee of the Blue Cross & Blue Shield Association

This benefit plan covers these services...and more, up to a lifetime maximum of $2,000,000 per member.

Who is eligible for benefits?

If you have family coverage, benefits are available for you, your spouse and eligible children. If you have single plus dependent coverage, you and your eligible children are covered. Eligible children must be unmarried and financially dependent on you or your covered spouse for their support. These include:

- Children under age 22.
- Children who are full-time students under age 26.
- Children placed with you or your covered spouse for adoption or whom you or your covered spouse have legally adopted.
- Children for whom you or your covered spouse have been appointed legal guardian by court order.
- Grandchildren of yours or your covered spouse if:
  - The parent of the grandchild is a covered eligible dependent.
  - The parent and grandchild are primarily dependent on you or your covered spouse for their support.
- Children for whom you or your covered spouse are required by court order to provide health benefits.
- Children incapable of self-support because of mental retardation or a physical handicap that began before they reached 22 years of age and who are primarily dependent on you or your covered spouse.

Outpatient prescription drug benefits.

This benefit plan includes a preferred pharmacy network. When you use this national network, your claims are filed for you. Participating pharmacists also use a computer database to:

- Check for possible interactions between prescriptions.
- Find any drug duplications.
- Identify overuse or underuse of your medication.
- Determine if a generic equivalent is available for your prescription drug and if the medication appears on a list of quality and cost-effective drugs. Drugs on this list, called formulary drugs, are covered at the maximum benefit amount.

Prescription drugs are categorized as formulary, nonformulary, nonpayable or restricted-use drugs. A restricted-use drug may have a dispensing limit and/or require prior approval.

Benefits are available nationwide at any pharmacy participating in the preferred pharmacy network. To locate a participating pharmacy, call the special toll-free number listed on the back of your ID card.

This benefit grid presents a brief overview of covered services and payment levels of this product. It should not be used to determine whether your health care expenses will be paid. The written benefit plan governs the benefits available.

DESCRIPTION OF BENEFITS	Co[illegible]en Amount you pay per visit
INPATIENT HOSPITAL SERVICES	
OUTPATIENT HOSPITAL SERVICES Physical Therapy	$15
Occupational and Speech Therapy	$15
PROFESSIONAL HEALTH CARE PROVIDER SERVICES Inpatient, Outpatient and Surgical Services	
WELLNESS SERVICES Preventive Screening Services	$20
Well Child Care	$20
Mammography, Pap Smear and Prostate Cancer Screening Services	
HOME & OFFICE VISITS	$20
DIAGNOSTIC SERVICES Lab, X-ray, MRI Allergy Testing	
RADIATION THERAPY, CHEMOTHERAPY & DIALYSIS	
MATERNITY SERVICES Inpatient, Outpatient, Pre and Postnatal Care	
PSYCHIATRIC & SUBSTANCE ABUSE SERVICES Inpatient, Ambulatory Behavioral Health Care (Partial Hospitalization), Residential Treatment and Outpatient Services	
EMERGENCY SERVICES Professional Health Care Provider Visit	$20
Emergency Room Charge	$50
URGENT CARE SERVICES Professional Health Care Provider Visit	$20
Emergency Room Charge	$50
AMBULANCE SERVICES	
SKILLED NURSING FACILITY SERVICES	
HOME HEALTH CARE SERVICES	
HOSPICE SERVICES	
CHIROPRACTIC SERVICES Home and Office Visit Therapy and Manipulations Diagnostic Services	$20 $15
MEDICAL SUPPLIES & EQUIPMENT Home Medical Equipment, Prosthetics, Orthotics, Therapeutic Devices, Ostomy and Oxygen Supplies	
Hearing Aids (for members up to age 18)	

DESCRIPTION OF BENEFITS
OUTPATIENT PRESCRIPTION MEDICATIONS AND DRUGS
Formulary
Nonformulary

IN-NETWORK [redacted] with an authorized referral		OUT-OF-NETWORK with a participating BCBSND provider		SPECIAL CONDITIONS
[redacted] as a % of the allowed charge after deductible has been met		Benefit Amount as a % of the allowed charge after deductible has been met		
Before out-of-pocket maximum	After out-of-pocket maximum	Before out-of-pocket maximum	After out-of-pocket maximum	
90%	100%	80%	100%	Preauthorization may be required.
90%	100%	80%	100%	
80%	100%	80%	100%	Benefits are based on the medical guidelines established by Blue Cross Blue Shield of North Dakota. Deductible does not apply in-network.
80%	100%	80%	100%	Maximum of 90 consecutive calendar days per condition beginning on the date of the 1st therapy treatment for the condition. Deductible does not apply in-network.
90%	100%	80%	100%	
100%	100%	No Coverage	No Coverage	Maximum benefit allowance of $200 per benefit period for members age 6 and older. Deductible does not apply.
100%	100%	No Coverage	No Coverage	Office visits and immunizations up to member's 6th birthday. Deductible does not apply.
100%	100%	80%	100%	The number of visits for mammography and prostate cancer screening varies by age group. Maximum benefit allowance of 1 Pap smear per benefit period. Deductible does not apply to these services in-network. Refer to the benefit plan for details.
90%	100%	80%	100%	Deductible does not apply in-network.
90%	100%	80%	100%	
80%	100%	80%	100%	
90%	100%	80%	100%	
[redacted]%	100%	80%	100%	Deductible does not apply for pre and postnatal care.
[redacted]%	100%	100%/80%	100%	The number of visits, hours or days and the benefit level vary. Out-of-state admissions require prior approval. Preauthorization may be required. Refer to the benefit plan for details.
90%	100%	90%	100%	Preauthorization is not required. In-network deductible applies.
90%	100%	90%	100%	Deductible does not apply to the office or emergency room visit.
90%	100%	90%	100%	Deductible does not apply.
90%	100%	80%	100%	Urgent care services received out-of-network will be reimbursed at the out-of-network level,
90%	100%	80%	100%	except when the member is outside the geographic area of their affiliated network. Refer to the benefit plan for details.
90%	100%	80%	100%	
80%	100%	80%	100%	In-network deductible applies.
80%	100%	80%	100%	Preauthorization is required.
80%	100%	80%	100%	Preauthorization is required.
80%	100%	80%	100%	Preauthorization is required. In-network deductible applies.
90%	100%	80%	100%	Deductible does not apply when seeing a BCBSND participating chiropractor.
80%	100%	80%	100%	Deductible does not apply when seeing a BCBSND participating chiropractor.
90%	100%	80%	100%	
80%	100%	80%	100%	Maximum benefit allowance of $6,000 per member per benefit period. In-network deductible applies. Additional benefits are available for prosthetic limbs.
80%	100%	80%	100%	Maximum benefit allowance of $3,000 per member every 3 years. Prior approval is required. Benefits are subject to the Medical Supplies & Equipment $6,000 maximum benefit allowance.

[redacted] you pay [redacted]cription	Before Prescription Drug Coinsurance Maximum	After Prescription Drug Coinsurance Maximum	SPECIAL CONDITIONS
[redacted]	80%	100%	When a generic drug is available but not accepted, the member is responsible for the difference between the cost of the generic and brand name drug. Prescriptions filled at a nonparticipating pharmacy must be paid in full and a paper claim submitted. All costs above the allowance are the member's responsibility. Prescription drug claim forms are available from Blue Cross Blue Shield of North Dakota. Benefits are subject to the Outpatient Prescription Drug Coinsurance Maximum Amount. Deductible does not apply.
$15	50% sanction	50% sanction	

SelectChoice	In-Network 100	In-Network 250	In-Network 500	Out-of-Network 100	Out-of-Network 250	Out-of-Network 500
Single Coverage (or an individual family member)						
Deductible amount	$ 100	$ 250	$ 500	$ 250	$ 500	$ 1,000
Coinsurance maximum	$ 750	$ 750	$ 1,000	$ 1,500	$ 1,500	$ 2,000
Out-of-pocket maximum	$ 850	$ 1,000	$ 1,500	$ 1,750	$ 2,000	$ 3,000
Single Plus Dependent Coverage (individual plus eligible children)						
Deductible amount	$ 150	$ 375	$ 750	$ 375	$ 750	$ 1,500
Coinsurance maximum	$ 1,125	$ 1,125	$ 1,500	$ 2,250	$ 2,250	$ 3,000
Out-of-pocket maximum	$ 1,275	$ 1,500	$ 2,250	$ 2,625	$ 3,000	$ 4,500
Family Coverage						
Deductible amount	$ 200	$ 500	$ 1,000	$ 500	$ 1,000	$ 2,000
Coinsurance maximum	$ 1,500	$ 1,500	$ 2,000	$ 3,000	$ 3,000	$ 4,000
Out-of-pocket maximum	$ 1,700	$ 2,000	$ 3,000	$ 3,500	$ 4,000	$ 6,000

This chart reflects the cost sharing amounts for each benefit period. In-network and out-of-network amounts accumulate jointly. Outpatient prescription drug cost sharing amounts do not apply to the out-of-pocket maximum.

Outpatient Prescription Drug Coinsurance Maximum Amount $1,000 per member per benefit period

When the prescription drug coinsurance maximum amount has been met, copayment amounts will continue to apply, and formulary drugs will be covered at 100% of the allowed charge for the remainder of the benefit period. Copayment amounts and the nonformulary sanction do not apply to this coinsurance maximum.

Employer contribution.

To qualify for a group health plan, the employer must contribute a minimum of 50% toward the single premium payment.

Waiting period for pre-existing conditions.

This plan applies a waiting period of 365 days to services, supplies or charges for the care or treatment a member receives for a pre-existing condition. A pre-existing condition is a condition, disease, illness or injury for which the member received medical advice or treatment within the 6-month period immediately preceding the individual member's enrollment date under the benefit plan.

Qualifying previous coverage.

Days of continuous coverage under qualifying previous coverage will apply toward the waiting period if continuous to a date within 63 days prior to the individual member's enrollment date under the benefit plan.

Late enrollees.

If an eligible employee or eligible dependent does not apply when first eligible, they may apply as late enrollees during the annual enrollment period. A waiting period for late enrollees will apply. See the benefit plan for special enrollment provisions.

Call toll-free 1-800-342-4718 • Fargo area call 277-2227

BlueCross BlueShield of North Dakota

An independent licensee of the Blue Cross & Blue Shield Association

www.BCBSND.com

For premium rates and further details of the coverage, including definitions; exclusions; criteria for medically appropriate and necessary care; credentialing process; confidentiality policy; description of experimental drugs, medical devices or treatments; grievance and appeals process; provider listings; drugs eligible for coverage; reductions or limitations; and the terms under which this benefit plan may be continued, see your Group Benefits Consultant or write to Blue Cross Blue Shield of North Dakota.

Basic Blue 70

An overview of benefits and services provided by this plan.

PRWG3

70 500 DEDUCTIBLE

BlueCross BlueShield of North Dakota

An independent licensee of the Blue Cross & Blue Shield Association

This benefit plan covers these services...and more, up to a lifetime maximum of $2,000,000 per member.

Who is eligible for benefits.

If you have family coverage, benefits are available for you, your spouse and eligible children. If you have single plus dependent coverage, you and your eligible children are covered. Eligible children must be unmarried and financially dependent on you or your covered spouse for their support. These include:

- Children under age 22.
- Children who are full-time students under age 26.
- Children placed with you or your covered spouse for adoption or whom you or your covered spouse have legally adopted.
- Children for whom you or your covered spouse have been appointed legal guardian by court order.
- Grandchildren of yours or your covered spouse if:
  - The parent of the grandchild is a covered eligible dependent.
  - The parent and grandchild are primarily dependent on you or your covered spouse for their support.
- Children for whom you or your covered spouse are required by court order to provide health benefits.
- Children incapable of self-support because of mental retardation or a physical handicap that began before they reached 22 years of age and who are primarily dependent on you or your covered spouse.

Outpatient prescription drug benefits.

This benefit plan includes a preferred pharmacy network. When you use this national network, your claims are filed for you. Participating pharmacists also use a computer database to:

- Check for possible interactions between prescriptions.
- Find any drug duplications.
- Identify overuse or underuse of your medication.
- Determine if a generic equivalent is available for your prescription drug and if the medication appears on a list of quality and cost-effective drugs. Drugs on this list, called formulary drugs, are covered at the maximum benefit amount.

Prescription drugs are categorized as formulary, nonformulary, nonpayable or restricted-use drugs. A restricted-use drug may have a dispensing limit and/or require prior approval.

Benefits are available nationwide at any pharmacy participating in the preferred pharmacy network. To locate a participating pharmacy, call the special toll-free number listed on the back of your ID card.

This benefit grid presents a brief overview of covered services and payment levels of this product. It should not be used to determine whether your health care expenses will be paid. The written benefit plan governs the benefits available.

DESCRIPTION OF BENEFITS
INPATIENT HOSPITAL SERVICES
OUTPATIENT HOSPITAL SERVICES Physical Therapy
Occupational and Speech Therapy
PROFESSIONAL HEALTH CARE PROVIDER SERVICES Inpatient, Outpatient and Surgical Services
WELLNESS SERVICES Well Child Care
Mammography, Pap Smear and Prostate Cancer Screening Services
HOME & OFFICE VISITS
DIAGNOSTIC SERVICES Lab, X-ray, MRI, Allergy Testing
RADIATION THERAPY, CHEMOTHERAPY & DIALYSIS
MATERNITY SERVICES Inpatient, Outpatient, Pre and Postnatal Care
PSYCHIATRIC & SUBSTANCE ABUSE SERVICES Inpatient, Ambulatory Behavioral Health Care (Partial Hospitalization), Residential Treatment and Outpatient Services
EMERGENCY SERVICES
AMBULANCE SERVICES
SKILLED NURSING FACILITY SERVICES
HOME HEALTH CARE SERVICES
HOSPICE SERVICES
CHIROPRACTIC Home and Office Visit Therapy and Manipulations Diagnostic Services
MEDICAL SUPPLIES & EQUIPMENT Home Medical Equipment, Prosthetics, Orthotics, Therapeutic Devices, Ostomy and Oxygen Supplies
Hearing Aids (for members up to age 18)

DESCRIPTION OF BENEFITS
OUTPATIENT PRESCRIPTION MEDICATIONS AND DRUGS Formulary
Nonformulary

NEFIT AMOUNT ticipating BCBSND provider mou[redacted]e a % of the allowed charge after deductible has been met		SPECIAL CONDITIONS
fore out-of-pocket naximum is met	After out-of-pocket maximum is met	
70%	100%	Preauthorization may be required.
70%	100%	
70%	100%	Benefits are based on the medical guidelines established by Blue Cross Blue Shield of North Dakota.
70%	100%	Maximum of 90 consecutive calendar days per condition beginning on the date of the 1st therapy treatment for the condition.
70%	100%	
100%	100%	Office visits and immunizations up to member's 6th birthday. Deductible does not apply.
70%	100%	The number of visits for mammography and prostate cancer screening varies by age group. Maximum benefit allowance of 1 Pap smear per benefit period. Refer to the benefit plan for details.
70%	100%	
70%	100%	
70%	100%	
70%	100%	
[redacted]70%	100%	The number of visits, hours or days and the benefit level vary. Out-of-state admissions require prior approval. Preauthorization may be required. Refer to the benefit plan for details.
70%	100%	Preauthorization is not required.
70%	100%	
70%	100%	Preauthorization is required.
70%	100%	Preauthorization is required.
70%	100%	Preauthorization is required.
70%	100%	
70%	100%	
70%	100%	
70%	100%	Maximum benefit allowance of $6,000 per member per benefit period. Additional benefits are available for prosthetic limbs.
70%	100%	Maximum benefit allowance of $3,000 per member every 3 years. Prior approval is required. Benefits are subject to the Medical Supplies & Equipment $6,000 maximum benefit allowance.

Copayment ount you pay prescription	Before Prescription Drug Coinsurance Maximum	After Prescription Drug Coinsurance Maximum	SPECIAL CONDITIONS
[redacted]	70%	100%	When a generic drug is available but not accepted, the member is responsible for the difference between the cost of the generic and brand name drug. Prescriptions filled at a nonparticipating pharmacy must be paid in full and a paper claim submitted. All costs above the allowance are the member's responsibility. Prescription drug claim forms are available from Blue Cross Blue Shield of North Dakota. Benefits are subject to the Outpatient Prescription Drug Coinsurance Maximum Amount. Deductible does not apply.
	50% sanction	50% sanction	

BASIC BLUE 70 — 500 DEDUCTIBLE

Single Coverage (or an individual family member)	
Deductible amount	$ 500
Coinsurance maximum	$ 2,500
Out-of-pocket maximum	$ 3,000
Single Plus Dependent Coverage (individual plus eligible children)	
Deductible amount	$ 750
Coinsurance maximum	$ 3,750
Out-of-pocket maximum	$ 4,500
Family Coverage	
Deductible amount	$ 1,000
Coinsurance maximum	$ 5,000
Out-of-pocket maximum	$ 6,000

This chart reflects the cost sharing amounts for each benefit period. Outpatient prescription drug cost sharing amounts do not apply to the out-of-pocket maximum.

Outpatient Prescription Drug Coinsurance Maximum Amount	$1,000 per member per benefit period

When the prescription drug coinsurance maximum amount has been met, copayment amounts will continue to apply, and formulary drugs will be covered at 100% of the allowed charge for the remainder of the benefit period. Copayment amounts and the nonformulary sanction do not apply to this coinsurance maximum.

Employer contribution.

To qualify for a group health plan, the employer must contribute a minimum of 50% toward the single premium payment.

Waiting period for pre-existing conditions.

This plan applies a waiting period of 365 days to services, supplies or charges for the care or treatment a member receives for a pre-existing condition. A pre-existing condition is a condition, disease, illness or injury for which the member received medical advice or treatment within the 6-month period immediately preceding the individual member's enrollment date under the benefit plan.

Qualifying previous coverage.

Days of continuous coverage under qualifying previous coverage will apply toward the waiting period if continuous to a date within 63 days prior to the individual member's enrollment date under the benefit plan.

Late enrollees.

If an eligible employee or eligible dependent does not apply when first eligible, they may apply as late enrollees during the annual enrollment period. A waiting period for late enrollees will apply. See the benefit plan for special enrollment provisions.

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For premium rates and further details of the coverage, including definitions; exclusions; criteria for medically appropriate and necessary care; credentialing process; confidentiality policy; description of experimental drugs, medical devices or treatments; grievance and appeals process; provider listings; drugs eligible for coverage; reductions or limitations; and the terms under which this benefit plan may be continued, see your Group Benefits Consultant or write to Blue Cross Blue Shield of North Dakota.

Proposed by St. Aubyn

50433.0300 **FIRST ENGROSSMENT**
Fifty-ninth
Legislative Assembly **ENGROSSED HOUSE BILL NO. 1332**
of North Dakota

Introduced by
Representatives N. Johnson, Devlin, Keiser, Price
Senators Fischer, J. Lee

A BILL for an Act to create and enact a new section to chapter 26.1-27 and chapter 26.1-27.1 of the North Dakota Century Code, relating to regulation of pharmacy benefits management.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:
SECTION 1. A new section to chapter 26.1-27 of the North Dakota Century Code is created and enacted as follows:

Pharmacy benefits manager. A pharmacy benefits manager, as defined under section 26.1-27.1-01, is an administrator for purposes of this chapter.

SECTION 2. Chapter 26.1-27.1 of the North Dakota Century Code is created and enacted as follows:

26.1-27.1-01. Definitions. In this chapter, unless the context otherwise requires:
1. "Covered entity" means a nonprofit hospital or a medical service corporation; a health insurer; a health benefit plan; a health maintenance organization; a health program administered by the state in the capacity of provider of health coverage; or an employer, a labor union, or other entity organized in the state which provides health coverage to covered individuals who are employed or reside in the state. The term does not include a self-funded plan that is exempt from state regulation pursuant to the Employee Retirement Income Security Act of 1974 [Pub. L. 93-406; 88 Stat. 829; 29 U.S.C. 1001 et seq.]; a plan issued for coverage for federal employees; or a health plan that provides coverage only for accidental injury, specified disease, hospital indemnity, medicare supplement, disability income, long-term care, or other limited-benefit health insurance policy or contract.
2. "Covered individual" means a member, a participant, an enrollee, a contractholder, a policyholder, or a beneficiary of a covered entity who is provided health coverage by the covered entity. The term includes a dependent or other individual provided health coverage through a policy, contract, or plan for a covered individual.
3. "De-identified information" means information from which the name, address, telephone number, and other variables have been removed in accordance with requirements of title 45, Code of Federal Regulations, part 164, section 512, subsections (a) or (b).
4. "Generic drug" means a drug that is chemically equivalent to a brand name drug for which the patent has expired.
5. "Labeler" means a person that has been assigned a labeler code by the federal food and drug administration under title 21, Code of Federal Regulations, part 207, section 20, and that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale.

6. "Payments received by pharmacy benefits manager" means the aggregate amount of any of the following payments:

a. Rebates collected by the pharmacy benefits manager and allocated to covered entity;

b. Administrative fees collected from the manufacturer in consideration of administrative services provided by the pharmacy benefits manager to the manufacturer;

c. Any other fees or amounts collected by the pharmacy benefits manager from a manufacturer or labeler for drug switch programs, educational support, or data sales related to covered individuals;

d. Pharmacy network fees.

~~6.~~ 7. "Pharmacy benefits management" means the procurement of prescription drugs at a negotiated rate for dispensation within this state to covered individuals; the administration or management of prescription drug benefits provided by a covered entity for the benefit of covered individuals; or the providing of any of the following services with regard to the administration of the following pharmacy benefits:

a. Mail service pharmacy;

~~b.~~ a. Claims processing, retail network management, and payment of claims to a pharmacy for prescription drugs dispensed to a covered individual;

~~c.~~ b. Clinical formulary development and management services; or

~~d.~~ c. Rebate contracting and administration.

~~7.~~ 8. "Pharmacy benefits manager" means a person that performs pharmacy benefits management. The term includes a person acting for a pharmacy benefits manager in a contractual or employment relationship in the performance of pharmacy benefits management for a covered entity and includes mail service pharmacy. The term does not include a public self-funded pool or a private single-employer self-funded plan that provides benefits or services directly to its beneficiaries. The term does not include a health carrier licensed under title 26.1 if the health carrier is providing pharmacy benefits management to its insureds and does not include a public self funded pool or a private single employer self funded plan that provides ~~pharmacy benefits management~~ directly to its beneficiaries.

~~8.~~ 9. "Rebate" means retrospective reimbursement of monetary amounts by a manufacturer under a manufacturer's discount program with a pharmacy benefits manager for drugs dispensed to covered individual. includes the nature, type, and amount of all other revenue received by the pharmacy benefits manager from each pharmaceutical manufacturer or labeler for any other product or service provided, including any formulary management and drug switch program, educational support, claims processing, and pharmacy network fees that are charged from retail pharmacies and data sales fees, with respect to programs that the covered entity offers or provides to the covered entity's enrollees.

~~9.~~ 10. "Utilization information" means de-identified information regarding the quantity of drug prescriptions dispensed to members of a health plan during a specified time period.

26.1-27.1-02. Licensing. A person may not perform or act as a pharmacy benefits manager in this state unless that person holds a certificate of registration as an administrator under chapter 26.1-27.

26.1-27.1-03. Disclosure requirements.

1. A pharmacy benefits manager shall disclose to the commissioner any ownership interest of any kind with:

a. Any insurance company responsible for providing benefits directly or through reinsurance to any plan for which the pharmacy benefits manager provides services.
b. Any parent company, subsidiary, or other organization that is related to the provision of pharmacy services, the provision of other prescription drug or device services, or a pharmaceutical manufacturer.
2. A pharmacy benefits manager shall notify the commissioner in writing within five business days of any material change in the pharmacy benefits manager's ownership.

26.1-27.1-04. Prohibited practices.
1. A pharmacy benefits manager may not request a substitution of one prescription drug for another unless:
a. The pharmacy benefits manager requests that a lower priced generic or therapeutically equivalent drug be substituted for a higher priced prescribed drug; or
b. The substitution is for medical reasons that benefit the covered individual and the pharmacy benefits manager obtains the approval of the prescribing health professional.
~~2.~~ 1. A pharmacy benefits manager may not require a pharmacist or pharmacy to participate in one contract in order to participate in another contract. The pharmacy benefits manager may not exclude an otherwise qualified pharmacist or pharmacy from participation in a particular network solely because the pharmacist or pharmacy declined to participate in another plan or network managed by the pharmacy benefits ~~manager.~~ provided the pharmacist or pharmacy accepts the terms, conditions, and reimbursement rates of the pharmacy benefits manager's contract.
3. When contracting with pharmacies, a pharmacy benefits manager may not discriminate on the basis of copayments or days of supply. A contract must apply the same coinsurance, copayment, and deductible to covered drug prescriptions filled by any pharmacist or pharmacy who participates in the network.
4.This section does not permit the substitution of an equivalent drug product contrary to section 19 02.1 02.

26.1-27.1-05. Contents of pharmacy benefits management agreement - Requirements.
1. A pharmacy benefits manager shall offer to a covered entity options for the covered entity to contract for services that must include:
a. A transaction fee without a sharing of rebates and other retrospective utilization ~~discounts~~ payments received by pharmacy benefits manager;
b. A combination of a transaction fee and a sharing of rebates and other retrospective utilization discounts payments received by pharmacy benefits manager; or
c. A transaction fee based on the covered entity receiving all the benefits of rebates and other retrospective utilization discounts payments received by pharmacy benefits manager.
2. The agreement between the pharmacy benefits manager and the covered entity must include a provision allowing the covered entity to audit the pharmacy benefits manager's books, accounts, and records, including de-identified utilization information, as necessary to confirm that the benefit of rebates and other retrospective utilization ~~discounts~~ payments received by pharmacy benefits manager are being shared as required by the contract.

26.1-27.1-06. Examination of insurer-covered entity.
1. During an examination of a ~~company~~ covered entity as provided for in chapter 26.1-03, 26.1-17, or 26.1-18.1, the commissioner shall examine any contract between the ~~company~~ covered entity and a pharmacy benefits manager and any related record to

determine if the rebates and other retrospective utilization discount benefits payments received by pharmacy benefits manager that the ~~company~~ covered entity received from the pharmacy benefits manager have been applied toward reducing the ~~company's~~ covered entity's rates or have been distributed to covered individuals.
2. To facilitate the examination of the company, the ~~company~~ covered entity shall disclose annually to the commissioner the benefits of rebates and other retrospective utilization discounts payments received by pharmacy benefits manager received under any contract with a pharmacy benefits manager and shall describe the manner in which the rebates and other retrospective utilization discounts payments received by pharmacy benefits manager are applied toward reducing rates or distributed to covered individuals.
3. Any information disclosed to the commissioner under this section is considered a trade secret under chapter 47-25.1.

26.1-27.1-07. Rulemaking authority. The commissioner shall adopt rules as necessary before implementation of this chapter.

Proposed Amendments to Engrossed HB 1332

Page 2, after line 12, add "6. "Payments received by pharmacy benefits manager" means the aggregate amount of any of the following payments:

a. Rebates collected by the pharmacy benefits manager and allocated to covered entity;
b. Administrative fees collected from the manufacturer in consideration of administrative services provided by the pharmacy benefits manager to the manufacturer;
c. Any other fees or amounts collected by the pharmacy benefits manager from a manufacturer or labeler for drug switch programs, educational support, or data sales related to covered individuals;
d. Pharmacy network fees."

Page 2, line 13, replace "6." with "7."

Page 2, line 18, delete entire line.

Page 2, line 19, replace "b." with "a."

Page 2, line 21, replace "c." with "b."

Page 2, line 22, replace "d." with "c."

Page 2, line 23, replace "7." with "8."

Page 2, line 26, after "entity" delete "and includes mail service pharmacy"

Page 2, line 30, delete "and does not include a"

Page 3, line 1, delete entire line

Page 3, line 2, delete "pharmacy benefits management directly to its beneficiaries"

Page 3, line 3, replace "8." with "9."

Page 3, line 3, after "Rebate" replace "includes the nature, type, and amount of all other revenue received by" with "means retrospective reimbursement of monetary amounts by a manufacturer under a manufacturer's discount program with a pharmacy benefits manager for drugs dispensed to covered individual."

Page 3, delete lines 4 through 9.

Page 3, line 10, replace "9" with "10"

Page 3, delete lines 29 and 30.

Page 4, delete lines 1 through 6.

Page 4, line 7, replace "2." with "1."

Page 4, line 10, after "network", replace "solely because the pharmacist or" with "provided the pharmacist or pharmacy accepts the terms, conditions, and reimbursement rates of the pharmacy benefits manager's contract."

Page 4, delete lines 11 through 18.

Page 4, line 17, replace "4." with "3."

Page 4, line 23 and 24, replace "rebates and other retrospective utilization discounts" with "payments received by pharmacy benefits manager"

Page 4, lines 25 and 26, replace "rebates and other retrospective utilization discounts" with "payments received by pharmacy benefits manager"

Page 4, line 28, replace "rebates and other retrospective utilization discounts" with "payments received by pharmacy benefits manager"

Page 5, lines 1 and 2, replace "rebates and other retrospective utilization discounts" with "payments received by pharmacy benefits manager"

Page 5, line 4, replace "company" with "covered entity"

Page 5, line 5, replace "company" with "covered entity"

Page 5, line 7, replace "rebates and other retrospective utilization discount benefits" with "payments received by pharmacy benefits manager"

Page 5, line 7, replace "company" with "covered entity"

Page 5, line 9, replace "company's" with "covered entity's"

Page 5, line 10, delete "of the company"

Page 5, line 10, replace the second "company" with "covered entity"

Page 5, lines 11 and 12, replace "rebates and other retrospective utilization discounts" with "payments received by pharmacy benefits manager"

Page 5, lines 13 and 14, replace "rebates and other retrospective utilization discounts" with "payments received by pharmacy benefits manager"

Page 5, line 14, after "rates" add "or distributed to covered individuals"

Renumber accordingly

Explanation of Proposed Amendments

1. Page 2, after line 12, add "6. "Payments received by pharmacy benefits manager" means the aggregate amount of any of the following payments:

b. Rebates collected by the pharmacy benefits manager and allocated to covered entity;

e. Administrative fees collected from the manufacturer in consideration of administrative services provided by the pharmacy benefits manager to the manufacturer;

f. Any other fees or amounts collected by the pharmacy benefits manager from a manufacturer or labeler for drug switch programs, educational support, or data sales related to covered individuals;

g. Pharmacy network fees."

2. Page 2, line 13, replace "6." with "7."

3. Page 2, line 18, delete entire line.

4. Page 2, line 19, replace "b." with "a."

5. Page 2, line 21, replace "c." with "b."

6. Page 2, line 22, replace "d." with "c."

7. Page 2, line 23, replace "7." with "8."

8. Page 2, line 26, after "entity" delete "and includes mail service pharmacy"

9. Page 2, line 30, delete "and does not include a"

10. Page 3, line 1, delete entire line

11. Page 3, line 2, delete "pharmacy benefits management directly to its beneficiaries"

12. Page 3, line 3, replace "8." with "9."

13. Page 3, line 3, after "Rebate" replace "includes the nature, type, and amount of all other revenue received by" with "means retrospective reimbursement of monetary amounts by a manufacturer under a manufacturer's discount program with a pharmacy benefits manager for drugs dispensed to covered individual."

14. Page 3, delete lines 4 through 9.

15. Page 3, line 10, replace "9" with "10"

16. Page 3, delete lines 29 and 30.

17. Page 4, delete lines 1 through 6.

18. Page 4, line 7, replace "2." with "1."

19. Page 4, line 10, after "network", replace "solely because the pharmacist or" with "provided the pharmacist or pharmacy accepts the terms, conditions, and reimbursement rates of the pharmacy benefits manager's contract."

20. Page 4, delete lines 11 through 18.

21. Page 4, line 17, replace "4." with "3."

22. Page 4, line 23 and 24, replace "rebates and other retrospective utilization discounts" with "payments received by pharmacy benefits manager"

23. Page 4, lines 25 and 26, replace "rebates and other retrospective utilization discounts" with "payments received by pharmacy benefits manager"

24. Page 4, line 28, replace "rebates and other retrospective utilization discounts" with "payments received by pharmacy benefits manager"

25. Page 5, lines 1 and 2, replace "rebates and other retrospective utilization discounts" with "payments received by pharmacy benefits manager"

26. Page 5, line 4, replace "company" with "covered entity"

27. Page 5, line 5, replace "company" with "covered entity"

28. Page 5, line 7, replace "rebates and other retrospective utilization discount benefits" with "payments received by pharmacy benefits manager"

29. Page 5, line 7, replace "company" with "covered entity"

30. Page 5, line 9, replace "company's" with "covered entity's"

31. Page 5, line 10, delete "of the company"

32. Page 5, line 10, replace the second "company" with "covered entity"

33. Page 5, lines 11 and 12, replace "rebates and other retrospective utilization discounts" with "payments received by pharmacy benefits manager".

34. Page 5, lines 13 and 14, replace "rebates and other retrospective utilization discounts" with "payments received by pharmacy benefits manager"

35. Page 5, line 14, after "rates" add "or distributed to covered individuals"

The term "Rebate" has been changed to better define what rebate really is and includes a separate definition for "Payments received by pharmacy benefits manager". Throughout the bill, the term "rebates and other retrospective utilization discounts" is replaced with this new term.

These amendments are included in the following: 1, 13, 14, 22, 23, 24, 25, 28, 33, and 34.

The following reflects renumbering amendments: 2, 4, 5, 6, 7, 12, 15, 18, and 21.

Amendments 3 and 8 delete "mail service pharmacy" from the definition of pharmacy benefits manager. Mail service pharmacies are permitted and recognized as a benefit in the new Medicare Part D drug plans. They state the following:

As noted above, Part D plans have the flexibility to establish different cost-sharing requirements for the pharmacies in their networks consistent with section 1860D-4(b)(1)(B) of the Act. Accordingly, Part D plans have the flexibility to establish differential cost-sharing requirements for mail delivery and in-facility pickup. [Federal Register/Vol. 70, No. 18/ Friday, January 28, 2005, Page 4255]

(10) .... A Part D plan may require an enrollee obtaining a covered Part D drug at a network pharmacy that is a retail pharmacy to pay any higher cost-sharing applicable to that covered Part D drug at the network pharmacy that is a retail pharmacy instead of the cost-sharing applicable to that covered Part D drug at the network pharmacy that is a mail-order pharmacy. [Federal Register/Vol. 70, No. 18/ Friday, January 28, 2005, Page 4537]

Amendments 9, 10, and 11 correct duplicative language, which was missed by the house.

Amendments 16 and 17 address issues addressed by the FTC letter.

Amendment 19 clarifies the contractual obligation of the pharmacist.

Amendment 20 deletes language that is addressed by the FTC letter and is duplicative of Section 26.1-36-12.2. However, the language in the bill would prevent the formation of PPO's for drug benefits, which is currently allowed in 26.1-36-12.2 and 26.1-47. This language also conflicts with the current Medicare rules as shown below:

(9) Differential cost-sharing for preferred pharmacies. A Part D sponsor offering a Part D plan that provides coverage other than defined standard coverage may reduce copayments or coinsurance for covered Part D drugs obtained through a preferred pharmacy relative to the copayments or coinsurance applicable for such drugs when obtained through a non-preferred pharmacy. [Federal Register/Vol. 70, No. 18/ Friday, January 28, 2005, Page 4537]

However, it is unreasonable to assume – the any willing pharmacist requirement notwithstanding – that a Part D plan could establish a network using a uniform set of terms and conditions throughout a service area because it will likely need to modify contracting terms and conditions to ensure access to certain pharmacies (for example, rural and long-term care pharmacies).

...

We believer that we have correctly interpreted the two related provisions in sections 1860D-4(b)(1)(A) and (B) of the Act, which require Part D plans to allow any willing pharmacy to participate in their pharmacy networks, while also allowing Part D plans to reduce cost-sharing differentially for network pharmacies.

....

We clarify that State any willing pharmacist laws would be preempted as applicable to plans' Part D business. This is consistent with section 1860D-12(g) of the Act which extends the State preemption provisions under section 1856(b)(3) of the Act to Part D plans. [Federal Register/Vol. 70, No. 18/ Friday, January 28, 2005, Page 4254]

As noted above, Part D plans have the flexibility to establish different cost-sharing requirements for the pharmacies in their networks consistent with section 1860D-4(b)(1)(B) of the Act. Accordingly, Part D plans have the flexibility to establish differential cost-sharing requirements for mail delivery and in-facility pickup. [Federal Register/Vol. 70, No. 18/ Friday, January 28, 2005, Page 4255]

Amendments 26, 27, 29, 30, 31 and 32 replaces the term "company" with the term "covered entity, which is currently defined in the bill.

Amendment 35 corrects an omission from the House to recognize that rebates can be returned to individual members of a health plan in addition to being applied toward reducing rates, as already indicated on Page 5, line 9 of Engrossed HB 1332.

Rod St. Aubyn

Executive Summary

The Federal Trade Commission, Office of Planning, Bureau of Economics, and Bureau of Competition has responded to a request by Sen. Richard Brown, dated January 19, 2005, whether HB 1332 "will likely result in the increased cost of pharmaceutical care for consumers." Their response was faxed to Senator Brown on March 8, 2005, and will soon be published. The FTC began monitoring this bill while it was still in the ND House. They continued to monitor the Engrossed House Bill 1332, noting changes to the bill. After careful analysis they noted several major concerns. Those areas of concern included:

- Prohibiting drug substitutions.
- Prohibiting a PBM from discriminating "on the basis of copayments or days of supply" when contracting with pharmacies.
- Requiring that "a contract must apply the same coinsurance, copayment, and deductible to covered drug prescriptions" to all pharmacies or pharmacists in a network.

More detail is provided for each of these areas. However, the significant findings are included in their conclusion that is noted below:

"HB 1332 is likely to limit a PBM's ability to reduce the cost of prescription drugs without providing consumers any additional protections. Any such cost increases are likely to undermine the ability of some consumers to obtain pharmaceuticals and health insurance they need at a price they can afford. Accordingly, we would urge the North Dakota legislature not to adopt HB 1332."

BlueCross BlueShield of North Dakota

An independent licensee of the Blue Cross & Blue Shield Association

4510 13th Avenue South
Fargo, North Dakota 58121-0001

Jim - FYI
Don -
IGL

GK

March 2005

Dear Group Health Plan Administrator:

Blue Cross Blue Shield of North Dakota (BCBSND) receives retrospective discount payments, referred to in the pharmaceutical industry as rebates, from some drug manufacturers for certain medications purchased by your employees. BCBSND receives the rebates about 12 to 15 months after the prescription drugs have been purchased and uses the rebates to offset premium increases. BCBSND believes it is appropriate that your members receive their share of such rebates.

We are pleased to introduce a program that will pass a portion of the rebates directly to your members. The member's portion will be based on a percentage of out-of-pocket expenses, less copayment amounts they paid for their prescriptions. To ensure each member receives the appropriate rebate, BCBSND established a Member Rebate Account (MRA) for each of your employees and their eligible dependents. A percentage of any applicable rebates from prescriptions purchased on or after October 1, 2003, has been placed into the MRA.

Beginning in April 2005, your employees who have accumulated rebates in their MRA, will automatically receive a discount off their out-of-pocket expenses the next time they purchase prescription drugs. As your employees utilize their MRA, a notice explaining this unique program will be included with their quarterly Prescription Drug Summary. The Prescription Drug Summary will indicate the total Member Rebate Account discount they used for the quarter. However, please note that not all prescription drugs are eligible for rebates and rebate percentages can fluctuate from year to year.

In addition, members will continue to be eligible to use any accumulated portion in their MRA as long as they remain eligible under a BCBSND health benefit plan. If they terminate coverage and become ineligible for the MRA, any unused rebates will be applied towards the cost of the health plan.

Please feel free to contact your BCBSND Group Benefits Consultant if you have any questions.

Sincerely,

Chad Niles

Chad Niles
Senior Vice President & Chief Marketing Officer
Blue Cross Blue Shield of North Dakota

BlueCross BlueShield of Minnesota

December 2, 2004

Mark Whittier
Canby Drug and Gifts
130 Saint Olaf Ave. N.
Canby, MN 56220

Re: Small Group Inquiry Prescription Drug Rebates

Dear Mr. Whittier:

P.O. Box 64560
St. Paul, MN
55164-0560
651.662.8000
1.800.382.2000
www.bluecrossmn.com

In response to your inquiry regarding Blue Cross and Blue Shield of Minnesota's (Blue Cross) policy on prescription drug rebates, I would like to share the following information.

It is Blue Cross' philosophy that prescription drug rebates are a part of an account's claims experience. As you know, we use a pharmacy benefit manager, Prime Therapeutics, who negotiates rebates with pharmaceutical companies. These rebates are passed through to Blue Cross and Blue Cross factors in these rebates in our rate setting process for calculating insurance premiums.

In order to determine each account's share of expected prescription drug rebates, we estimate the total of all drug rebates that we expect to receive in the coming year on an organization-wide basis, less any administrative fees associated with the rebate process. Subsequently, the average expected rebate per prescription is estimated and credited as an offset to each of our fully-insured customers' prior pharmacy experience. For fully-insured customers, such as Canby Drug, expected rebates are based on the actual number of prior prescriptions written for each member of the individual group as well as the actual number of prior prescriptions written for the insurance pool in which you participate.

As with any claims experience within your group and the pool, we assign credit to your group's past net claims experience (that is, net of expected average rebate credits) based on the amount of experience we have collected for your members over the previous thirty months. Because of the size of your organization, the majority of your insurance premium change each year is based on the experience of the insurance pool in which you participate.

Because Canby Drug is a fully-insured account, Blue Cross remains at risk for pharmaceutical use, much as we are at risk for any medical claim. Blue Cross is committed to providing quality, affordable health care to you and your employees and I hope that this explanation helps you to understand Blue Cross' policy on prescription drug rebates. As always, feel free to call me direct at 651-662-8758 if you have any questions or concerns.

Sincerely,

Alan H. Heaton
BS (Pharm), Pharm.D.R.Ph.
Director of Pharmacy

Blue Cross and Blue Shield of Minnesota is an independent licensee of the Blue Cross and Blue Shield Association

Access to info ONLY to BCBS

-----Original Message-----
From: CANBY DRUG & GIFTS [mailto:canbyrx@frontiernet.net]
Sent: Thursday, November 18, 2004 11:56 AM
To: Kupchella, Rick
Subject: Prime therapeutics transparency (or lack of)

11/18/04
Rick: I was called today by Lisa Waageester from BCBS of MN regarding my request to see the their books regarding drug manufacturer rebates and drug pricing because I am the group leader and have a policy with them. She said the ONLY entities allowed to see this information from Prime Therapeutics are the BCBS companies in various states that OWN them. (Lisa's phone #651-662-1585)

THIS DOESN'T SOUND LIKE OPEN BOOKS TO ME AS STATED IN YOUR INTERVIEW.

THEY WILL BE SENDING ME A LETTER OF DENIAL AND I WOULD LIKE TO FAX IT TO YOU BUT I DON'T CURRENTLY HAVE YOUR FAX #

I SHOULD HAVE THE LETTER IN A WEEK OR TWO.

THANKS
MARK WHITTIER R.PH PH 507-223-5955

ROBINS, KAPLAN, MILLER & CIRESI L.L.P.
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DAVID A. BALTO
(202) 736-2637
dbalto@rkmc.com

March 14, 2005

The Honorable Duane Mutch
State Capitol
600 East Boulevard Avenue
Bismarck, North Dakota 58505-0360

Re: House Bill No. 1332 – Regulation of Pharmacy Benefit Management

Dear Mr. Chairman:

I write to you to express my concerns regarding the Federal Trade Commission staff's letter of March 8 about North Dakota House Bill No. 1332 which is now before the Senate and your committee. As a former government enforcement official with years of experience in enforcing antitrust and consumer protection laws, I believe the proposed statute is a refined and carefully constructed approach to the numerous consumer protection problems posed by Pharmacy Benefit Managers ("PBMs"). The FTC staff's comments may be based on economic theory, but they miss the mark because they ignore the economic realities of the North Dakota marketplace and the legitimate problems addressed by the proposed legislation.

I was the Policy Director of the Bureau of Competition of the Federal Trade Commission from 1998 to 2001, and attorney advisor to then-Chairman Robert Pitofsky from 1995-1997. In these positions, I was actively involved in the Commission's advocacy program and regularly advised state and federal legislators on proposed legislation.[1] This advocacy role can be valuable where it is based on empiricism, careful industry-specific studies and enforcement actions. However, where the Commission or any other Washington-regulator provides advice that lacks an empirical foundation or ignores the unique nature of specific markets, those comments have frequently and appropriately been rejected by state legislatures.

PBMs pose a myriad of difficult consumer protection and competition problems. I know this first hand as a former enforcement official and as a private practitioner advising both PBMs

[1] In private practice I have, and continue, to advise state legislatures and attorneys general offices on health care competition and consumer protection issues including the need for states to regulate PBMs.

and pharmacies. At the FTC, I helped spur the initial PBM enforcement actions against the Merck-Medco and Lilly-PCS PBM mergers and other investigations of anticompetitive PBM conduct. Through its orders in those cases, the FTC attempted to provide a greater level of transparency to enable covered entities to get a fair deal. Unfortunately, as described below, those efforts were not successful as demonstrated by the large number of government and private enforcement actions challenging anticompetitive and fraudulent conduct by PBMs.

As a private practitioner, I regularly counsel participants in the pharmaceutical marketplace including manufacturers, PBMs, and pharmacies about how to comply with the competition and consumer protection laws and other regulations. As in most markets, most participants attempt to comply with the letter of the law. But frequently federal statutes may fall short and provide limited protections. In these situations, state legislation is appropriate. That is why numerous state legislatures are currently considering and enacting PBM regulations.

I write to you as counsel for the North Dakota Pharmacists Association (NDPhA). As the professional society representing all pharmacists in the state of North Dakota, the objectives of the NDPhA are to: (1) advocate the role of the pharmacist as an essential provider of healthcare; (2) support pharmacists in providing optimal pharmaceutical care; and (3) improve pharmacists' services and delivery of products needed by health care consumers. NDPhA stands fully behind House Bill No. 1332. It addresses much needed reform to the operation of PBMs, helps deter fraudulent and anticompetitive conduct, and makes PBM activity much more transparent.

Through my work with NDPhA I have learned about the unique marketplace for the delivery of pharmaceuticals in North Dakota. Because there are less than 200 pharmacies in a geographically disperse state with few metropolitan areas the pharmacy market is very unconcentrated. In contrast, the PBM market is dominated by a single firm. Pharmacies operate on very low margins and rely increasingly on insurance plans for revenue. The elimination of even a small number of pharmacies can significantly harm North Dakota consumers who, in many instances, already travel significant distances to secure their drugs. That is why the state has enacted patient freedom of choice legislation to assure a diverse set of providers in the market and to protect otherwise underserved localities. *See* N.D. Cent. Code 26.1-36-12.2.

The FTC staff's letter of March 8, 2005 to Senator Richard Brown fails to recognize the nature of the North Dakota market or the legitimate reasons for the proposed legislation.[2] While I respect the views of my former colleagues, I believe their comments on North Dakota's pending PBM legislation are not based on empirical study, ignore the significant problems of fraud and deception in the market, and fail to recognize the unique nature of the North Dakota market. Most, if not all, of their viewpoints in the March 8 letter are based upon a theoretical analysis which is not keyed to the PBM market and certainly not North Dakota.

Attached is testimony that I recently gave before the National Legislative Alliance on Prescription Drug Prices ("NLARX"), a bipartisan alliance of state legislators in over a dozen

[2] I believe that the FTC staff failed to speak with any of the proponents of the proposed legislation.

states.[3] The purpose of the NLARX is to facilitate efforts by states to control prescription drug prices. My testimony outlines in detail the numerous state and federal enforcement actions and private consumer protection and fraud cases taken against PBMs. I know of no other market in which there has been such a significant amount of prominent enforcement actions, and many of these actions are led by a multi-state coalition of state attorneys general. Simply put, throughout the United States, numerous states are devoting considerable resources to combating fraudulent and anticompetitive conduct by PBMs. However, despite this growing body of hard evidence, the FTC has remained silent. It has not initiated any significant investigations nor has it joined in any of the state or federal investigations.

The Growing Body of Evidence as to the Anticompetitive Practices of PBMs

While the Department of Justice and multiple states Attorneys General Offices have several investigations and significant enforcement actions against PBMs, the FTC has remained on the sideline. Although your committee may be aware of some of these actions, allow me to summarize the most prominent case. On April 26, 2004, the United States, 20 state attorneys generals, and the defendants Merck & Co., Inc., Merck-Medco Managed Care, L.L.C., and Medco Health Solutions, Inc. (together referred to as "Medco"), agreed to a settlement of claims for injunctive relief and violations of unfair trade practice laws.[4] The complaint attacked a wide variety of fraudulent and deceptive conduct by Medco, documenting at length Medco's efforts to prefer higher priced drugs, engage in unwarranted and harmful "therapeutic interchange," and fail to pass on payments to the covered entities.

For this fraudulent and deceptive conduct the states secured $20 million in damages, $6.6 million in fees and costs, and about $2.5 million in restitution to patients who incurred expenses related to drug switching between a set of cholesterol controlling drugs. As important is injunctive relief.

This settlement prohibits Medco from soliciting drug switches when:

- The net drug cost of the proposed drug exceeds the cost of the prescribed drug;
- The prescribed drug has a generic equivalent and the proposed drug does not;
- The switch is made to avoid competition from generic drugs; or
- The switch is made more often than once in two years within a therapeutic class of drugs for any patient.

[3] I have also attached two other articles that discuss the need for reform of the PBM market.

[4] Consolidated Case No. 00-cv-737; U.S. District Court for the Eastern District of Pennsylvania. The United States and the following state Attorneys Generals joined in the settlement: Arizona, California, Connecticut, Delaware, Florida, Illinois, Iowa, Louisiana, Maine, Maryland, Massachusetts, Nevada, New York, North Carolina, Oregon, Pennsylvania, Texas, Vermont, Virginia, and Washington.

The settlement requires Medco to:

- Disclose to prescribers and patients the minimum or actual cost savings for health plans and the difference in co-payments made by patients;
- Disclose to prescribers and patients Medco's financial incentives for certain drug switches;
- Disclose to prescribers material differences in side effects between prescribed drugs and proposed drugs;
- Reimburse patients for out-of-pocket costs for drug switch-related health care costs and notify patients and prescribers that such reimbursement is available;
- Obtain express, verifiable authorization from the prescriber for all drug switches;
- Inform patients that they may decline the drug switch and receive the initially prescribed drug;
- Monitor the effects of drug switches on the health of patients; and
- Adopt the American Pharmacists Association code of ethics and principles of practice for pharmaceutical care for employees at its mail order and call center pharmacies.

This case and its settlement was a significant step forward in holding PBMs accountable for their actions, making their activities more transparent, and ensuring that consumers are protected. Further enforcement actions are expected as investigations by over 20 attorneys general continue.[5] For your review and consideration, I attach an index of recent federal and state enforcement actions. To the best of my knowledge, the FTC has not commented on any of these legal actions. Not surprisingly, the FTC staff's letter relies upon general theoretical reports and studies, and makes no reference to the growing landslide of enforcement actions that states are undertaking against PBMs.

Comments on House Bill No. 1332's Provisions Relating to Contracting with Retail Pharmacies and Restrictions on Certain Drug Substitutes

House Bill No. 1332 is a modest, carefully refined effort to protect consumers in the state. The FTC staff argues that House Bill No. 1332 would limit PBM's freedom in contracting with retail pharmacies and prohibit certain drug substitutions. As detailed below, the FTC staff is mistaken on both counts.

A. Restrictions on Contracting with Pharmacies

In order to assure that consumers receive the full range of benefits from their pharmaceutical plans, the legislation prohibits certain forms of price discrimination among pharmacies. The concerns addressed by the proposed legislation are legitimate. Some PBMs

[5] One should not expect that the Merck enforcement action, or other future enforcement actions will completely solve the competitive and consumer protection problems in the market. These actions are time-consuming and costly and solve only the symptoms of the problem. Legislation may be the only effective tool to deal with these issues.

refuse to permit pharmacies to dispense 90-day prescriptions, enabling only mail order pharmacies to dispense long-term prescriptions.

The FTC staff appears to suggest that such price discrimination is efficient, but provides no empirical basis for why that is true for PBMs generally or PBMs in North Dakota. The FTC staff seems to suggest that the ability to price discriminate will improve "negotiating leverage" by the PBMs against the pharmacies, but there is no reason to believe that the PBMs can not secure whatever price they want for access under the current environment. The FTC staff also seems to assume that pharmacies have some choice as to which programs to participate in or the reimbursement level. But this assumption is belied by the reality of the market. Retail pharmacies in North Dakota are given contracts on a take it or leave it basis with little or no room for negotiation.

As a general matter price discrimination may be harmful, especially when used by a dominant firm to raise entry barriers and harm competition (and that certainly is a possibility in this market). On the other hand, if preventing price discrimination was anticompetitive, as suggested by the FTC staff's comments, then one would expect that the FTC could cite specific enforcement actions against that type of conduct.

The FTC staff also seems to suggest that mail order is less expensive than securing drugs through retail pharmacies. It relies on two dated studies of the issue. More recent studies and articles suggest that consumers may pay more for drugs through mail order or that PBMs favor more expensive drugs through their mail order operations.[6] Mail order might not be less expensive in North Dakota if that market is dominated by a single provider. Moreover, even if that was true that mail order was less expensive the State could appropriately make the judgment that the access, choice, and service provided by retail pharmacies are more important than price.

There are legitimate reasons for the State of North Dakota to seek to prevent these types of price discrimination. North Dakota is a sparsely populated state where consumers may have to travel significant distances to a pharmacy. It is legitimate and sound public policy for the state to adopt a law that facilitates access to a large number of pharmacies and this access may be more important than the ability to negotiate lower prices for pharmacy services. This may be one reason why the state has adopted a statute guaranteeing freedom of choice for pharmacy participation in managed care plans. *See* N.D. Cent. Code 26.1-36-12.2. Certain types of price discrimination could force numerous small town pharmacies out of business and in turn, create a severe diminution in service for many North Dakota consumers living in rural areas.

B. Prohibitions on Certain Drug Substitutions

I disagree with the FTC staff's claim that House Bill No. 1332 may limit a PBM's ability to effect certain drug substitutions. House Bill No. 1332 specifically identifies the circumstances

[6] Barbara Martinez, "Generic Drugs By Mail Can Be a Raw Deal," Wall Street Journal, Feb.15, 2005 (Page B1).

when drug substitution is allowed, including the option to get a less expensive generic drug in place of a more expensive brand name, and when the substitution is confirmed by a physician to be in the best medical interest of the patient. This provides additional and important safeguards for consumers not already codified under N.D. Cent. Code 19-02.1-14.1(3). Contrary to the FTC's broad claim (unsupported by any empirical evidence) that the language of the bill would make safe and cost-reducing drug substitutions less common, and could increase the cost of pharmaceuticals, the outcome of this section of the bill will ensure that the doctor and patient will control any drug substitution, not the PBM. The consumer will still have a choice, and the consumer and his/her doctor will have the final say in whether to allow for a drug substitution.

This is as it should be. The record provided by numerous enforcement actions either completed or underway indicate that PBMs have engaged in the practice of switching patients' medication to earn financial rewards. This improper drug interchange/substitution has taken place via PBM practice which: (1) induces physicians to switch patient medications by providing misleading, false or incomplete information that subverts patient care to profit motives; and, (2) secretly increases the cost of drugs provided to beneficiaries by knowingly interchanging patients' medications to prevent them from taking advantage of soon to be released generic drugs. The language of House Bill No. 1332 ensures that PBMs will not be allowed to subvert the intent of a physician in his/her care for a patient, but it does allow substitution for lower-priced generic or therapeutically equivalent drugs once a PBM requests such a substitution. In other words, the physician will have the final say in providing medication to the patient, not the PBM. This is an important step forward and an important safeguard against abusive PBM practices in the area of drug substitution.

Finally, the FTC staff's concern over the definition of "therapeutically equivalent" drugs may no longer be relevant. It is my understanding that this issue was resolved in the other chamber of this Assembly. During the hearings held by the House, the Pharmaceutical Research & Manufacturer's of America (PhRMA) noted the possibility for confusion. An amendment was proposed and accepted by the House which corrected this portion of House Bill No. 1332. This provision is important as it will provide the oversight to complement what is already in North Dakota's statute which guides the prescriptions made by doctors and prescription dispensing by pharmacists

Reasons Why the FTC Staff's Comments are not Relevant to this Legislation

Let me briefly provide several reasons why the FTC's comments are off the mark.

- **The FTC Staff's comments ignore the problems being addressed by the legislation.** As noted above, the two provisions seek to address central problems of potentially fraudulent or misleading conduct by PBMs. For example, there have been allegations that PBMs discriminate in providing mail order, and ultimately mail order provides higher priced drugs. In addition, there have been allegations that PBMs engage in therapeutic substitution which ultimately leads to the use of higher priced drugs. The proposed legislation is a narrow and refined

effort to address both of these problems. It is notable that the FTC's comments do not even acknowledge the existence of these problems. This is not surprising because the FTC, unlike several state attorneys general, has declined to even investigate these issues.

- **There is inadequate empirical basis to support their arguments.** Rather than relying on investigations or enforcement actions, the FTC staff relies on their healthcare hearings and one merger investigation. The FTC did address PBMs in their healthcare hearings, but those hearings addressed solely the issue of transparency and not the issues of price discrimination, therapeutic interchange, or the fraudulent or deceptive conduct engaged in by PBMs. The FTC staff also mentions an investigation of a merger of two of the largest national PBMs. However, the fact that the FTC might have concluded in the course of that investigation that there was vigorous competition does not suggest whether these firms could engage in deceptive or fraudulent conduct or whether regulation was unnecessary.

- **The comments ignore the realities of the North Dakota market.** The FTC staff's criticism of House Bill No. 1332 is based on an inaccurate understanding of the market in North Dakota. Rather than investigating the market prior to providing comments, or basing those comments on the nature of competition in North Dakota, the FTC staff recites facts from a merger investigation that the market is robustly competitive with over 60 PBMs. In fact, in North Dakota a single firm has over 70% of the market. Furthermore, when a North Dakota state employees group, the North Dakota Public Employees Retirement System sent a Request for Proposals, only one PBM participated. The North Dakota market is not vigorously competitive. Moreover, there has been relatively little entry into the North Dakota PBM market. The FTC staff's comments assume that if pharmacies are unhappy with the terms or conditions of a proposed contract with a PBM there are several other PBMs they can turn to. Again, that is simply not the case in North Dakota.

The FTC staff's position is inconsistent with current marketplace realities, especially those of the North Dakota market, and lacks a sound empirical foundation. The proposed legislation may lead to a more equitable and desirable combination of choice, cost control and quality in the delivery of pharmaceuticals. Moreover there are significant competition and consumer protection problems addressed by this legislation which deserves serious consideration. Thus, I urge the North Dakota legislature to adopt House Bill No. 1332 for the aforementioned reasons.

I appreciate the opportunity to provide these comments. Please contact me if I can be of assistance.

Sincerely,

David A. Balto/gr

David A. Balto

DAB/gr

Enclosures

ATTACHMENT 1

ROBINS, KAPLAN, MILLER & CIRESI L.L.P.
ATTORNEYS AT LAW

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Proactive Litigation Against PBMs
January 28, 2005
National Legislative Association on Prescription Drug Prices

David A. Balto, Esq.
202-736-2637
dbalto@rkmc.com

There are numerous recent cases brought by both state and federal enforcement agencies and by private parties challenging a variety of conduct by Pharmacy Benefit Managers (PBMs). Most of these cases focus on whether PBMs have taken advantage of their business structure and engaged in fraudulent or deceptive conduct in failing to pass on savings to their clients, switching patients' medication to earn financial rewards, or manipulating their mail order operations. Other cases, as Councilman Cantania and Representative Brautigam have discussed this morning, directly challenge state legislation enacted to regulate the activities of PBMs. Although some of these cases have been settled, none of the cases has been fully litigated nor has there been any finding of liability.

Other than the District of Columbia and Maine lawsuits challenging enacted legislation, I believe the other most prominent case involving the activity of PBMs is a case brought by the U.S. Attorney's Office for the Eastern District of Pennsylvania in *United States of America v. Merck-Medco Managed Care L.L.C., et al.* This case has grown exponentially since the first complaint was filed in 2000, and now involves 20 state Attorneys General and the U.S. Attorney who allege that Medco engaged in a variety of fraudulent activity including making false

statements to doctors and patients about drug substitutions favoring higher priced drugs in which they earned a greater financial reward (via rebates) and failing to disclose their financial arrangement with manufacturers. The state Attorneys General and the U.S. Attorney reached a partial settlement in April 2004 in which Medco admitted no wrongdoing but paid over $29 million and agreed to adhere to new standards for switching patients' prescriptions. The new standards included not changing any prescription if it resulted in higher costs and a promise to inform doctors and patients of any financial incentives Medco might have to switch a drug. Among the remaining allegations in the federal suit against Medco are charges the company destroyed, canceled, shorted and falsified patients' drug orders at its mail-order centers so it could meet production goals and other contractual performance guarantees

The state Attorneys General also have established a multi-state task force which continues to lead several investigations of PBMs. Most of these investigations focus on whether the PBMs have defrauded the individual state's healthcare plans by improperly switching drugs or pocketing drug rebates. In addition, there are numerous private cases that have been filed. Some of these cases are whistleblower cases alleging violations of federal claims acts statutes. Other cases allege violations of state unfair trade practice statutes or breach of contract claims. Finally, there are numerous cases filed by pharmacies against PBMs for their activities in preventing pharmacies from engaging in mail order or conspiring to reduce the amount of compensation that pharmacies receive for filling PBM claims.

Numerous class actions lawsuits have also been filed against PBMs over the past several years. One of the better known cases, *American Federation of State County and Municipal Employees v. AdvancePCS, et al.* was filed on March 18, 2003, in the Superior Court of California against Advance PCS, Caremark Rx, Inc., Express Scripts, and Medco Health

Solutions. This lawsuit, as do most of the other pending class action suits, alleges that PBMs inflate prescription drug prices by steering health insurers and consumers into reliance on more costly drugs. The complainants argue that the defendant PBMs negotiated rebates from drug manufacturers and discounts from retail pharmacies but did not pass on those savings to health plans and consumers. The complaint also alleges that the PBMs developed a pricing system based on fraudulently using the Average Wholesale Price to inflate prices set by the drug manufacturers, and that defendants' pocketed secret rebates, spreads and other payments from drug manufacturers. Given these alleged activities, the complaint argues that the defendants violated California's Unfair Competition Law with their unfair trade practices.

Finally, in August 2004, New York state Attorney General Elliot Spitzer sued Express Scripts, Inc. for breach of contract. In *People of the State of New York v. Express Scripts, Inc., et al.*, filed in New York State Supreme Court, the state of New York alleged among other things that this PBM: (1) enriched itself at the expense of the New York State's largest employee health plan by inflating the cost of generic drugs; (2) diverted to itself millions of dollars in manufacturer rebates that belonged to the state health plan; and, (3) induced the State to enter into the contract by misrepresenting the discounts the state health plan was receiving for drugs purchased at retail pharmacies. The lawsuit also alleges, that in furtherance of its scheme to divert and retain manufacturer rebates that belonged to the state health plan, Express Scripts disguised millions of dollars in rebates as "administrative fees," "management fees," "performance fees," "professional services fees," and other names.

In reviewing the summary of ongoing federal and state litigation (see attached), a pattern is clearly discernable in the issues being litigated. Most of these cases involve one or more of the following claims against a PBM: (1) conflict of interest in engaging in unfair, deceptive or

fraudulent activity with a drug manufacturer; (2) improper prescription drug switching to a higher priced drug without medical justification and without the authorization of the prescribing physician; (3) failing to disclose material facts in the conduct of trade by not disclosing the full extent of rebates and other incentives received from drug manufactures, and failing to pass through such discounts to pharmacies and consumers; and, (4) price fixing.

In 2004, about a dozen states each sought to regulate PBMs or require them to disclose marketing costs. Even with the current court challenges to legislation enacted in the District of Columbia and Maine, which focus on the fiduciary aspects of PBMs and the "taking" of property and trade secrets, state level efforts to regulate the activities and conduct of PBMs will continue in an effort to make them more transparent and more responsive to the needs of consumers.

Ongoing Federal and State Litigation Regarding Pharmacy Benefit Managers

I. *Qui Tam* – "Whistleblower" Lawsuits

United States, ex rel. George Bradford Hunt and Walter W. Gauger, et al. v. Merck & Co., Inc., Merck-Medco Managed Care, L.L.C. and Medco Health Solutions, Inc., and *United States, ex rel. Joseph Piacentile v. Merck & Co., Inc. and Merck-Medco Managed Care, L.L.C.*; Consolidated Case No. 00-cv-737; U.S. District Court for the Eastern District of Pennsylvania; Judge Anita B. Brody. (Also cited as *United States of America v. Merck-Medco Managed Care L.L.C., et al.*)

In these whistleblower lawsuits, complaints were filed under the federal False Claims Act and state False Claims Acts against Medco Health Solutions, Inc. ("Medco"). The cases allege that Merck and Medco systematically defrauded government-funded health insurance programs by accepting kickbacks in exchange for referring patients to certain products, secretly accepting rebates from drug manufacturers in exchange for increasing product market share, secretly increasing long-term drug costs, and failing to comply with state-mandated quality of care standards. This manner in which this was done included: (1) inducing physicians to switch patient medications (drug interchange) by providing misleading, false or incomplete information that subverted patient care to profit motives; (2) secretly increasing the cost of drugs provided to beneficiaries by knowingly interchanging patients' medications to prevent them from taking advantage of soon to be released available generic drugs; and, (3) violating basic state requirements governing pharmacist supervision of prescription drug fulfillment processes. Through such conduct the United States alleges that Merck and Medco violated their contracts with government-funded health insurance programs.

These cases were brought by the whistleblowers on behalf of the United States. The *Hunt and Gauger* amended complaint was filed on March 18, 2003. The *Piacentile* complaint was filed on February 10, 2000. On June 20, 2003, the United States intervened following an extensive investigation of the factual allegations and evidentiary support provided by the relators. This investigation was conducted by numerous federal agencies, including the U.S. Attorney's Office, the Eastern District of Pennsylvania, the Office of Inspector General of the Office of Personnel Management, the Office of Inspector General of the Department of Health and Human Services, and the Defense Criminal Investigative Service. On December 9, 2003, the United States amended its complaint adding two executives of Medco as defendants. In the amended complaint these executives were accused caused of (1) covering up the intentional destruction of patient prescriptions, (2) destroying and directing the destruction of patient prescriptions, and (3) making misleading statements about the cover-up when questioned by the Department of Justice. The amended complaint also added a count against Medco under the Public Contract Anti-Kickback Act for making improper payments to health plans to induce them to select Medco as a pharmacy benefit manager for government contracts.

On April 26, 2004, the United States, 20 state attorneys generals, and the defendants agreed to a settlement of claims for injunctive relief and unfair trade practice laws.[1] A separate consent order was filed by the states to cover the injunctive and monetary claims. This order instructs Medco to pay $20 million to the states in damages, $6.6 million to the states in fees and costs, and about $2.5 million in restitution to patients who incurred expenses related to drug switching between a set of cholesterol controlling drugs. The consent order filed in the federal district court of the Eastern District of Pennsylvania excluded claims for damages, penalties, or restitution under federal statutes and common law. These components of the federal case are pending.

The settlement prohibits Medco from soliciting drug switches when:

- The net drug cost of the proposed drug exceeds the cost of the prescribed drug;
- The prescribed drug has a generic equivalent and the proposed drug does not;
- The switch is made to avoid competition from generic drugs; or
- The switch is made more often than once in two years within a therapeutic class of drugs for any patient.

The settlement requires Medco to:

- Disclose to prescribers and patients the minimum or actual cost savings for health plans and the difference in co-payments made by patients;
- Disclose to prescribers and patients Medco's financial incentives for certain drug switches;
- Disclose to prescribers material differences in side effects between prescribed drugs and proposed drugs;
- Reimburse patients for out-of-pocket costs for drug switch-related health care costs and notify patients and prescribers that such reimbursement is available;
- Obtain express, verifiable authorization from the prescriber for all drug switches;
- Inform patients that they may decline the drug switch and receive the initially prescribed drug;
- Monitor the effects of drug switches on the health of patients; and
- Adopt the American Pharmacists Association code of ethics and principles of practice for pharmaceutical care for employees at its mail order and call center pharmacies.

II. Other Federal District Court Lawsuits

Alabama

North Jackson Pharmacy, Inc., et al. v. Medco Health Solutions, Inc., et al.- On October 1, 2003, three related lawsuits were filed in the U.S. District Court for the Northern District of Alabama against Advance PCS and Caremark (Case No. CV-03-2695), Express Scripts (Case No. CV-03-2696-NE, and designated as the lead case), and Medco Health Solutions, Inc. (Case

[1] The United States and the following state Attorneys Generals joined in the settlement: Arizona, California, Connecticut, Delaware, Florida, Illinois, Iowa, Louisiana, Maine, Maryland, Massachusetts, Nevada, New York, North Carolina, Oregon, Pennsylvania, Texas, Vermont, Virginia, and Washington.

No. CV-03-2697). In these actions, *North Jackson Pharmacy* plaintiffs allege that the PBM defendants engaged in price fixing and other unlawful concerted actions to restrain trade in the dispensing and sale of prescription drugs. The complaint alleges that the defendants actions have harmed participants in programs or plans who have purchased their medications from retail pharmacies. *North Jackson Pharmacy* plaintiffs allege that the defendants engaged in various forms of anticompetitive conduct citing violations of the Sherman Act, including: (1) setting pharmacy reimbursement rates at unreasonably low levels; (2) imposing vertical maximum prices restrictions for how much pharmacies can charge PBMs and how much the PBMs may reimburse the retail pharmacies; and (3) operating illegal tying arrangements through horizontal price-fixing.

On October 13, 2004, the court in the Express Scripts (Case No. CV-03-2696-NE, and designated as the lead case), and Medco Health Solutions, Inc (Case No. CV-03-2697) cases denied defendants' motion to dismiss the second amended complaint. (*see* Opinion Regarding Motion to Dismiss Second Amended Complaint, October 13, 2004). The defendants alleged that the *North Jackson Pharmacy* plaintiffs' allegations failed to convincingly explain how consumers or the marketplace were injured as a result of the defendants' alleged anticompetitive behavior. The court, however, ruled that the complaint provided the PBMs and drug manufacturers with fair notice as to the nature and basis of the claims set forth against them. On November 1, 2004, defendants filed their answers to the second amended complaint.

On August 3, 2004, the *North Jackson Pharmacy, Inc, v. Caremark Rx, Inc.* case (Case No. CV-03-2695) was transferred to the U.S. District Court for the Northern District of Illinois. (Case No. 04-c-5674). In November 2004, citing to the Alabama court's October 13 denial of defendants' motion to dismiss in the related actions, the Illinois court also denied Caremark's motion to dismiss (*see* Memorandum Order, November 2, 2004). Accordingly, that court proceeded and on November 19, 2004 heard arguments on class certification.

District of Columbia

·*Pharmaceutical Care Management Association v. the District of Columbia, et al.* - On June 29, 2004, the Pharmaceutical Care Management Association (PCMA) filed suit in the U.S. District Court for the District of Columbia (Civil No. 04-cv-01082) seeking an injunction to block enforcement of Title II of the Access Rx Act of 2004. Title II of this Act requires transparent business practices among PBMs and states that PBMs owe a fiduciary duty to a covered entity. The Act requires that PBMs notify a covered entity of any conflict of interests, and that PBMs pass payments or benefits on in full to a covered entity where the PBM has received from any drug manufacturer or labeler any payment or benefit of any kind in connection with the utilization of prescription drugs by covered individuals, including payments or benefits based on volume of sales or market share. The Act also requires that PBMs, upon request by a covered entity, must provide information showing the quantity of drugs purchased by the covered entity and the net cost to the covered entity for the drugs (including all rebates, discounts, and other similar payments). It requires that PBMs disclose to covered entities all financial terms and arrangements for remuneration of any kind that apply between the PBM and any prescription drug manufacturer or labeler. Finally, the Act sets forth certain provision which must be applied to the dispensation of a substitute prescription drug for a prescribed drug to a covered individual.

In its lawsuit, PCMA argues that Title II is pre-empted by ERISA and the Federal Employees Health Benefits Act in determining who is (and who is not) a fiduciary of an ERISA-covered plan and FEHBA's comprehensive regulation of federal employee plans. Second, PCMA asserts that the law's disclosure requirements effect an unconstitutional taking of PBMs' property by destroying the value of trade secrets. And, finally, in seeking an injunction, PCMA argues that Title II violates the Commerce Clause of the Constitution. AARP has filed a motion for leave to file an *amici curiae* brief in support of defendants (*see* Motion for Leave to File a Brief *Amici Curiae*, July 22, 2004).

On December 21, 2004, the Court granted PCMA's motion for interim injunctive relief enjoining the District of Columbia from enforcing Title II of the Act. The court concluded that the plaintiff had demonstrated substantial likelihood that at least part of Title II may be unconstitutional; that aspects of Title II would represent an illegal takings of private property; and, that Title II could have the unintended effect of actually driving the PBM business and its attendant benefits out of the District of Columbia.

Maine

Pharmaceutical Care Management Association v. Rowe – This lawsuit filed on September 3, 2003, in the U.S. District Court for the District of Maine (Civ. No. 03-153-B-W), seeking declaratory and injunctive relief from LD 554 with regard to the fiduciary obligations and disclosure requirements set forth in this Maine law enacted in 2003. LD 554 imposes extensive duties of disclosure from the PBM to the client, including the duty to disclose: (1) any "conflict of interest"; (2) "all financial and utilization information requested by the covered entity relating to the provision of benefits"; and, (3) "all financial terms and arrangements for remuneration of any kind that apply between the [PBM] and any prescription drug manufacturer or labeler, including, without limitation, formulary management and drug-switch programs, educational support, claims processing and pharmacy network fees. . . ." While the Act allows a PBM to substitute a lower-priced generic drug for a therapeutically equivalent higher-priced prescriptive drug, it prohibits the PBM from substituting a higher-priced drug for a lower-priced drug unless the substitution is made "for medical reasons that benefit the covered individual" and the "covered entity". The Act also imposes disclosure and approval obligations on the PBM before any drug interchange. It also requires that benefits of special drug pricing deals negotiated by a PBM be transferred to consumers rather than being collected as profit by a PBM. The Act contains a limited confidentiality provision, as well: if a covered entity requests financial and utilization information, the PBM may designate the information as confidential and the covered entity is required not to disclose the information except as required by law.

In its lawsuit, PCMA alleged violation of the Commerce Clause by having extraterritorial effect and discriminating against out-of-state companies in favor of in-state companies; and, "taking" of property for which just compensation is due under the Fifth and Fourteenth Amendments of the United States Constitution. PCMA also argued that ERISA preempts this state law. On March 9, 2004, a decision by the judge temporarily blocked the implementation by issuing a preliminary injunction of LD 554. The court held that:

•The Court found that LD 554 conflicted with the federal Employee Retirement Income Security Act (ERISA) by designating PBMs as fiduciaries. By imposing additional rules and requirements on ERISA plans, LD 554 conflicted with Congressional intent to preserve the uniformity ERISA provides to make health care benefits including prescription drugs more affordable.

•The Court found that by imposing requirements for the disclosure of PBMs' proprietary pricing arrangements, LD 554 represents a "taking" of PBMs' trade secrets.

(*see* Order Granting Motion for Preliminary Injunction, March 9, 2004). The Court's injunction was affirmed by a new judge in July 2004, despite amendments to the law which would have protected trade secrets. (*See* Order on Defendant's Motion to Amend the Order of Preliminary Injunction, July 7, 2004; and *see also* Maine legislation discussion, above). Also in July 2004, the Maine Attorney General filed an interlocutory appeal to the U.S. Court of Appeals for the First Circuit (Case No. 04-2004), but this appeal was voluntary dismissed in September 2004 (*see* Mandate of U.S. Court of Appeal, September 1, 2004). Subsequently, PCMA filed for summary judgment (*see* Motion for Summary Judgment, October 15, 2004). Pending the decision on the motion for summary judgment, trial is scheduled for early 2005.

Massachusetts

In re Pharmaceutical Industry Wholesale Price Litigation – Originally filed in multiple jurisdictions in 2001, this consolidated class action case was initiated on September 6, 2002 in the U.S. District Court for the District of Massachusetts. (MDL No. 1456; Civil Action No. 01-cv-12257-PBS). The consolidated complaint alleges that the forty-two (42) defendant drug manufactures violated RICO and eleven (11) unfair and deceptive trade practices acts, including the Clayton Act, the Sherman Act, antitrust status of 22 states, state consumer protection statutes in 11 states, and civil conspiracy law. Specifically, defendants allegedly engaged in fraudulent conduct by artificially inflating the average wholesale prices ("AWP") for at least 321 identified drugs causing plaintiffs to substantially overpay for those drugs. Plaintiffs allege that defendants used this AWP fraud to increase market share for their drugs covered by MediCare Part B, and to maintain the high price of their brand name drugs outside of MediCare Part B. Plaintiffs claim that they are damaged by this fraudulent conduct since they are frequently required to make either full payment or copayments for a covered drug or a brand name drug and such payments are based on inflated AWPs.

In February 2004, the court issued a ruling that the plaintiffs had set forth sufficient facts to state claims concerning: (1) the alleged RICO enterprises between the drug manufacturer and four PBMs with the common objective of promoting fraudulent AWPs; (2) the alleged price-fixing conspiracy of one prescription card program in violation of antitrust laws; and, (3) RICO claims involving multi-source drugs. The court accepted class plaintiffs arguments which proposed that the drug companies had manipulated the prices of multi-source and generic drugs, claims which had previous been dismissed by the court without prejudice. Importantly, the order let stand the allegation of an ongoing conspiracy between the drug manufacturers and PBMs, who allegedly profit from the spread between the discounted price they pay and the AWP for

which they are reimbursed by patients and other payers. (*See* Memorandum and Order, February 24, 2004).

Missouri

·*Peabody Energy Corp. v. Medco Health Solutions, Inc., et al.* - Peabody filed this lawsuit suit against Medco Health Solutions on April 2, 2003 (Case No. 03-cv-417-ERW) alleging violations of ERISA; this case was filed under seal. In December 2003, the case was transferred to the multidistrict litigation case in the Southern District of New York, in order to consolidate pretrial proceedings (*see* Order of MDL Transfer, December 10, 2003) (*see* below, *In re Medco Health Solutions, Inc., Pharmacy Benefits Management Litigation*, which was initiated on March 12, 2003).

·*Peabody Energy Corp. v. Merck & Co., Inc.*, - Peabody Energy Corporation filed this second lawsuit in the U.S. District Court for the Eastern District of Missouri against Merck & Co. on December 23, 2003 (Case No. 03-cv-1839-ERW). This case alleges violations of RICO in that: (1) Merck directed its former Medco Health Solutions subsidiary to steer Peabody employees towards Merck manufactured medications rather than offering them therapeutically equivalent and less expensive alternative drugs; (2) required Medco to provide drugs made by Merck to patients at rates that exceeded Merck's general market share nationwide; and (3) directed Medco to encourage patients to use Merck's cholesterol drug Zocor instead of Pfizer's rival treatment Lipitor. The complaint also alleges tortuous interference by Merck with Peabody's PBM contract with Medco and unjust enrichment. It also alleges violation of state antitrust statutes. In May 2004, the defendant filed a motion to stay the proceedings pending resolution of a conditional transfer order issued by the Judicial Panel on Multidistrict Litigation (*see* Memorandum in Support of Motion to Stay Proceedings, May 11, 2004). On July 9, 2004, this motion was denied; however, in August 2004 the case was transferred to the multidistrict litigation case in the Southern District of New York (*see* Order of MDL Transfer, September 7, 2004) (*see* below, *In re Medco Health Solutions, Inc., Pharmacy Benefits Management Litigation*, which was initiated on March 12, 2003).

New York

· *Gruer v. Merck-Medco Managed Care, L.L.C.*; *Green v. Merck-Medco Managed Care, L.L.C.*; *Bellow v. Merck-Medco Managed Care, L.L.C.*; *Janazzo v. Merck-Medco Managed Care, L.L.C.*; and, *O'Hare v. Merck-Medco Managed Care, L.L.C.* (also referred to as *In re Medco Health Solutions, Inc., Pharmacy Benefits Management Litigation*, MDL Case No. 1508) - This action was initially commenced on December 17, 1997, with the filing of the *Gruer* complaint. The Gruer case was soon consolidated by the court with five other cases each of which asserted substantially similar claims to those presented in the Gruer complaint. The complaints that comprise the action, sought class action status on behalf of all individuals who were fiduciaries, beneficiaries, or participants or in employee welfare benefit plans that provided prescription benefit coverage. Class status applied to individuals who: (1) had contracts with Medco or any subsidiaries of Merck; (2) received prescription benefit services from Medco during the Class Period; and (3) used on an "open" formulary basis Medco's Preferred Prescriptions Formulary or

Medco's Rx Selections Formulary. The action asserts claims against Medco and Merck for breaches of fiduciary duty and other violations under ERISA.

The Court preliminarily approved settlement of the cases on July 31, 2003. On May 25, 2004 the court approved a $42.5 million settlement proposal offered by Medco Health Solutions to the employee welfare benefit plans. The settlement applied to those who directly or indirectly (through third party administrators, HMOs, insurance companies, Blue Cross Blue Shield entities or other intermediaries) held contracts with Medco between December 17, 1994 and May 25, 2004. This settlement was reached to conclude lawsuits which alleged that Medco violated its fiduciary duty by promoting more expensive drugs made by Merck and other manufacturers over less costly alternatives. The court did not rule on the merits of either the plaintiffs' claims or the defendants' defenses.

· *Healthfirst, et al v. Merck-Medco, et al.* - In this lawsuit filed on July 11, 2003, Healthfirst, a managed care prescription drug benefit program consisting of retail and mail pharmacy services, claimed that Medco breached its contract obligations by: (1) concealing the full amounts of manufacturer rebates and discounts it received with regard to Healthfirst's plans, and failing to pass through to Healthfirst any payments to which it was due; (2) demanding additional dispensing fee payments, which were outside the scope of the contract; (3) demanding monies for alleged savings derived from the Managed Rx Coverage Program and the Managed Prior Authorization Programs, while concealing both the amounts and sources of these alleged savings. Discovery in this case continues.

Pennsylvania

·*Brady Enterprises, Inc., et al. v. Medco Health Care Solutions, Inc., et al.* and *Bellvue Drug Co., et al. v. Advance PCS* - These companion lawsuits were filed on August 15, 2003 in the U.S. District Court for the Eastern District of Pennsylvania by individual pharmacies, as well as the Pharmacy Freedom Fund and the National Community Pharmacists Association. (Civ Nos. 03-4730 and 03-4731, respectively). The lawsuits allege that each of the defendant PBMs have violated Section I of the Sherman Act by engaging in anticompetitive conduct which substantially affects interstate commerce. These alleged violations include: negotiating and fixing reimbursement levels and rates, restricting the level of service offered to customers, and arbitrarily limiting the ability of retail pharmacies to compete on a level playing field with the PBMs' mail order pharmacy. The lawsuits seek class action status and allege that, acting as the common agent for plan sponsors, the two PBMs limited competition by: (1) setting reimbursement rates for pharmacies far below the rates that would apply in a competitive market; (2) fixing and artificially depressing the prices to be paid to pharmacies for generic drugs; (3) prohibiting retail pharmacies from providing more than a 30-day supply of drugs while the PBMs' own mail order pharmacies routinely provide a 90-day supply; (4) requiring retail pharmacies to charge an effectively higher co-pay than the co-pay that the PBMs' own mail order pharmacies charge; and, (5) imposing one-sided contracts and added costs and inefficiencies on retail pharmacies.

The lawsuit against Advance PCS asserts two antitrust violations: (1) horizontal price-fixing conspiracy/agreement among buyers of prescription drugs; and, (2) abusive business conduct by

the defendant to harm retail pharmacies. In March 2004, the court denied Advance PCS' motion to dismiss (*see* Memorandum and Order, March 3, 2004). In June 2004, the defendant filed a motion seeking to compel arbitration of the claims and dismissing the court action. (*see* Motion to Compel Arbitration, June 21, 2004). In August 2004, this motion was granted and the lawsuit was stayed pending the outcome of arbitration (*see* Memorandum and Order, August 23, 2004). Plaintiffs have filed a motion for reconsideration, or in the alternative, for certification for interlocutory appeal (*see* Motion for Reconsideration, September 7, 2004).

The lawsuit against Medco asserts the same antitrust violations as in the Advance PCS case and names Merck as a co-defendant on the grounds that Medco is merely the "alter ego" for Merck in promoting its brand name drugs. On November 17, 2003, defendants filed a motion to dismiss for failure to state a claim. In August 2004, the judge issued an order denying this motion to dismiss (citing to and supporting the judge's March 2004 ruling in the Advance PCS case); concluding that the Pharmacy Freedom Fund and the National Community Pharmacists Association do have standing to seek declaratory and injunctive relief; and, that plaintiffs' assertions of Merck's control over Medco were sufficient to withstand dismissal. (*See* Memorandum and Order, August 2, 2004). As such, a scheduling order was issued in September 2004 setting forth the discovery schedule which will extend well into 2005 (*see* Scheduling Order, September 30, 2004).

Wisconsin

·*American Medical Security Holdings Inc. v. Medco Health Solutions, Inc.* – This lawsuit was filed on May 14, 2003 in the U.S. District Court for the Eastern District of Wisconsin (Case No. 03-cv-431-WCG) by American Medical Security Holdings Inc., a former customer of Medco based in Green Bay. The suit alleged breach of contract involving discounted pricing and prescription dispensing fees. This case settled on March 24, 2004.

III. State Court Lawsuits

California

·*Alameda Drug Co., Inc, et al.. v. Medco Health Solutions, Inc., et al.*- On January 20, 2004 this lawsuit was filed in the Superior Court of California (San Francisco) (Case No. CGC-04-428109) seeking class action status for California retail pharmacies and pharmacists. The complaint alleges violation of California's Cartwright Act (Section 16720, *et seq.*, of the California Business & Professions Code) by fixing, raising, stabilizing and maintaining prices of prescription drugs manufactured by Merck and others at supra-competitive levels. The complaint also alleges violations of the California Unfair Competition Law by the defendants' unfair, unlawful and/or fraudulent business acts, omissions misrepresentations, practices and non-disclosures. The complaint relies upon information from the U.S. government's *qui tam* case in the Eastern District of Pennsylvania and alleges that Medco has unfairly increased its market share, increased its market power and restricted price competition at the expense of the plaintiffs and to the detriment of consumers. The complaint alleges that since the expiration of a 1995 consent injunction entered by the U.S. District Court for the Northern District of California, the defendants have failed to maintain an Open Formulary (as defined in the consent injunction).

Furthermore, the complaint alleges that Merck has fixed and raised the prices of its drugs and those of other manufacturers' who do business with Medco above competitive levels, while at the same time reducing the amount of reimbursement to the plaintiffs for dispensing these drugs under Medco Health Plans.

·*American Federation of State County and Municipal Employees v. AdvancePCS, et al.*- Originally filed on March 18, 2003, in the Superior Court of California (Los Angeles)(Case No. BC 292227), this class action against Advance PCS, Caremark Rx, Inc., Express Scripts, and Medco Health Solutions alleges that they inflate prescription drug prices by steering health insurers and consumers into reliance on more costly drugs. The complaint states that the defendants negotiated rebates from drug manufacturers and discounts from retail pharmacies but did not pass on those savings to health plans and consumers. It also alleges that the PBMs developed a pricing system based on fraudulently using the Average Wholesale Price to inflate prices set by the drug manufacturers, and that defendants' pocketed secret rebates, spreads and other payments from drug manufacturers. Given these alleged activities, the complaint argues that the defendants violated California's Unfair Competition Law with their unfair trade practices, and that plaintiffs have been damaged by defendants' practices by making inflated prescription drug payments. Among other things, plaintiffs allege violation of the Unfair Competition Law by the defendants: (1) failing to disclose material facts in the conduct of trade by not disclosing the full extent of rebates and other incentives received from drug manufacturers; (2) that the average wholesale price does not reflect the true average of the drugs they sell; (3) making false or misleading statements of fact concerning drug prices; (4) making misrepresentations as to the accuracy of the average wholesale price; (5) making misrepresentations that the PBMs exercise their formulary and contracting discretion in their health plans' interests; and, (6) making misrepresentations by claiming that they would put forth their best efforts to obtain prescription drugs for their health plans at the lowest prices available.

Florida

·*Fowler, Florida ex rel. v. Caremark Rx Inc.* – This whistleblower case was filed in January 2003, in Leon County Circuit Court by two pharmacists, Michael and Peppi Fowler who worked at Caremark's mail-order center in Fort Lauderdale. The case was filed under Florida's False Claims Act. The state of Florida declined to become involved in the case initially but then sought to intervene. However, on July 27, 2004, the judge ruled that the Florida's Attorney General Office had not provided sufficient legal reasoning to justify its intervention more than a year after it had declined to become involved.

New Jersey

Group Hospitalization and Medical Services, d/b/a CareFirst Blue Cross Blue Shield v. Merck Medco Managed Care, L.L.P., et al. - No. 03-cv-4144 (N.J. Super. Ct. 2003) – In this suit, the plaintiff Group Hospitalization and Medical Services, d/b/a CareFirst Blue Cross Blue Shield ("CareFirst") alleges state law claims for breach of fiduciary duty, breach of contract, negligent misrepresentation and unjust enrichment, and claims arising under District of Columbia and New Jersey state statutes against Merck-Medco Managed Care, L.L.P. ("Medco"). As a common law fiduciary, Medco had a duty to manage CareFirst's prescription drug benefits solely its best

interest, and to act with undivided loyalty toward CareFirst. Medco was precluded via its fiduciary status from self-dealing or profiting at CareFirst's expense. Subsequent to the expiration of its Agreements with Medco, CareFirst has alleged that Medco breached those Agreements and its fiduciary duties in at least the following ways:

1. failing to require generic substitution at mail and retail;
2. manipulating pricing at retail and mail so as to regularly and systematically bill claims at rates other than those set forth in its Agreements with CareFirst, in order to profit at CareFirst' s expense;
3. concealing the full amounts of manufacturer rebates and discounts it received with regard to CareFirst's plans, and failing to pass through to CareFirst the full amount of rebates to which it was due;
4. choosing drugs for its Preferred Prescriptions Formulary based on which drugs would garner the most rebate monies for Medco, rather than based on which drugs would be most cost-effective and efficacious for CareFirst;
5. engaging in drug switching to higher priced drugs without medical justification; and
6. failing to meet performance standards defined in its Agreements with CareFirst.

New York

·*New York Unions v. Express Scripts, Inc., et al.* – This lawsuit was filed before the New York State Supreme Court in New York County on December 31, 2003, by the United University Professions ("UUP") and the Organization of New York State Managerial Confidential Employees ("OMCE"). The complaint alleges that Express Scripts engaged in fraudulent practices at the expense of union members. According to the suit, Express Scripts negotiated discounts and rebates with drug manufacturers and then unlawfully withheld them from union members. The suit also holds that Express Scripts distorted the Average Wholesale Price (AWP) of its drugs which artificially inflated drug prices to union members. This case is pending.

·*People of the State of New York v. Express Scripts, Inc., et al.* – This breach of contract lawsuit was filed on August 4, 2004 in New York State Supreme Court in Albany County. The suit was the result of a one-year investigation by Attorney General Spitzer's office in cooperation with the Department of Civil Service and the Office of State Comptroller. The investigation was sparked by audits of Express Scripts conducted by Comptroller in 2002. Plaintiffs are seeking injunctive relief, restitution, damages, indemnification and civil penalties resulting from defendants' breaches of contract. The lawsuit alleges that Express Scripts: (1) enriched itself at the expense of the Empire Plan (New York State's largest employee health plan) and its members by inflating the cost of generic drugs; (2) diverted to itself millions of dollars in manufacturer rebates that belonged to the Empire Plan; (3) engaged in fraud and deception to induce physicians to switch a patient's prescription from one prescribed drug to another for which Express Scripts received money from the second drug's manufacturer; (4) sold and licensed data belonging to the Empire Plan to drug manufacturers, data collection services and others without the permission of the Empire Plan and in violation of the State's contract; and, (5) induced the State to enter into the contract by misrepresenting the discounts the Empire Plan was receiving for drugs purchased at retail pharmacies. The lawsuit also alleges, that in furtherance of its scheme to divert and retain manufacturer rebates that belonged to the Empire Plan, Express

Scripts disguised millions of dollars in rebates as "administrative fees," "management fees," "performance fees," "professional services fees," and other names. It further alleges that the drug switches caused by Express Scripts often resulted in higher costs for plans and members.

Ohio

-*Ohio v. Medco Health Solutions, Inc.* - On December 22, 2003 the state of Ohio filed a lawsuit in Hamilton County Common Pleas Court against Medco Health Solutions. The suit held that the State Teachers Retirement System of Ohio was overcharged millions of dollars for prescription drugs. The State Teachers Retirement System is seeking up to $50 million from Medco, including $36 million in alleged overcharges for the dispensing fees on mail-ordered medications. Other allegations claim that Medco undercounted pills when filling prescriptions and permitted non-pharmacists to dispense and cancel patient prescriptions without the necessary oversight by a licensed pharmacist. The case also contends that Medco steered doctors, pharmacists, and patients to choose brand-name and higher-cost medications manufactured by Merck rather than selecting generic equivalents.

West Virginia

-*West Virginia v. Medco Health Solutions* - Filed in November of 2002 in Kanawha Circuit Court, the West Virginia Attorney General alleged that Medco withheld prescription drug rebates and other savings from the State's Public Employee Insurance Agency ("PEIA"). A central complaint of the case held that Medco deliberately steered PEIA members to purchase Merck manufactured medications even though they were more expensive than therapeutically equivalent alternatives. Another allegation against Medco charged that Medco failed to pass manufacturer rebates on to the consumer. Concurrent to the suit filed by the State against Medco, Medco filed a suit against the State alleging that the State failed to pay for $2.2 million owed Medco by the State of West Virginia. In December 2003, the circuit court granted Medco's motion to dismiss several of the claims. The judge dismissed allegations of Medco's fraud, conspiracy and tortuous interference, and violations of the Consumer Protection Act. The court has permitted the West Virginia Attorney General to re-allege its claims of fraud if it can offer necessary evidence.

ATTACHMENT 2

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Beginning Steps for PBM Reform

Probably no other market faces the amount of litigation and myriad government investigations as the pharmaceutical benefit manager (PBM) market. PBMs are intermediaries in the delivery of pharmaceutical benefits. As in many healthcare markets, intermediaries may improve the delivery of benefits by bringing new network relationships and streamlining processes. PBMs also have engendered significant controversies, however, because of the appearance of conflicts of interest.

In recent years, there have been numerous federal and state investigations into the PBM market. In April 2004, the Attorneys General of 20 states and the U.S. Attorney settled charges against Medco Health Solutions, Inc. (Medco) and Merck-Medco Managed Care, L.L.C. for alleged violations of various consumer protection and unfair trade practice statutes.[1] The settlement imposed far-reaching legal obligations on the company relating to its drug-switching practices, and is likely to serve as a blueprint for future regulation of PBMs.

The Complaint

Medco Health Solutions, Inc., the corporate successor to Merck-Medco Managed Care, L.L.C., provides PBM services to healthcare plans nationwide. Medco also operates prescription drug mail order pharmacies under the names of various wholly-owned subsidiaries. Medco is the nation's largest PBM, with 2002 net revenues of more than $32 billion and a network of more than 55,000 pharmacies.[2]

Virtually all health insurance plans include a pharmacy benefit component that pays for prescription drugs for the plan members. This pharmacy benefit often is managed by a PBM. The PBM is engaged in the business of administering the pharmacy benefit for the client health plans, and performs some or all of the following tasks for its clients: a) organizing a network of retail pharmacies that agree to fill prescriptions, and negotiating prices at which to fill those prescriptions; b) operating mail order pharmacies that sell prescription drugs directly to patients; c) processing and paying prescription drug claims on behalf of its clients through a computerized system; d) providing patients, physicians, and clients with information about available pharmacy benefit and prescription drug plans; and e) providing advice regarding the development of so-called "formularies," which are lists of preferred drugs that a plan agrees to pay for its member patients. Medco's Pharmacy & Therapeutics Committee (P&T Committee), composed of independent physicians and pharmacists, is obligated to use its professional judgment to determine which drugs should be included in Medco's formularies.

The complaint alleged that Medco represented to its clients that it saved them money by providing prescription drugs at a contractual discount off the average wholesale price (AWP). In addition, the complaint alleged that Medco also promised cost savings for its clients by a) negotiating and obtaining "rebates" from drug manufacturers for including their branded drugs in Medco's formularies; and b) conducting so-called "therapeutic interchange programs," which allowed Medco to switch prescription drugs to ensure greater compliance with Medco's formularies. Critical to Medco's cost-savings claims, the complaint further alleged, was its promise to "pass through" such manufacturer rebates to its clients.

The complaint also alleged that Medco's formulary decisions, as well as its drug switching programs, were influenced

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largely by its desire to receive money from the drug manufacturers, not by the desire to save clients' money. The complaint further alleged that Medco actively encouraged pharmacists and prescribers to switch patients to different prescription drugs, but failed to pass on the resulting savings to patients or their healthcare plans. The drug switches generally benefited only Medco, despite Medco's claims that it saved money for both patients and health plans. Moreover, Medco did not disclose to prescribers or patients that the proposed drug switches would increase rebate payments from drug manufacturers to Medco. Finally, the complaint alleged that the drug switches resulted in increased costs to health plans and patients, including additional costs for follow-up doctor visits and tests.

In particular, the complaint alleged that Medco's proposed drug switches "either favored target drugs that were more expensive than drugs originally prescribed, or had the effect of favoring drugs without a generic equivalent over drugs with a generic equivalent."[3] Because Medco engaged in conduct designed to maximize revenues for itself without passing through those revenues to its clients, the complaint alleged, both Medco's formulary decisions and its drug switching programs were "driven by Medco's conflicted interest, not by cost savings for the client."[4]

Moreover, the complaint alleged that Medco's proposed drug switches required clients and patients to pay substantial additional costs. For certain drug therapies, a switch from one to drug to another often requires additional doctor visits and/or medical tests to ensure the new drug's efficacy. Medco did not pay for these additional costs. Often these switch-related costs outweighed the incremental cost savings, if any, resulting from the drug switches.

Principal Provisions of Consent Decrees

To remedy Medco's conduct, the Consent Order set forth several categories of prohibited drug switches. The Order carved out the following four specific instances in which Medco may *not* make drug switch solicitations to physicians and prescribers:

(1) when the cost of the proposed drug exceeds that of the current drug;
(2) when the current drug has generic equivalents, while the proposed drug does not have generic equivalents (except in situations in which the proposed drug is cheaper than *all* of the generic equivalents of the initially-prescribed drug);
(3) when the patent for the current drug expires within six months, or the proposed drug switch would have the effect of avoiding competition from future generic equivalents; and
(4) when—within the past two years—a patient either already has switched a drug in the same therapeutic class in response to Medco's solicitations or subsequently has reversed such a switch. This "two-year rule" does not apply if all of the proposed drugs were not part of the prior drug switch solicitation by Medco.

The Order also established a number of affirmative obligations for Medco during permissible solicitations for drug switches to prescribers, including:

(1) identifying the person and the entity (e.g., Medco) making the solicitations;
(2) clearly disclosing to prescribers both the annual minimum or actual cost savings of proposed drug switches and the effect of such proposed drug switches on patients' copayments (even if the drug switch does not alter copayments, Medco must communicate this to patients);
(3) clarifying whether—and under what circumstances—patients' healthcare plans will continue to cover the current drug (should the patient decide to stay with the current drug);
(4) disclosing whether Medco receives any payments from manufacturers for promoting drug switches;
(5) disclosing the right to reimbursement for all out-of-pocket healthcare costs incurred by a drug switch (e.g., costs for return doctor visits and additional laboratory tests necessitated by the drug switch); and
(6) describing any material differences in side effects between the initial and the proposed drug.

With respect to reimbursing patients for their out-of-pocket healthcare costs imposed by a drug switch, the Order requires Medco to:

(1) allow patients and prescribers—as well as physicians—to initiate reimbursement requests either by phone or in writing;
(2) provide a *single-page* claims form to be filled out; and
(3) reimburse patients for all out-of-pocket costs within 30 days of receiving a claims form.

If the drug-switch costs to be reimbursed by Medco exceed $500, the Order permits Medco to designate a third party to review the costs submitted by patients and prescribers.

The Order also requires Medco to follow specific procedures when implementing permissible drug switches that comport with the above obligations. Before switching to a

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proposed drug, the Order requires Medco to obtain express, verifiable authorization from the prescriber for the switch of the current drug. Such authorization can be communicated either to Medco directly by the prescriber (verbally or in writing), or by another person who affirms the prescriber's authorization. The Order requires Medco to maintain all records of such authorization.

After obtaining authorization, the Order requires Medco to issue a *written* confirmation of the switch to the prescriber. For patients receiving home delivery prescriptions, Medco must issue patients a written *and* a telephonic confirmation of the switch (only written confirmation will suffice for non-home delivery prescriptions). Among other things, written confirmations must:

(1) state that Medco, *not* the prescriber, requested a drug switch;
(2) disclose all relevant items noted above (e.g., cost savings, copayment differences, and the existence of manufacturer payments); and
(3) advise the patient that he or she may decline the proposed drug switch.

The Order expressly allows patients to reject Medco's proposed drug switches. If the patient declines the proposed drug switch, the Order requires Medco to honor such requests and to provide the initially-prescribed drug. In addition, Medco also must maintain a toll-free phone number to receive and process such requests. Following the drug switch, Medco must monitor the effects of the new drug on the patient at least on a quarterly basis, and must report its findings to the P&T Committee.

The Order also imposed on Medco a number of affirmative disclosure obligations for its clients that are aimed at promoting price transparency with respect to the manufacturer payments it receives. Medco must make quarterly *and* annual disclosures (Manufacturer Payments Report) to its client health plans that account for all compensations from drug manufacturers that such health plans have contracted to receive. In addition, any time Medco enters into a contractual relationship with a healthcare plan—whether new or renewing clients—it must disclose: 1) Medco's policy of soliciting, receiving, and passing through manufacturer payments; 2) information contained in the Manufacturer Payments Report for the most recent fiscal year; and 3) Medco's policy of publishing quarterly and annual payments reports. Furthermore, Medco may not refuse proposals or bids from a potential health plan client simply because the proposal does not use AWP or prohibits the use of AWP in pricing terms. Medco also may not conceal relative prices of drugs by using symbols or other indirect means.

To further ensure that Medco conducts its business in an open and fair manner, the Order required Medco to adopt the code of ethics of the American Pharmacists Association (APhA),[5] and to provide these documents to its entire staff of pharmacists to ensure compliance. Medco also must make these documents available to its client health plans as well as to its patients.

The Order required Medco to pay $20.2 million to the 20 states, either in cash or through free prescription medications targeted for the low-income, the elderly, and the disabled. Medco also will pay another $6.6 million to the states to cover their investigation costs. Finally, the Order required Medco to establish a $2.5 million fund to reimburse patients $25 for additional costs (e.g., for medical tests or follow-up visits to their physician) attributable to any medication switch by Medco.

Conclusion

With more than 150 million Americans using a pharmacy benefit component of healthcare and the critical role PBMs will play in the new Medicare pharmaceutical benefit, the *Medco* Order provides a framework for improving the working of PBM markets. According to Pennsylvania Attorney General, Jerry Pappert, PBM reforms will lead to greater competition, more transparency, and ultimately, lower drug costs for consumers.[6] Δ

[1] The states included in the settlement are Arizona, California, Connecticut, Delaware, Florida, Illinois, Iowa, Louisiana, Maine, Maryland, Massachusetts, Nevada, New York, North Carolina, Oregon, Pennsylvania, Texas, Vermont, Virginia, and Washington. Ohio and West Virginia are in litigation with Medco, while Tennessee has expressed an interest in pursuing negotiations with the PBM.

[2] Complaint at 3, State of Maine v. Merck-Medco Managed Care, L.L.C. et al., (2003)(CV-04___), *available at* http://www.maine.gov/ag/dynld/document-viewedcomplaint.pdf (last accessed May 28, 2004).

[3] *Id.* at 10.

[4] *Id.*

[5] *See* American Pharmacists Association, Code of Ethics for Pharmacists (adopted Oct. 27, 1994), *available at* www.aphanet.org (click on "About APhA," then "Code of Ethics") (last accessed May 18, 2004).

[6] Press Release, PA Press Office, AG Pappert Sues 15 Major Drug Companies for Unlawful and Deceptive Pricing and Sales Practices; Alleges Illegal Conduct Caused Pennsylvanians to Pay Higher Prices for Prescription Medications (Mar. 10, 2004), *available at* http://www.attorneygeneral.gov/press/release.cfm?p=35A2F9C9-017B-3BF1-703540A339D7DC11 (last accessed May 28, 2004).

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ATTACHMENT 3

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Competitive Concerns and Price Transparency in the PBM Market

As Congress struggles with providing a prescription drug benefit under Medicare, many proposals include the use of pharmaceutical benefit managers (PBMs). PBMs are fiscal intermediaries that specialize in the administration and management of prescription benefit programs. PBMs provide these services for insurers, unions, and employers (plan sponsors). PBMs help control and manage pharmaceutical spending and provide services for over 180 million Americans.

Although PBMs can provide a valuable service, consumers and plan sponsors often do not receive their full benefits due to certain market characteristics and a lack of transparency in the process. Substantial entry barriers and significant switching costs dampen the degree of competition in PBM markets. A lack of transparency about the compensation PBMs receive from pharmaceutical manufacturers prevents plan sponsors from effectively securing the lowest pharmaceutical prices. Before Congress extends the use of PBMs in a Medicare pharmaceutical benefit, it must reform PBM markets to provide substantially greater transparency.

PBM Markets and Competitive Concerns

PBMs are intermediaries in the complex pharmaceutical distribution chain; they negotiate contracts with pharmaceutical manufacturers and pharmacies. PBMs steer healthcare consumers and physicians by placing certain drugs in a preferential status on formularies—lists of approved drugs used to manage drug spending. Manufacturers pay a variety of fees for preferential placement on a formulary, including 1) access rebates, 2) market share rebates for meeting certain market share goals, and 3) administrative and other fees. Some PBMs also have their own mail order operations.

In theory, a PBM serves as a middleman attempting to secure favorable pharmaceutical prices. But unlike a true group purchasing operation that may be efficient, PBMs do not actually purchase the drugs. Rather, they receive rebates from manufacturers for placement of drugs on a formulary, a list of approved drugs. Generally these rebates can benefit consumers where they are transparent. Secret rebates, however, can lead to discrimination that ultimately may harm buyers and the ultimate consumer. Secret rebates may encourage a PBM to choose a higher priced drug with a higher rebate, instead of a lower priced drug, resulting in higher costs to consumers. Consumers do not necessarily receive the benefit of these middleman rebates.

Competitive concerns have arisen in the PBM market—a highly concentrated industry in which the four largest firms hold about a combined 80% market share. The market for full-service PBM providers capable of bidding on Medicare contracts is even more concentrated. Moreover, concentration in the market has increased substantially over the past decade. Substantial costs have prevented any successful entry into the PBM market for quite some time, and substantial switching costs create obstacles for plan sponsors to change PBMs.

This situation is one in which PBMs can act opportunistically—easily increasing prices or decreasing service. Indeed, the Federal Trade Commission (FTC) placed the two largest PBMs—Merck and PCS—under regulatory consent orders to prevent opportunistic conduct that would harm consumers.[1] The FTC found that 1) there was a national market for PBMs with very few competitors; 2) PBMs had the ability and incentive to engage in exclusionary conduct; 3) there was the potential for collusion among PBMs; and 4) PBMs could disadvantage rivals by establishing closed formularies.[2] To address these potential competitive concerns, the FTC required PBMs to establish independent and open formularies to provide plan sponsors with greater choice and transparency.

The competitive practices of PBMs are the subject of several investigations and regulatory enforcement actions.

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A group of 21 state attorneys general is investigating anticompetitive conduct by the major PBMs.[3] The Attorney General of New York recently subpoenaed Express Scripts for information "regarding the company's compliance with certain state and federal antitrust and consumer protection statutes."[4] The Department of Health and Human Services (DHHS) Office of Inspector General has warned that rebates collected by PBMs under state Medicaid programs might violate federal anti-kickback laws. The Department of Justice recently joined a *qui tam* lawsuit filed by a former employee against Merck/Medco.[5] The complaint alleges that as a result of long-standing fraudulent business practices, Merck/Medco's services to plan sponsors resulted in price increases and a threat to the prescription users' health.

Much of the concern over PBMs focuses on whether the rebates and other payments received from pharmaceutical manufacturers are passed on to plan sponsors in lower prices; PBMs consistently decline to provide systematic and complete payment information to their plan sponsors. The American Federation of State, County, and Municipal Employees (AFSCME) sued the nation's four largest PBMs,[6] alleging that they violated California's Unfair Competition Law.[7] The complaint charges, *inter alia*, that the four PBMs have negotiated rebates from drug manufacturers and discounts from retail pharmacies, yet have not passed those savings on to healthcare plans and consumers. In addition, the complaint also alleges that the PBMs developed a pricing system based on the average wholesale price (AWP), which is widely considered an inflated "sticker" price set by drug manufacturers.

The Need for Transparency and the Proposed Reforms

PBM market reforms are major components in the Medicare reform packages currently before both houses of Congress.[8] The bills would require reforms to current Medicare prescription drug provisions, including expanded governmental audit rights of prescription providers, financial statements and records, and competitive bidding rules for Medicare contracts. Disclosures and price transparency enable buyers to determine whether they are receiving the full benefit of the price concessions received by PBMs from manufacturers. Armed with information about rebates, buyers such as Medicare can more effectively encourage PBMs to compete.

In addition, these reforms will transform PBMs into more traditional insurers by giving them fixed premiums from plan beneficiaries, rather than allowing them to earn their profits from a complex set of fees, discounts, and rebates produced from their dealings with pharmaceutical companies.[9]

Mandated price transparency, as called for in the proposed legislation, will help solve the competitive issues in the national PBM market, and will play an essential role in securing for consumers the benefits of a competitive marketplace. Arguments to the contrary, are inconsistent with common sense, economic learning, and decades of antitrust law.

"Secret" rebates may encourage a PBM to choose a higher priced drug with a higher rebate instead of a lower priced drug, resulting in higher costs to consumers and higher rebates to the PBMs. By disclosing rebates, buyers can monitor and prevent this potential discrimination. Congress enacted legislation to prevent such conflicts of interest and possible discrimination.[10] Under the Medicare/Medicaid anti-kickback law, criminal penalties attach to any person who knowingly solicits, receives, offers, or pays remuneration (including rebates) in exchange for a payment or service under a federal healthcare program. A U.S. attorney's office in Pennsylvania currently is investigating whether the rebates that PBMs receive from manufacturers constitute illegal kickbacks. Congress and the DHHS require full disclosure of any rebates or price concessions as a prerequisite to application of the discount safe harbor to the anti-kickback law.[11]

Transparency Is Essential to Competitive Markets and Consumer Choice

Price and service transparency is a cornerstone to competition because when it exists, purchasers can make fully informed choices. Transparency in the process forces firms to compete more aggressively because they know that purchasers can and will make such choices. Price transparency invariably leads to lower prices, not higher prices. As economists observe, "Firms obtain market power from consumer lack of knowledge about prices and quality . . . . Limited information can lead to a monopolistic price in what would otherwise be a competitive market."[12]

Antitrust litigation reflects the fact that transparency is vital to the effective functioning of markets. For example, in *Bates v. State Bar of Arizona*,[13] the U.S. Supreme Court struck down a ban on lawyer advertising. Petitioners, members of the Arizona Bar, offered low-cost legal services to low-income clients in need of routine legal services. The attorneys' financial success depended on high case volume

from unsophisticated legal consumers, and advertising was one of the best avenues to achieve that success. Although the state bar expressly forbade the activity, petitioners nevertheless placed a newspaper advertisement for their practice. In declaring the rule illegal, the Court noted that advertising can help the bar better serve the general community: "Advertising is the traditional mechanism in a free-market economy for a supplier to inform a potential purchaser of the availability and terms of exchange. The disciplinary rule at issue likely has served to burden access to legal services."[14]

Transparency also plays an important role in efforts by managed care to control healthcare costs. In *FTC v. Indiana Federation of Dentists*,[15] the FTC challenged an effort by a group of dentists to collectively refuse to provide x-rays to managed care providers. The insurers needed this information to make coverage decisions. The FTC deemed the boycott violative of antitrust laws, and the Supreme Court agreed, finding the conspiracy had the actual effect of suppressing competition.[16] The Court noted, "While this is not price fixing as such, no elaborate industry analysis is required to demonstrate the anticompetitive character of such an agreement."[17]

A lack of transparency invariably leads to less competition and higher prices. As the Supreme Court has observed, restrictions on price transparency "increase the difficulty of discovering the lowest cost seller of acceptable ability[,] . . . [reduce] the incentive to price competitively," and "serv[e] to perpetuate the market position of established [market participants]."[18] As a result, "where consumers have the benefit of price advertising, retail prices often are dramatically lower than they would be without advertising."[19] The importance of transparency, however, attaches not only to price information, but also to all material aspects of the transaction. In *United States v. National Society of Professional Engineers*, the Court indicated that "all elements of a bargain—quality, service, safety, and durability—and not just the immediate cost, are favorably affected by the free opportunity to select among alternative offers."[20]

Regulation Often Is Necessary to Protect Transparency

Markets often work well to provide the type of transparency consumers need; in some cases, however, it is necessary for the government to intervene. This is especially true in complex markets like pharmaceutical distribution and in concentrated markets with high entry barriers.

Federal antitrust enforcement agencies have brought several enforcement actions and adopted regulations to protect the vital role of price transparency in many markets.[21] In several cases the FTC has required disclosure of the underlying terms of transactions to help consumers make fully informed choices. For example, in the funeral industry—an industry that resisted disclosing price information to consumers—the FTC enacted regulations requiring price disclosure. Among the numerous goods and services listed by the regulations for disclosure, the regulations designate certain core components of the total funeral package as mandatory disclosure items.[22] Sections of those regulations include mandatory posting of notices regarding prices, and items required to be included on billing statements.

The FTC instituted similar rules concerning telemarketing companies. To ensure complete disclosure to customers purchasing goods and services over the telephone, the regulations require disclosure of certain information before customers pay for the good or service, and prohibit nondisclosure of such information as a deceptive telemarketing act or practice.[23] A company must disclose, among other information, the price of shipping, any restrictions or conditions on the sales offer, the refund policy, and the total cost of the transaction in a clear and conspicuous manner. Offers of consumer credit products are subject to the additional requirements of the Truth in Lending Act (TILA).[24] Misrepresenting any of the information required for disclosure also is considered deceptive, as is causing billing information to be submitted to the company in violation of TILA or the Electronic Fund Transfer Act.[25] The FTC rule also classifies any false or misleading statement to induce a person to make a charitable contribution as a violation.[26]

That a "middleman" such as a PBM may face a conflict of interest and that disclosure may alleviate the potential for such conflicts has been recognized in other contexts. For example, Internet search engines often receive payments from companies that place advertising on websites. By letter, the FTC informed Internet search engine companies that they must disclose the existence of these payments on the website.[27] Although the Commission elected not to commence actions against the search engine companies, it noted that disclosure of payments made by companies to them in exchange for preferential placement in search results "would put consumers in a better position to determine the importance of these practices in their choice of search engines to use."[28] The FTC specifically recommended that any paid-for search result rankings be distinguished from nonpaid-for results; that paid-for inclusion be clearly and conspicuously disclosed; and that no affirmative statement be made that might mislead consumers about the basis of search results.

Conclusion

Providing pharmaceutical benefits under Medicare is a laudable goal and intermediaries such as PBMs can play an important role in delivering those benefits. Like all markets, however, PBM markets work most effectively where there is real transparency so consumers can make fully informed choices. Congress should make sure that transparency is an essential element in providing comprehensive pharmaceutical benefits. Δ

[1] Eli Lilly, 61 Fed. Reg. 31,117 (FTC July 31, 1996); Merck & Co., 63 Fed. Reg. 46,451 (FTC Sept. 1, 1998).

[2] *See* Elizabeth L. Mitchell, *The Potential for Self-Interested Behavior by Pharmaceutical Manufacturers Through Vertical Integration With PBMs: The Need for a New Regulatory Approach*, 54 Food & Drug L.J. 151 (1999); David A. Balto, *A Whole New World?: Pharmaceutical Responses to the Managed Care Revolution*, 52 Food & Drug L.J. 83 (1997) (detailing the competitive problems posed by PBMs and FTC enforcement actions).

[3] *More Disclosure for Drug Plans*, N.Y. Times, July 19, 2003, *at* http://www.nytimes.com/2003/07/19/business/19CARE.html (last visited Aug. 8, 2003); *Express Scripts Gets Subpoena from NY Attorney General*, *available at* http://sbk.biz.yahoo.com/030620/80/e2we6.html (last visited Aug. 8, 2003) ("[s]everal states including North Carolina and West Virginia have launched queries into PBM practice").

[4] *Express Scripts Subpoenaed by NY Attorney General*, St. Louis Bus. J., June 20, 2003, *at* http://sanfrancisco.bizjournals.com/stlouis/stories/2003/06/16/daily76.html (last visited Aug. 8, 2003).

[5] United States ex. rel. Hunt v. Merck & Co. Inc., Mo. 00-737, notice of intervention (E.D. Pa. Jun. 23, 2003).

[6] The largest PBMs are PCS, Express Scripts, Medco, and Caremark.

[7] *See* First Amended Representative Action and Complaint for Violations of the Unfair Competition Law, *available at* http://www.hagens-berman.com/files/PBM%20Complaint%20-%20Amended%20-%20NP1049738021600.pdf (last visited July 3, 2003).

[8] *See* Prescription Drug and Medicare Improvement Act of 2003, S. 1, 108th Cong. (2003); Medicare Prescription Drug and Modernization Act of 2003, H.R. 1, 108th Cong. (2003).

[9] *See* http://www.kaisernetwork.org/daily_reports/print_report.cfm?DR_ID=18741 (last visited Aug. 8, 2003).

[10] *See* Medicare-Medicaid Anti-Fraud and Abuse Amendments, 42 U.S.C. § 1320a-7b(b) (2003).

[11] *Id.*

[12] Dennis W. Carlton & Jeffrey M. Perloff, Modern Industrial Organization 431 (2000).

[13] Bates v. State Bar of Arizona, 433 U.S. 350 (1977).

[14] *Id.* at 376.

[15] FTC v. Indiana Federation of Dentists, 476 U.S. 447 (1986).

[16] *Id.* at 454-55.

[17] *Id.* at 459 (quoting United States v. National Society of Professional Engineers, 435 U.S. 679, 692 (1978)).

[18] *Bates*, 433 U.S. at 377-78.

[19] *Id.* at 377.

[20] *National Soc'y of Professional Engineers*, 435 U.S. at 695.

[21] *See, e.g., In re* Detroit Auto Dealers Ass'n, 955 F.2d 457 (6th Cir. 1992), *cert. denied*, 506 U.S. 973 (1992).

[22] 16 C.F.R. § 453.2(a), (b)(2)(B)(4) (2003).

[23] 16 C.F.R. § 310.3(a).

[24] *Id.*; Truth in Lending Act, 15 U.S.C. §§ 1601 et seq.

[25] 16 C.F.R. § 310.3(a)(3); *see also* Electronic Fund Transfer Act, 15 U.S.C. § 1693(b).

[26] 16 C.F.R. § 310.4(a)(4).

[27] *See* Letter to Gary Ruskin, Exec. Dir., Consumer Alert (June 27, 2002), *available at* http://www.ftc.gov/os/closings/staff/commercialalertletter.htm (last visited Aug. 8, 2003).

[28] *Id.*

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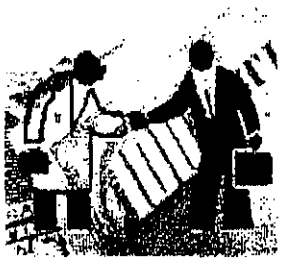

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Memorandum

TO: Senator Krebsbach

FROM: Sparb

DATE: March 22, 2005

SUBJECT: HB 1332

I recently was made aware of a provision in HB 1332 which could have an effect on the PERS Health Benefits Plan. I am writing to let you know of our concern.

Section 2 of the Bill would impose restrictions on mail order prescriptions as follows:

> *When contracting with pharmacies, a pharmacy benefits manager may not discriminate on the basis of copayments or days of supply. A contract must apply the same coinsurance, copayment, and deductible to cover drug prescriptions filled by any pharmacist or pharmacy who participate in the network.* (HB 1332, First Engrossment, page 4, lines 13-16)

The plain meaning of the first sentence of this subsection would prohibit NDPERS from a including a pharmacy benefit that offered lower copayments for prescription drugs purchased through a mail order pharmacy even if the cost of those drugs was less than

those purchased through other sources. While NDPERS does not have any current plans to provide incentives for any such purchases, this provision could limit the flexibility of NDPERS in the design of future prescription drug benefit coverage.

The second sentence of the mail order provision is also problematic. It provides: "A contract must apply the same coinsurance... to covered... prescriptions." It is not clear which "contract" this provision applies to. Is it the contract between an employer and the employer's health insurance company? Or, is it the contract between the insurance company and retail pharmacies participating in the insurance company's "network" of providers? If it is the former, then the issue regarding flexibility in plan design regarding mail order pharmacies is simply repeated. If it is the latter, then NDPERS may be restricted in terms of establishing and negotiating the specific amount of copayments, percentage of coinsurance, and other terms of coverage for drug benefits. NDPERS would be required to have exactly the same terms as every other employer insurance plan in North Dakota, which would restrict our flexibility in plan design and would increase the cost of our plan if that plan has lower out of pocket expenses for our members.

I appreciate there are many important complex issues involved in your deliberations on HB 1332, but I wanted to take this opportunity to draw these features to your attention since they could limit the ability of PERS to control our costs by mandating these benefit provisions.

Please let me know if you have any questions regarding these issues. I will be happy to visit with you or provide additional information.

Kasper, Jim M.

From: Collins, J. Sparb
Sent: Thursday, April 07, 2005 7:27 AM
To: Kasper, Jim M.
Subject: HB1332

Good Morning

I am writing in response to your voice mail. We would not have any concerns with a study of PBM benefits or the disclosure requirements to the Insurance Commissioner as presently contained in the bill. We did have a concern with a provision of the bill as previously drafted that I only became aware after the Senate had its hearings. I shared that concern with Senator Krebsbach and I am attaching a copy of that letter for your information (that provision is not in the engrossed version). I also discussed our concerns with the Pharmacy Association at the time as well. If I can be of any other assistance please let me know. I will give you a call at 9 this morning to follow-up. I have a conference call from 8-9 but if you need to get in touch with during that time please feel free to call my cell at 471-6339.

sparb

4-7-05
Senator Nething

HB 1332: Restrictions on Copayments, Coinsurance, and Mail-Order Drugs

Summary

1. The restrictions on copayments, coinsurance, and deductibles, and the restriction on mail-order pharmacies *go beyond* the original and primary purpose of HB 1332 – to require "transparency," i.e., disclosure of rebates received by pharmacy benefit managers.

2. The restrictions (on copayments, etc... and mail-order pharmacies) are not included in the Maine or South Dakota laws that were the models for HB 1332.

3. The second sentence of subsection 3 of proposed section 26.1-27.1-04, which provides:

> "A contract must apply the same coinsurance, copayment, and deductible to covered drug prescriptions filled by any pharmacist or pharmacy who participates in the network" (ENGROSSED HOUSE BILL NO. 1332, page 4, lines 13-16) –

would impair the flexibility of the NDPERS health plan to develop its own specifications for copayments, coinsurance, and deductibles.

4. The limitations on the terms of copayments and the days of drug supplies contained in HB 1332 are contrary to the provisions of the Medicare Part D prescription drug regulation relating to mail-order pharmacies, which expressly permits lower copayments for drugs obtained from a mail-order pharmacy.

5. Tie-in sales. To the extent that a PBM is "steering" mail order business to a higher priced, wholly-owned mail order pharmacy, the PBM may be engaged in an illegal "tie-in" sale, which is already a violation of the antitrust laws.

Provided by Senator Nething

Attorney General's Office Stenehjem 4-7-05

HB 1332: Restrictions on Copayments, Coinsurance, and Mail-Order Drugs

1. The restrictions on copayments, coinsurance, and deductibles, and the restriction on mail-order pharmacies *go beyond* the original and primary purpose of HB 1332 – to require "transparency," i.e., disclosure of rebates received by pharmacy benefit managers.

2. These restrictions (on copayments, etc... and mail-order pharmacies) are not included in the laws that were the models for HB 1332. **Neither the Maine law nor the South Dakota pharmacy benefit manager legislation** – which have been touted as models for HB 1332 – includes any provision relating to copayment or coinsurance for drugs obtained from a mail order pharmacy. See Me. Rev. Stat. Ann. tit. 22 § 2699; S.D. Codified Laws §§ 58-29E 1–11.

3. The second sentence of subsection 3 of proposed section 26.1-27.1-04, which provides:

> "A contract must apply the same coinsurance, copayment, and deductible to covered drug prescriptions filled by any pharmacist or pharmacy who participates in the network" (ENGROSSED HOUSE BILL NO. 1332, page 4, lines 13-16) –

would impair the flexibility of the NDPERS health plan to develop its own specifications for copayments, coinsurance, and deductibles. This could impair the plan's ability to develop the most cost-effective and medically useful benefit plan. In effect, all health plans in North Dakota receiving prescription drug benefits through a specific "pharmacy benefits manager" would be required to have the same specifications. A plan could not use its own experience to develop a better benefits package.

4. Fourth, the limitations on the terms of copayments and the days of drug supplies contained in HB 1332 are contrary to the provisions of the Medicare Part D prescription drug regulation relating to mail-order pharmacies, which expressly permits lower copayments for drugs obtained from a mail-order pharmacy.

The Medicare Part D drug benefit regulation provides:

> "(10) Level playing field between mailorder and network pharmacies. A Part D sponsor must permit its Part D plan enrollees to receive benefits, which may include a 90-day supply of covered Part D drugs, at any of its network pharmacies that are retail pharmacies. A Part D plan may require an enrollee obtaining a covered Part D drug at a network pharmacy that is a retail pharmacy to pay any higher cost-sharing applicable to that covered Part D drug at the network pharmacy that is a retail pharmacy instead of the cost-sharing applicable to that covered Part D drug at the network pharmacy that is a mailorder pharmacy."

70 Fed. Reg., No. 18, 4537 (January 28, 2005).

6. Tie-in sales. To the extent that a PBM is "steering" mail order business to a higher priced, wholly-owned mail order pharmacy, the PBM may be engaged in an illegal "tie-in" sale in violation of the antitrust laws. An unlawful "tie-in" occurs when a seller requires the purchaser to purchase a separate product from the seller that the buyer could obtain on better terms from an independent mail order pharmacy. Because coercive tie-in sales are already unlawful under the antitrust laws, no new law is required to prohibit this conduct.

4-7-05
Senator
Nethercutt

"The [Supreme] Court has viewed with particular suspicion state statutes requiring business operations to be performed in the home State that could more efficiently be performed elsewhere. Even where the State is pursuing a clearly legitimate local interest, this particular [economic] burden on commerce has been declared to be virtually per se illegal."

Pike v. Bruce Church, Inc., 397 U.S. 137, 145 (1970).

STATE OF NORTH DAKOTA
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Wayne Stenehjem
ATTORNEY GENERAL

April 11, 2005

Honorable Jim Kasper
House Chambers
600 E Boulevard Ave
Bismarck, ND 58505

Re: HB 1332, Mail Order Pharmacies and Medicare Part D

Dear Representative Kasper:

disregard page 1 most of page 2

You asked if the mail-order provisions of the House-passed version of HB 1332 conflict with the authority of a Medicare beneficiary to obtain prescription drugs from a mail-order pharmacy under the Medicare part D prescription drug benefit program. In my view, for the reasons explained below, there is a conflict between the provisions of House-passed version of HB 1332 and the federal Medicare prescription drug benefit program because the provisions of HB 1332 (which are found on page 4, lines 13-16 of the First Engrossment of HB 1332) prohibit offering any lower copayment for drugs purchased from a mail-order pharmacy, while the Medicare law expressly permits lower copayments. Therefore, there is a conflict between the provisions of the House-passed version of HB 1332 and federal law. But, the provisions of Medicare part D expressly preempt any conflicting state law, and, therefore, the restrictions on mail-order copayments contained in that version of HB 1332 are invalid.

The Medicare Part D drug benefit regulation provides, with respect to mail-order pharmacies:

> Level playing field between mailorder and network pharmacies. A Part D sponsor must permit its Part D plan enrollees to receive benefits, which may include a 90-day supply of covered Part D drugs, at any of its network pharmacies that are retail pharmacies. A Part D plan may require an enrollee obtaining a covered Part D drug at a network pharmacy that is a retail pharmacy to pay any higher cost-sharing applicable to that covered Part D drug at the network pharmacy that is a retail pharmacy instead of the cost-sharing applicable to that covered Part D drug at the network pharmacy that is a mailorder pharmacy.

70 Fed. Reg. 4537 (Jan. 28, 2005), to be codified at 42 C.F.R. § 423.120(a)(10).

Section 1860D-12(g) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 extends the State preemption provisions under section 1856(b)(3) of the Social Security Act, 42 U.S.C. § 1395w-26(b)(3), to Part D plans. 70 Fed. Reg. 4319 (Jan. 28, 2005) ("We [HHS] believe that because the Congress incorporated the same preemption standard into the Part D program, and because the Congress required the preemption rules to apply consistently in Parts C and D, this same reasoning would apply to Part D"). Section 1856(b)(3) provides:

> RELATION TO STATE LAWS.—The standards established under this part shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to MA [Medicare Advantage] plans which are offered by MA organizations under this part.

42 U.S.C. § 1395w-26(b)(3).

Therefore, because the regulation permits a Medicare part D (prescription drug plan) sponsor to permit lower copayments (or other lower cost-sharing) for a drug obtained through a mail order pharmacy, and because this regulation preempts state law, the restrictions in the House-passed version of HB 1332 are invalid. Because those restrictions are not contained in the Senate amendments to HB 1332, the Senate version of HB 1332 does not conflict with Medicare part D regulations.

These comments are limited to the effect of HB 1332 on Medicare Part D prescription drug plans, and should not be construed to conflict with the comments of the North Dakota Public Employees Retirement System regarding the effects of HB 1332 on non-Medicare mail order drug benefits.

Please let me know if you have any additional questions regarding this matter.

Sincerely,

Michael J. Mullen
Assistant Attorney General

mjm/vkk
cc: Wayne Stenehjem, Attorney General
Sandi Tabor, Deputy Attorney General

Mike Mueller, Health Dept

AMENDMENTS TO HOUSE BILL 1332

Page 2, after line 2, insert " 'De-identified information' means information from which the name, address, phone number, and other variables have been removed in accordance with requirements of title 45, Code of Federal Regulations, part 164, section 512, subsections (a) or (b)."

Page 3, line 1, after "secret" insert a quotation mark and remove "information" includes a formula, pattern, compilation, program," and insert "has the meaning set forth in subsection (4) of section 47-25.1-01."

Page 3, remove lines 2 through 8

Page 3, after line 8, insert " 'Utilization information' means de-identified information regarding the quantity of drug prescriptions dispensed to members of a health plan during a specified time period."

Renumber Accordingly

Dosch, Mark A.

From: Boehler, Gary W. [GBoehler@ThriftyWhite.com]

Sent: Wednesday, January 26, 2005 2:57 PM

To: Keiser, George J.; Johnson, Nancy; Amerman, Bill D.; Boe, Tracy L.; Clark, Dennis D.; Dietrich, Donald D.; Dosch, Mark A.; Ekstrom, Mary O.; Froseth, Glen A.; Kasper, Jim M.; Nottestad, Darrell D.; Ruby, Dan J.; Thorpe, Elwood C.; DVigessa@state.nd.us

Cc: phill@nodakpharmacy.com

Subject: HB 1332 Testimony 01-25-05

Good Afternoon Chairman Kaiser and IBL Committee Members:

I am most appreciative of the opportunity afforded for those of allowed to testify yesterday in support of H.B. 1332 which would require PBM transparency in North Dakota. It is a complex topic, and after hearing the opposition testify, I send this e-mail to provide some clarification and I believe misconceptions about certain statements made during that testimony.

The representative from Express Scripts stated that their annual net profit is 1.5%. What he failed to mention is that when Express Scripts calculates their net profits, included in those sales figures are all of the prescription transactions (for millions of prescriptions) from all pharmacies across the country that are contracted with Express Scripts. Those sales should not be calculated into their gross revenues, a practice for which Medco Health Solutions found themselves in trouble four or five years ago. By overstating sales, naturally their ending net profit will APPEAR to be smaller than what is reality. It's kind of strange that for a company only making 1.5% that their CEO makes $12,000,000 to $14,000,000 annually. His compensation is more than the combined total of 1,100 Thrifty White employees!

The representative from Express Scripts also stated during his testimony that his PBM does not require mandatory mail order. Again, what he failed to mention for those patients who may choose to have their maintenance fills done at a local community pharmacy, there is a disincentive to that patient by having to pay a higher copay at the local pharmacy. As was said during the proponents' testimony, it may an example of where the patient pays a $30 copay at a local pharmacy, but a lesser amount when using mail order. I also question his statement of them not having any mandatory mail order plans. In several instances, when our stores have attempted to fill a 90 day or 100 day supply for a patient, those prescriptions have been rejected with an over-utilization reject code.

The representative from Blue Cross Blue Shield ND challenged my statement about our cash and private charge prescriptions being filled at a generic rate 8.8% higher than third party by saying "it would be nice if they would work as hard on our third party patients." What he failed to say (through either smoke or naievete) and what really is fact is that when we attempt to fill a prescription for a generic that is not covered by Prime Therapeutics, that prescription is either rejected as non-formulary or the patient is penalized for taking a generic with a higher copay! Again, it points to the rebate dollars flowing back to the PBM from the brand name drug manufacturer. I failed to bring along a folder of examples not less than two inches thick of examples from Prime Therapeutics where claims that have been submitted for generics are either rejected or if accepted, the patient is penalized with a higher copay.

For the other representative from Blue Cross Blue Shield ND to say that purchasers of health care are intelligent, well informed, understanding purchasers is also an answer biased to their side. The purchasers only know what they are told. I have spoken both in person and over the phone to parties responsible for determining drug spend, and they are certainly intelligent people, but understand very little about how the system actually works. They are only told by the PBM what that PBM wants them to hear, and nothing more. As I stated during testimony plan sponsors I have spoken to are told by what percentage their upcoming premiums will rise and those projections are put into the next operating budget.

The other topic that was just barely touched upon was spread pricing (where the plan sponsor is charged more than what the pharmacy is paid for a prescription). The representative from Express Scripts painted a very simple picture, using the example that if a plan sponsor was willing to accept a 15% discount from average wholesale price (AWP) and Express Scripts contracted with a provider pharmacy to accept AWP – 17%, then Express

Scripts would keep the 2% "spread." Representative Kasper questioned Tom Christianson from BCBSND about them auditing Prime Therapeutics to make sure that Prime was returning the rebates to the plan sponsor (i.e., the fox guarding the henhouse). From my conversations with Prime Therapeutics and other PBMs here are questions that need to be asked in a manner that is so specific the PBMs in question cannot dodge the question and must answer truthfully.

1. Does Prime Therapeutics keep any amount of rebate received from drug manufacturers? If yes, how much? If not, do those rebates flow to BCBSND?
2. When BCBSND bills the plan sponsor for prescriptions, are 100% of the rebates passed back to the plan sponsor? If not, what percentage is kept by BCBSND? Is the plan sponsor aware of that percentage, and is in written in the contract?
3. Does Prime Therapeutics operate with more than one MAC (Maximum Allowable Cost) list? *Note: a MAC list is the listing of generic drugs that shows the cost per tablet or capsule paid by the PBM to the pharmacy.*
4. Does Prime Therapeutics have a different MAC list for its PRIMEMAIL mail order facility in Texas? If so, how does the list differ in the number of MAC items compared to the Prime Therapeutics MAC list? Is it more or less expansive? By how many items? Do the MAC prices per item differ? If so, are they higher or lower? Provide 20 examples. *My purpose here is to show that "spread pricing" occurs even within MAC lists, not just what the representative from Express Scripts stated during his testimony.*
5. Does Prime Therapeutics offer an incentive to the patient's copay for using mail order? If so, what is that incentive? Is one month's copay waived? If that copay is waived, does that waived copay then get billed to the plan sponsor? *This is being asked to show that the PBM is not absorbing the one month's copay, but the plan ends up paying for it! No savings to the employer.*
6. For the Express Scripts representative, he needs to be asked if their MAC list for regular community pharmacy is different for that of their own mail order facility. I believe the answer you will receive is that it is the same list (same number of items – approximately 1,150). However, the next question to ask him is that if the list is identical, are the MAC prices on both mail order and regular community pharmacy the same? If he is honest, he will answer that they are not. *The MAC prices on the mail order list are higher, so again, the PBM uses spread pricing to pay the pharmacy less than what is being charged to the employer, and Express Scripts pockets the margin.*
7. There are other examples of spread pricing where the pharmacy is paid a MAC price but the plan sponsor is charged a discount from the average wholesale price (AWP). Because generics often have a much higher difference between cost and average wholesale price, the PBM drives down the cost of the MAC price on the generic to the pharmacy but then bills the plan sponsor from AWP leaving a big spread for the PBM. Please allow me to illustrate with this example of a generic.

   *A generic has a cost of $10.00 per bottle of 100 and an average wholesale price (AWP of $22.00). The PBM has a maximum allowable cost (MAC) of $0.15 per tablet. For a pharmacy filling 60 tablets, that pharmacy will have a cost of $6.00 and will receive a payment from the PBM of $9.00 plus a dispensing fee of $2.25, for a total reimbursement to the pharmacy of $11.25, or a gross profit of $5.25. The cost to AWP spread on this item is ($22.00-$10.00)/$22.00, or 54.5%. Now, if the PBM has a contract with the plan sponsor to charge that plan AWP – 20% per tablet plus the dispensing fee, the calculations would be as follows: ($22.00 x 20%) x 0.6 + $2.25 = $15.33. *AWP is $22.00, 20% is the discount from AWP, 0.6 is 60% of 100 tablets dispensed, and $2.25 is the dispensing fee. In this scenario, the pharmacy received payment of $11.25, the plan sponsor was charged $15.33, the difference of $4.08 is the spread that the PBM keeps. The plan sponsor thinks that what the pharmacy is being reimbursed is what the plan sponsor is being charged. Nothing more than a smoke & mirrors game.*

If Tim Dickman, CEO of Prime Therapeutics, is such a proponent of being upfront about rebates and transparency, it is rather disturbing to me that four representatives from Blue Cross Blue Shield and Prime Therapeutics were at the hearing to present testimony against what he openly advocates. Were that truly Prime's goal, they would have endorsed the bill to try to gain more than the 80% market share they already have in North Dakota.

I have absolutely no doubt in my mind that PBMs are one of the driving forces in the excessively rising prescription drug costs because of kickbacks they extort from drug manufacturers. Manufacturers then simply raise their prices to cover their increased costs, since they also have shareholders who expect a return on their investments. I had lunch with a manufacturer's sales rep today, and I was told that his company has written

letters to several PBMs asking for huge sums of money back from the PBMs because the PBMs are not delivering on their promises to the manufacturers. In another article I read this week the president of a large regional drug chain said pharmaceutical manufacturers look at their pricing and at what they pay to PBMs and say "we are not getting our money's worth."

Until transparency is required by all PBMs, and until the current model that exists today in which PBMs demand money from drug manufacturers to be on a formulary is broken, the rapid spiral in drug costs will never go away. PBMs need to go back to being pharmacy benefit administrators, not middlemen, and return to the original model they began with in the 1980's with a fee for service structure.

My apologies for this being so lengthy; however, until the real story is told and understood, the PBMs will continue their shell game intentionally designed to create confusion and lack of clarity.

Because of the potential for retaliation from the PBM (increased audits, threats of canceling contracts) I ask you to maintain anonymity as to where you received these questions to be asked.

Thank you all again for the opportunity to testify and provide this additional documentation.

Sincerely,

Gary W. Boehler
Executive V.P. of Pharmacy
Thrifty White Pharmacy
6901 E. Fish Lake Road #118
Maple Grove, MN 55369
Phone (763) 513-4357
Fax (763) 513-4388
Email: gboehler@thriftywhite.com

Vigesaa, Donald W.

From: Vigesaa, Dan
Sent: Wednesday, February 02, 2005 2:13 PM
To: Vigesaa, Donald W.
Subject: FW: HB 1332 Testimony 01-25-05

----- Forwarded by Dan Vigesaa/DOT/NoDak on 02/02/2005 02:17 PM -----

"Boehler, Gary W." <GBoehler@ThriftyWhite.com>
01/26/2005 03:00 PM

To: <DVigesaa@state.nd.us>
cc:
Subject: FW: HB 1332 Testimony 01-25-05

Dear Representative Vigesaa,

I am sending this e-mail to you a second. I misspelled your name during my first transmission, and for that I do apologize.

Sincerely,

Gary W. Boehler
Executive V.P. of Pharmacy
Thrifty White Pharmacy
6901 E. Fish Lake Road #118
Maple Grove, MN 55369
Phone (763) 513-4357
Fax (763) 513-4388
Email: gboehler@thriftywhite.com
-----Original Message-----
From: Boehler, Gary W.
Sent: Wednesday, January 26, 2005 2:57 PM
To: 'gkeiser@state.nd.us'; 'njohnson@state.nd.us'; 'bamerman@state.nd.us'; 'tboe@state.nd.us'; 'dclark@state.nd.us'; 'ddietrich@state.nd.us'; 'mdosch@state.nd.us'; 'mekstrom@state.nd.us'; 'gfroseth@state.nd.us'; 'jkasper@state.nd.us'; 'dnottestad@state.nd.us'; 'druby@state.nd.us'; 'ethorpe@state.nd.us'; 'DVigessa@state.nd.us'
Cc: 'phill@nodakpharmacy.com'
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Sincerely,

Gary W. Boehler
Executive V.P. of Pharmacy
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6901 E. Fish Lake Road #118
Maple Grove, MN 55369
Phone (763) 513-4357
Fax (763) 513-4388
Email: gboehler@thriftywhite.com

PRIME -

Phone:
Fax:

WITH A COMMITMENT TO THE
COMMUNITIES WE SERVE.

November 30, 2004

Rick Kupchella
Kare 11 News
8811 Olson Memorial Highway
Golden Valley, MN 55427

Dear Rick:

I have just finished listening to all of the Kare 11 Extra segments you have covered in recent broadcasts regarding the costs of prescription drugs and the middlemen, or PBMs.

Even though it has been difficult to coordinate schedules, I will continue to send information on PBMs that show examples of how they oftentimes do not work in the best interest of the plan recipient or plan sponsors being represented.

Today I am sending two examples, again both of which come from Prime Therapeutics, the PBM that told you they have complete disclosure with their plan participants.

1. In this first example, one of our pharmacies attempted to fill a prescription for the generic equivalent of Glucophage XR 750 mg., a drug used to treat diabetes. Prime allowed the brand name to be dispensed, but when our pharmacist attempted to dispense the generic equivalent (metformin XR 750 mg.), the claim was rejected as being non-formulary. *See exhibits A and B attached.*

In this example, a less costly generic alternative was denied and as a result the cost to the patient winds up being $0.22 per dose higher because the more expensive brand had to be dispensed.

2. In the second example (exhibit C), the drug Plendil 5 mg., used to treat high blood pressure, was dispensed. In this scenario, the patient could choose either the brand name or the generic. If the generic was selected, the copay for the patient rose from $43.96 to $69.24, a $25.28 disincentive for the patient! On the other hand, by selecting the brand name drug Plendil to be dispensed, the patient copay was less by $25.28; however, the cost to the plan sponsor rose from $44.24 to $86.88, or $42.64 (96.4%). And all of this an example of how to save a plan sponsor money?

Some pointed questions to ask Prime Therapeutics include the amount of the kickback received from AstraZeneca. Additionally, what, if any of the kickback was passed back

to the plan sponsor? Did that cover all of the $42.64 that the plan sponsor had to spend for this one prescription?

I realize fully that these are only two examples of PBM mismanagement. There are many more where we are not made aware.

As Stephen Schondelmeyer stated so accurately, all of these negotiations are shrouded in cloaks of secrecy between PBMs and manufacturers, and neither the plan recipient nor the plan sponsor are made privy to any of the details.

Mark Merritt should have been hanging his head in shame during your interviews with him. I do have to admit he is good at "dodging the bullet."

Thank you for your time. As I find more examples I will forward them to you, and if I may try to answer more questions for you, please don't hesitate to call.

Sincerely,

[redacted], R.Ph.
[redacted]
[redacted], Inc.
[redacted]

Attachments

RickKarel1(2)

DETAIL FOR RX #[redacted] FILL 00 PAY PLAN IS 24-262 RETRY COUNT IS 1

Patient Name [redacted] Number 15141

	BILLED	PAID		
	------	------		
Cost	39.90	34.31	ACCUM DEDUCT AMT	.00
Fee	7.00	2.10	REMAIN DEDUCT AMT	.00
Tax		.69	REMAIN BENEFIT AMT	99999.99
Other Insur			PERIOD DEDUCT AMT	.00
Co-Pay	.00	37.10	COPAY CO-INSURANCE	37.10
Total	46.90	.00	BENEFITS EXCEEDED	.00
			INCENTIVE FEE PAID	.00
			REIMBURSEMENT BASIS	03

REFERENCE 43295960575000 **[CO-PAY PRICE USED]**

0_

27/2004 11:52:35 AM TigerTerm - Thrifty

- Brand name Glucophage XR accepted.
- COST IS $0.22 HIGHER PER TABLET.
- FOR 100 TABLETS COST TO PLAN IS $22.00 MORE (IN THIS CASE HIGHER PATIENT COPAY)
- PATIENT COPAY ON BRAND IS GENERALLY HIGHER UNLESS PBM HAS A DISINCENTIVE BY HAVING A HIGHER GENERIC COPAY.

EXHIBIT A

CLAIM HAS BEEN REJECTED

Patient Name [redacted]
Primary Plan 24-262
BC/BS GOLDNET
Desk 000-000-0000

Group GOLDNET
Cardholder [redacted]
ID # [redacted]
Person 00 Relationship SELF

Drug METFORMIN HCL 750 MG ER TABLET
NDC 00555-0107-02
Quantity 30.0
Days Supply 30

Rx-Fill [redacted]
Last Fill 11/24/04
Orig Date 11/24/04
Dr [redacted]

Messages:
F-generic metformin,metformin extended-release 500mg;Glucophage XR 750mg
Non-Formulary Drug. Contact Prescriber

70 NDC NOT COVERED

F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
Accept/ Go On		Fix TL/ Resend		Edit/ Resend			Delete	Convert to P/O w/ Cash	

Generic for Glucophage-XR rejected as being non-formulary, yet is $0.22 less costly per tablet.

This is a relatively new generic and will likely come down in cost, thus widening the gap between brand and generic even more.

EXHIBIT B

Letter to the Editor :

Mail order prescription:

Do they really save you money? I had to find the answer to the question. I had 3 prescriptions filled at a local pharmacy. I pay a $15.00 co-pay per one month supply or 3 co-pays ($45.00) for 3 months supply The results are listed next

medication	qty	plan paid	member paid
alprazolam 0.5 generic xanax	270	$00.00	$21.19
doxazosin 2mg generic cardura	90	$00.00	$18.27
Ibuprofen 800mg generic motrin	270	$00.00	$19.35
	total	$00.00	$58.81

I then mailed the same 3 prescriptions to Prime Therapeutics in Dallas Texas. I can get a 3 month supply for 2 co-pays (30.00) therefor saving me money. The results are listed

Alprazolam 0.5	270	$00.00	$19.06
Doxazosin 2mg	90	$8.34	$30.00
Ibuuproen 800 mg	270	$7.03	$30.00
	Total	$15.46	$79.06

The member paid $20.25 more to Prime Therapeutics than to the local drug store. Prime Therapeutics also billed the plan $15.46. The local drug store billed $00.00 The answer to my original question is self explanatory. The question I can't answer is why would anyone promote mail order when it cost the plan and member more money? Prime Therapeutics collected a total of $35.71 more than the local pharmacy. Where is the savings they say I should receive by using their service? The issue is one of patient choice. I am able to select where I buy my medication. I am not opposed to mail order prescriptions, but I am opposed to forcing patients to us mail order service. This practice eliminates patient choice and deprives them of patient counseling. At worst it is unfair and anticompetive as the above comparison illustrates

Arnold S Zimmerman
Pharmacist
Marshall, MN 56258

Testimony on HB 1332 Tony Welder Pharmacist Bernardt
January 25, 2005, House Committee on Industry, Business and Labor
Mr. George Keiser, Chairman

Mr. Chairman and members of the committee.

I am here to testify in favor of House Bill 1332, regarding Pharmacy Benefit Managers. Similar bills have been introduced in 21 states. South Dakota passed a similar bill in their last session.

This bill concerns the transparency of transactions of prescription claims by PBM's. It affects employers who provide coverage of prescription drugs to their employees. This will allow that payer to compare payments to pharmacies and charges of the same prescription to the employer. I think employers should have the ability to see both sides of these transactions. The difference is sometimes called the "spread" and this spread can sometimes be significant. I think the employer should know when the pharmacy is paid 15 dollars for a prescription and the payer is being charged 115 dollars.

The other major concern is the switching of drugs by the PBM's according to their formulary list, which are driven by rebates from manufacturers. This involves calling the patients and/or their physician and asking them to change the prescription to a drug different than the original. If the patient or doctor doesn't allow that change, most likely the patient will be charged a much higher co-pay. At times, this may involve changing a prescription which can be filled with a generic drug to a higher priced brand name. Generally, generic manufacturers do not pay rebates. PBM's and their mail order operations have a lower utilization rate of generics than community pharmacies have.

Pharmacy Benefit Managers typically offer pharmacies a take it or leave it contract with a reimbursement schedule that is sometimes below the cost of operating a business. There is no negotiating these contracts. While that is not the primary concern here, it has the power of decreasing access to pharmacies in North Dakota, so it can become a patient-care issue.

There are other concerns with this unregulated industry.

Some of the activities we deal with on an almost daily basis include very lengthy phone times "on hold" to get a rejected claim resolved. The other day, one of my pharmacists was on hold because of a rejected claim. Prime Therapeutics, a PBM, had changed identification numbers and had incorrectly re-keyed the birth date of a child. The child was sick and her mother had to go back to work. We finally got a real person on line and had to run the claim with the incorrect birth date. Time on hold? 43 minutes. Then the mother had to call Blue Cross to get the birth dates corrected.

We just heard that some of the so called help desks are being operated from India.

When the Medicare discount program was announced, Medco, a very large PBM, predicted that they would get about 54% of the prescriptions switched to mail order. In my many years of pharmacy practice, I judge this to be a very poor way of serving patients. Most people don't like it, particularly if mail order is mandated. Many problems can be solved with face-to-face consults with a pharmacist, especially with the elderly who need help with multiple prescription therapy.

As an aside, Medco raised their transaction fee charges to pharmacies from 3 cents to 10 cents recently. While that doesn't sound like much, it raised our fees 333% and will add from 75 million to 100 million dollars to their bottom line. An official said they hadn't taken an increase for a while, so they just decided to do it.

The PBM's had a good role to play originally, and still have a necessary role. They made it possible to transmit claims electronically and that was a huge advance in billing claims, making it efficient for the pharmacy and the patient. Unfortunately, they got into rebates, formularies and switching prescriptions.

PBM's boast that they save money in the prescription market by negotiating with pharmaceutical manufacturers. Just think about how much prescription prices have gone up the last few years.

In conclusion, disclosure and transparency is an important consideration to both patients and our employers.

More important, the ultimate decision for the choice of medication prescribed should be between the patient and the physician. That choice should not be affected by the money paid in rebates to someone who is more concerned about their financial report.

Tony Welder

Senate IBL Committee
Senator Duane Mutch, Chair
March 7, 2005

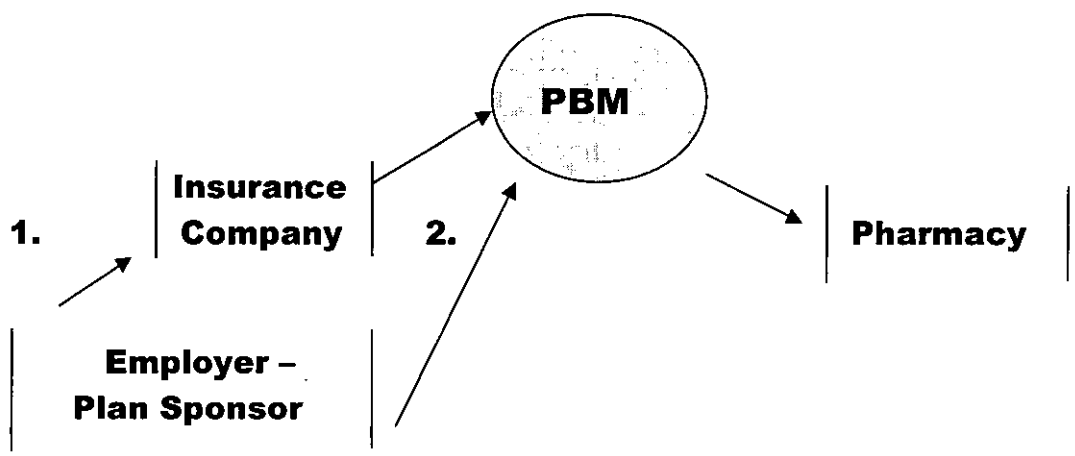
Testimony in Support of HB 1332

Good morning Chairman Mutch and committee members. My name is Bob Treitline, and I am a licensed pharmacist and owner of a pharmacy in Dickinson, North Dakota. It is my pleasure to be here this morning to provide on overview of how prescription drug claims are processed and the role of PBMs. My intent is to provide background information that helps us understand why HB 1332 is so important to patients all across North Dakota.

First let me say from a professional point of view, HB 1332 is about patient care – the focus of pharmacy practice. I can tell you from personal experience that the rising cost of drugs is keeping more and more folks from taking the very medications that would improve their quality of life and lower the long term costs of providing healthcare. I've actually given drugs to an elderly woman who was forced to choose between her medications or food, and this is not the life we want for our neighbors and friends.

HB 1332 can provide some relief in terms price, and by making drugs more affordable you are giving more people a chance to purchase and take the medications they need.

Here is basically how prescription drug claims are processed:



Pharmacy benefit managers – or PBMs – are largely not recognized by employers, but they have a tremendous impact on health care and decisions about what drugs are purchased. Sometimes a PBM operates on behalf of an employer and they process claims *directly (2)* for the employer, but in North Dakota the PBM usually works *through an insurance company (1)* that provides a healthcare plan for the employer and a drug benefit is part of the total plan.

The original purpose of PBMs was straightforward- get paid a service fee for processing claims. A patient gets a prescription filled at the pharmacy and the PBM pays the pharmacy for providing the medication, then turns around and charges the employer for the cost of that transaction. So, in fact, they were data processors.

Today, PBMs are much more complex and use various strategies to try to control costs while

generating profits for themselves. As noted in the attached article, the CEO of a PBM operating in our region said several questionable business practices are used by PBMs a profit centers [*1]. Some of these common business practices add to consumer costs and may include:

1. **Rebates & discounts** negotiated with drug manufacturers but not entirely passed on to the employer, who is sponsoring the plan and paying the premiums for employees.

   PBMs establish the **preferred drug lists**, or formularies, based on the manufacturers offering the best rebates and discounts and not necessarily on which products have the most health benefit to patients. Drug manufacturers compete to have their products included because the formularies drive the market to prescribe and purchase specific products. This is done by discriminating co-pays paid by the patient.

2. **Drug switching** – changing products on the list of preferred drugs that are covered by the plan in order to receive a higher rebate from the manufacturer, which often costs the patient more.

3. **Disguise rebate revenues as other types of funds** – some PBMs reclassify rebates using categories like education grants, research, advertising, promotion, access fees, formulary management fees and data collection fees. This practice allows the PBM to 'hide' these funds from the plan sponsor and keep most of them.

4. **Spread pricing** – this is the difference between the amount reimbursed to the pharmacy for filling a prescription and the amount charged to the employer, which is higher and the PBM retains the difference.

5. **Mail order pricing schemes and incentives** – major PBMs own their own mail order pharmacies, and use various strategies to drive consumers to their pharmacy rather than using the local pharmacy. For example:

   - **Different MAC lists** - generic drugs have a pricing list called MAC or Maximum Allowable Cost. The PBM contract to the pharmacy (which is NOT negotiated …the pharmacy can simply take it or leave it) includes a MAC price list with 1100 products and prices. The PBM's mail order pharmacy has a MAC list with only 165 products. With 1100 products there is usually a product available, but with only 165 products there is often not a generic option, so the PBM mail order pharmacy can fill the request with another drug and charge considerably more to the patient and the plan sponsor and keep the payments.

   Incentives to use mail order – the PBM can include lower or fewer patient co-payments and 90 day supplies to entice patients to use their mail order rather than the local pharmacy. At the same time the PBM contract to the local pharmacy limits their ability to compete by mandating one co-pay for each 30-day fill, and only allowing fills up to 30 days.

1. Quote in Wall Street Journal by Tim Dickman, CEO Prime Therapeutics, a PBM owned by BCBS - is attached

- **Less cost to patient but more charged to plan sponsor** – the example below is a real one where the consumer purchased the same three medications locally and again through Prime Therapeutics mail order [*2]. As you can see, mail order may appear to be a good deal but ended up costing more.

At the local pharmacy -

Medication	Quantity	Plan Paid	Member Paid
Alprazolam 0.5	270	0	$21.19
Doxazosin 2 mg	90	0	$18.27
Ibuprofen 800 mg	270	0	$19.35
	Total	0	$58.81

Patient paid 3 co-pays at $15 for each one month supply (total $45).

Through Prime Therapeutics mail order pharmacy in Texas -

Medication	Quantity	Plan Paid	Member Paid
Alprazolam 0.5	270	0	$19.06
Doxazosin 2 mg	90	$8.34	$30.00
Ibuprofen 800 mg	270	$7.03	$30.00
	Total	$15.46	$79.06

Patient paid 2 co-pays, or $30 ($15 incentive to use mail order.)

RESULTS:
Mail order cost the member and plan $35.71 more than the local pharmacy.

- **Repackaging licenses at mail order facilities** – Many PBMs buy drugs in bulk purchases then "repackage" into smaller units to dispense to patients. Their license allows them to assign new codes to the smaller packages, which correspond to a higher price for the smaller quantities of product. Typically the difference between what was paid for the product and what is charged to the consumer is retained by the PBM, rather then passed on. In fact, no one even realizes this ever happened!

6. **Selling patient and utilization data** – in the business of drugs, information equals revenue. Every drug manufacturer would like to know about the demographics and use patterns of each plan's members. Many PBMs sell this data and retain those funds also.

The House IBL committee sat through many hours of detailed explanation on these various pricing strategies, but I think the general concern is clear -- PBMs are able to hide numerous revenue streams because they are NOT regulated. They are not held accountable for the contributions they make to the increasing costs of prescription medications. HB 1332 not only recognizes PBMs and supports their continued role as proficient claims processors, but requires that they accept responsibility and begin to operate in fair and equitable ways to deliver lower drug costs to consumers.

2. Letter to the Editor from Arnold Zimmerman showing comparison of local vs. mail order purchase – is attached

You should know three important facts about HB 1332:

- it does NOT have a financial advantage for me. Whether this bill passes or not will not affect the bottom line at my pharmacy. Like any other small business owner in North Dakota, it would provide new opportunities to lower the cost of healthcare coverage for my employees.

- it does provide all North Dakotans with the freedom of choice to get their medications from the pharmacy they prefer without any financial disadvantages to anyone

- HB 1332 can potentially keep millions of dollars IN our state's economy by not allowing PBMs to mandate use of their mail order facilities in other states.

I ask for your support of HB 1332, and I will answer any questions you may have at this time.

Bob Treitline, RPh
ND Pharmacy
Dickinson, ND 58601
(701) 225-4434

Senate IBL Committee
Senator Duane Mutch, Chair
March 21, 2005

Testimony in Support of HB 1332

Good morning Chairman Mutch and committee members. My name is Bob Treitline, and I am a licensed Pharmacist and owner of ND Pharmacy Inc. in Dickinson, North Dakota.

First let me say from my professional point of view, HB 1332 is about two issues, 1) transparence of the PBM's rebates and discounts and 2) patient care.

It has been said PBM's perform several important functions, below is a list of at least four of these functions.

1) To establish pharmacy networks throughout the state for the benefit of the insured.
2) To process drug claims.
3) To assist the health plan in the development of a drug formulary (a list of preferred drugs included in the benefit plans).
4) To apply and secure drug rebates and volume discounts from pharmaceutical manufacturers.

These first two items are what PBM's do and do very well. Items #3 and #4 do also, but there are many questions associated with these two items. Are the formularies in the best interest for the patient and do the rebates and discounts get to the people they are suppose to help??

I would like to address some issues concerning patient care. In my opinion there are many factors that put patients at risk when dealing with health care plans through the PBM's.

1) Many drug benefit plans designed by PBM's create drug formularies or preferred drug lists. They, the PBM's, say these formularies reduce cost to the patient and/or the plan sponsor through rebates and discounts from the drug manufactures .This is were transparency is essential. Are the patients and/or plan sponsors getting these rebates or discounts?? They may get a small potion of these savings but here is what they, the patients, may be giving up. In effect, the PBM's through discriminatory co-payments for non-formulary drugs , many times force patients to go back to their physician and ask for the formulary drug so they can afford the co-payment. This type maneuvering is basically a therapeutic interchange, forcing the physician to prescribe a drug he or she did not choose as first line therapy for their patient. (Patient may be at risk in the name of saving $$). I can tell you from calls we make on a weekly basis the physicians hate this. I have had many comments by physicians saying I don't know why they (PBM's) just don't write the prescription for me and take the liability with it.

The next issue of patient concern of mine is the mail order situation. Many PBM's either mandate or impose such discriminatory co-payments that the patients have no choice but to use mail order in order to afford their medication. There are may risks for patients using mail order.

1) There local pharmacy would not have a complete history of medication on the patient, therefore would not be able to effectively watch for potential interactions such as drug to drug or drug to disease interactions.

2) Many times patients complain of not receiving medication in a timely manor.

3) Patients have told of medications being shipped and exposed to adverse weather conditions which may compromise the effectiveness of the medication. (exp: extreme heat or freezing).

With all these potential risks they, the PBM's , still expose the very people they are suppose to help to these types of situations in the name of saving money, that they the people may or may not benefit from.

I know this is a very complicated and confusing issue ,but this type of legislation has a chance to begin to improve cost to the patient and/or sponsor companies and improve patient care. Again, I urge a do pass on HB 1332!! Thank you.

I would be happy to answer and questions you might have.

Bob Treitline

Senate IBL Committee
Senator Duane Mutch, Chairman
March 21, 2005

SUPPORT OF HB 1332

Mr. Chairman and members of the committee, my name is Arlin Fisher and I am here in support of House Bill 1332. You've spent a lot of time today trying to understand the details of the money side of this issue, and I must admit it is very complex. The finances are important, especially if you plan to lower the cost of drugs so more people can afford them.

That's the side I come from... the "people" side or the "consumer" view. I am here today because I don't want you to think that the problems you've heard about today only happen somewhere else. I am here to share a personal experience ...it happened right here in North Dakota and you are in a position to make sure it doesn't happen to anyone else.

My wife, Megan, and I were expecting twins last summer and to keep this fragile pregnancy in tact for as long as possible Megan had to, religiously, take a daily medication prescribed by her OBGYN. Our healthcare plan mandates mail order, so we got a little nervous when Megan's refill hadn't arrived on August 30 and she only had ten days left.

Missing one day of this prescription meant contractions could start and our twins would be born too soon, so I placed another order for Brethine on August 30 with our PBM and we were promised that the refill would arrive within 8 days. Four days to go and still no medication from the PBM, so I called again. I am told the "meds are in the mail." Two days to go and we are worried, so we call Megans doctor who has the local pharmacy fill a five-day supply, expecting the refill from the PBM to arrive soon. I went to the pharmacy and personally paid for the 5-day refill.

On September 10, the last day of Megan's current supply, a letter arrives from the PBM saying they could not reach her doctor to verify the refilled prescription so it was not sent. Knowing the time-sensitive nature of Megan's condition and the critical need for the medication to keep her pregnancy in tact, our PBM did not bother to follow through and guarantee the refill was sent and received.

We were never notified that the PBM would be communicating with the doctor to gain approval on a refill, we were simply told it had been taken care of. As you can imagine, this created a great deal of stress. Again, we called the doctor who called the PBM himself to arrange for the prescription to be sent, and I went back to the local pharmacy for a few more days supply.

By mid-September the refill had still not arrived as promised, so once AGAIN I called the PBM and was told that Megan's doctor had cancelled the refill so the medication had not been sent. We called the doctor who absolutely denied any such

conversation, and contacted the local pharmacy for a third time to be sure I could pick up additional doses for Megan.

At this point I contacted the home office of my employer – the sponsor of my family's healthcare plan – and explained what had been going on. Within the hour, the human services department at Microsoft in Seattle had made the necessary calls to help us with this crisis. We were granted an exemption from mail order, so Megan's prescription could be filled locally until the babies were born. That same day the local pharmacy issued me a refund check for $157 to reimburse me for the ten days of medication I had been forced to purchase.

Fortunately, Megan and I were able to make it through this crisis and had the finances to pay for Megan's medications. Jerrod and Jacob were born about 2 months ago – just a couple weeks shy of a full term. They are doing very well, thank goodness.

We would prefer to go to the local pharmacy for many reasons, but we don't have the freedom to make that choice. Megan and I hope as you deliberate on this issue you will consider more than just money issues, and remember the impact on patients. In this case, the PBM made choices for us that put our babies' lives at risk.

I know beyond a doubt that PBMs operating in North Dakota can make choices for us - about the drugs and services they provide - that are not based on our the health and welfare. I understand that you represent me, and Megan and our children and you are responsible for making decisions to protect us and others from situations like this. So I strongly urge you to support HB 1332, and make these companies more responsible for the quality of patient care in our state.

Thank you for your support.

Arlin, Megan, Jerrod and Jacob Fisher
Fargo, ND

March 20, 2005

HB 1332

To whom it may concern,

My name is Valerie J. Geisinger and I live in Bottineau, ND. I am very disappointed in the new prescription policies that Tri-West has implemented since last fall. My husband is AGR in the North Dakota National Guard. He was stationed at Bottineau in December of 2000 which is considered a Prime Remote Area since it is greater than 50 miles from a military base. In the past we have always been able to pick up our prescriptions at our local pharmacy and send in the signed receipts and were reimbursed the amount with the exception of the $3.00 (generic) or $9.00 (name brand) co-pay. We were able to hold on to our receipts and send them in annually for reimbursement. The last time we did this we found out that things have changed. Tri-Care handed over their contract to Express Scripts we are no longer able to do this and we are now stuck with some VERY undesirable choices.

#1 Pay for our prescriptions in full until we meet a $300.00 deductible

#2 Go through the mail order pharmacy

#3 Drive 90 miles round trip to the nearest Tri-Care participating pharmacy which is in Rugby, ND.

First of all let me state that I would have no problem with this ***IF*** it was implemented all the way across the board. If this was a policy for ALL Tri-Care users. But it isn't. The only ones that are affected are the ones in the Prime Remote Area's. Just as my husband and I are affected so are others in his unit. SFC Childs from Cando and SSG Bartlett also from Cando and many others that are stationed in small towns. I want to know why it is that we are being punished for living in a remote area. Since this has happened I have had a chance to visit with one of our local pharmacist and find out why it is that they have not become a Tri-Care participating pharmacy. He has tried many times and has more or less been shut out and turned down. This is not right! Why shouldn't we get the same benefits that someone who lives in a larger town gets. Obviously the network that Express Scripts claims they have is NOT big enough.

Now to address our options.

#1- Pay the first $300.00 for our medication before we have some type of reimbursement. Why should we have to pay $300.00 first to have the same benefits of someone living in a town with a participating pharmacy? Why should we be penalized for that?

#2 Go through the mail order pharmacy. I believe this has to be my biggest concern. Mail order pharmacy is fine if it works the way it is suppose to. I am on 2 different medications that I take daily. They are both for Allergies. I have year round allergies so I take them year round. If I don't take them regularly then I end up with severe sinus infections that many times have drained back behind my ear drums. This is extremely painful. This pain only gets worse for the first couple of days of starting my antibiotics I can't possibly imagine what it would be like if I had to wait any longer before any relief was to begin. If a person is bad enough to be put on antibiotics then I don't believe that it would be a positive thing to make them wait for their medication to arrive in the mail. First of all there is NO guarantee that it will arrive in the mail. But second how much worse can the condition get while they are waiting.

#3 Drive 90 miles to pick up a prescription. Now this is also something that is possible for us but not all the time. Since we do live in the North and we do get extreme weather the roads are not always suitable for driving. This again leads me back to my explanation of # 3. Now if the roads are good then that means that we must take off work and now your talking about lost wages plus the cost for gas. Who is going to reimburses us for that?

I think that this bill needs to be looked at again. There are many inconveniences occurring with this that I believe are very unnecessary. I believe it to be very prejudice against the remote area's. In a bad situation ordering your prescriptions through the mail could be the difference between life or death.

Thank You

Valerie J. Geisinger

Valerie J. Geisinger

Geisinger, David SSG NDARNG

From: Dave and Val Geisinger
Sent: Tuesday, December 28, 2004 1:25 PM
To: david.geisinger@nd.ngb.army.mil
Subject: Fw: Pharmacy for tri care prime remote

----- Original Message -----
From: Humphrey, Richard, CON, OASD(HA)/TMA
To: geisinger@srt.com
Sent: Tuesday, December 28, 2004 8:30 AM
Subject: RE: Pharmacy for tri care prime remote

SSG Geisinger,

By using a non-network pharmacy, you will have a deductible and cost share per fiscal year and pay either $9 or 20% whichever is greater. This is the law. This can only be changed by a new law.
I can not say what the previous contract was or was not doing. I do know this contractor, Express Scripts, is being held to the rules.
I can only suggest you contact TRiWest Healthcare, your Regional Office, @ 888-874-9378 and try to get them to get a network pharmacy in the area.

Richard - TRICARE

-----Original Message-----
From: Dave and Val Geisinger [mailto:geisinger@srt.com]
Sent: Monday, December 27, 2004 11:47 AM
To: Web Questions
Subject: Pharmacy for tri care prime remote

To whom it may concern

My name is SSG David J. Geisinger (501-90-3397)
I am stationed in Bottineau ND 58318 which is a remote area with no participating pharmacy within the mileage range. The closest participating Pharmacy is 45 miles away in Rugby, ND 58368. In the past I just picked up my medications locally here in Bottineau and sent in my receipt in and I was reimbursed all but my co pay. Now they are Appling a deductible on my medication of $150.00 per person and $300.00 per family. In the past there was no deductible for active duty personal for pharmacy in Tri Care Prime Remote. Has this changed? and if it has this means I have to drive 90 miles round trip just to pickup antibiotics for myself and my dependents. I feel that I am being penalized for being stationed in a remote area. I don't feel this is fare. I have made many phone calls and nobody can seem to give me a straight answer. And most don't know anything about Tri Care prime Remote. I understand the mail order process, but I am questioning the antibiotics that a person needs right away. I don't have the time to take off from work to drive 90 miles round trip to pick this medication up for myself and my depends. There is a problem here and it need to be fixed. Please get back with me as soon as you can. My office phone (701)228-3295 or my Home Phone (701)228-3494

Sincerly

SSG David J. Geisinger

KENT CONRAD
NORTH DAKOTA

http://conrad.senate.gov

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COMMITTEES:
BUDGET, RANKING MEMBER
FINANCE
INDIAN AFFAIRS
AGRICULTURE, NUTRITION, AND FORESTRY

United States Senate

January 11, 2005

STATE OFFICES:

1-800-223-4457

FEDERAL BUILDING
220 EAST ROSSER AVENUE, ROOM 228
BISMARCK, ND 58501-3866
(701) 258-4648

FEDERAL BUILDING
657 2ND AVENUE NORTH, ROOM 306
FARGO, ND 58102-4727
(701) 232-8030

FEDERAL BUILDING
102 NORTH 4TH STREET, SUITE 104
GRAND FORKS, ND 58203-3738
(701) 775-9601

FEDERAL BUILDING
100 1ST STREET, S.W., ROOM 105
MINOT, ND 58701-3846
(701) 852-0703

Note:
Tricare is administed by Expresscripts.
We need your support on HB 1332 or
those type of letters will become all too common.

Kenneth Fix
711 Kersten Street
Bottineau, ND 58318-1435

Dear Kenneth:

I am terribly sorry that I am unable to help you and the retired military members in your community with the reimbursement issue through TRICARE. The Department of Defense negotiated the reimbursement rate for the participating network and encourages the use of mail order for those who do not live near a participating pharmacy.

In rural North Dakota this is a real problem, especially for retirees who wish to support their local businesses. I have forwarded this concern to the Senators and was assured they will keep this in mind when legislation dealing with TRICARE comes before Congress.

Sincerely,

Gail

Gail Bergstad
State Representative for
Senator Kent Conrad and
Senator Byron L. Dorgan

GB:min

Bottineau Clinic Pharmacy
314 Ohmer Street
Bottineau, ND 58318

Medco Health Solutions, Inc.
100 Parsons Pond Drive
Franklin Lakes, NJ 07417
www.medcohealth.com

medcohealth
live life well

fax

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To: **Ken Fix**
Bottineau Clinic Pharmacy
35 00318

Fax: **701-228-5827**

Date: **5/20/2004**

Re: Medco Health
Provider Pharmacy Application

Thank you for your interest in becoming a Medco Health Provider Pharmacy. In order to begin the application process, we will need you to provide the following items:

- A nonrefundable check in the amount of $50 for the application fee. Please include your NCPDP number on the check and make payable to "Medco Health" and mail it to:

  Medco Health Solutions
  100 Parsons Pond Dr. (MS E2-6)
  Franklin Lakes, NJ 07417
  Attn: Craig Falberg

- A business card or sheet of letterhead if available
- A pharmacy label with your preprinted pharmacy name and address
- Your pharmacy website, if applicable
- A mailing address where we can send your application materials

Upon receipt of these items, we will mail the application materials to you. If you have any questions, please call 1 800 530-3755 or 1 201 269-3736. Thank you for your interest in becoming part of the Medco Health network of provider pharmacies.

Pharmacy Administration & Contracting
Medco Health

HB 1332

Thank you for the opportunity to tell my story. My name is Trudy Lehmann, I live in Bottineau with my husband and two sons. I also have a daughter attending college at UND. I have had high blood pressure since the birth of my children and I have been taking medication to control it for about 7 years. I tried several medications before finding the one that worked for me which was Atacand. In January of 2004 I was notified that due to BCBS I would be unable to continue taking Atacand. I was prescribed several different medications over the last year and 3 months, none of which have been able to control my high blood pressure.

After trying several medications my doctor wrote a letter to BCBS telling them that I had already tried several medications and none were controlling my blood pressure and asked that I be able to continue taking Atacand, but BCBS denied her request. Again she began trying to find something that would work for me, but as recently as March 11, 2005 I am starting a different medication. Once again I can already tell this drug is not going to work either as in the last week I have been experiencing severe headaches.

A couple of months ago a medication I was taking resulted in a trip in the middle of the night to the emergency room as a result of depleting my potassium level to a dangerously low number for which I was supposed to be hospitalized to receive potassium by IV, but I asked not to be admitted to the hospital as my sons were very upset by what has happened and I did not want to distress them any further. I was started on a dose of potassium which I am still taking today. After 4 appointments and 4 blood tests I was taken off the blood pressure medication because my potassium level is still too low.

If I had been allowed to stay on Atacand I would have continued with my appointment every six months and renewed my prescription, but due to BCBS discontinuing that medication it has cost me and my insurance company a lot of money. I would estimate in the past 15 months I have tried between 15 and 20 different medications, none of which have worked for me. This has resulted in a vicious cycle of doctor appointments to try and find a medication that does work and several changes in medications which resulted in taking a

prescription for a short term finding out it was not working so I would try something new and throw away the unused portion. This is costing both myself and my insurance company money, but more importantly for me has seriously upset my life and my health in the last year and several months. I am extremely upset that a insurance company can make decisions about my life and my health which can drag out in excess of a year of trial and error and still have no resolution.

I have been very patient with this process, but I am not going to continue my patience any longer. I have an appointment in April at which time I am going to ask my doctor to write to you once again and request that I be able to go back to using Atacand. I implore you to consider this request which will save both of us a great deal of money and myself a great deal of stress. Please make the right decision and help me get my life back on track with a medication that will work for me.

Sincerely,

Trudy Lehmann

Trudy Lehmann

Senate IBL Committee
Senator Duane Mutch, Chairman
March, 21, 2005

Support for HB 1332 – regulation of PBMs operating in North Dakota

Chairman Mutch and members of the committee, my name is Shantel Thomas. I grew up in Harvey North Dakota, and currently commute between Williston – where my husband works as an Engineer, and Bismarck – where I am completing experiential rotations to graduate in May from the College of Pharmacy at NDSU.

I am speaking to you today from the perspective of a young adult and future professional pharmacist. You have been asked on many occasions to come up with a solution to stop the mass exodus of young people from our state. This bill gives you the opportunity to do that by regulating firms who not only affect the cost of medication to our citizens, but directly impact the ability of pharmacies in North Dakota to remain viable.

Small towns are at risk of losing their pharmacies because the industry is dictated by PBMs who are running the show and driving small town pharmacies out of business. Gordy Mayer owns Service Drug Pharmacy in Harvey, and he will probably retire within a few years. I have worked with Gordy in his store and enjoy the idea of also being able to serve my community as a local pharmacist. However, today I don't have the confidence needed to make an investment so risky due to the strong-armed tactics of PBM's over price setting and the restricted choice of consumers. Two other pharmacies in Wells county may also be at risk of losing their pharmacy services due to retirement within the next 10 years--one in Harvey and the other in Fessenden. Your decision about HB 1332 will have a direct impact on pharmacy business opportunities in rural areas like Wells County. You can see the dilemma – entrepreneurs want to stay and practice pharmacy, but need assurances that you really want them here.

PBMs currently have a choke hold on the practice of pharmacy and HB 1332 forces them to release some of that pressure so the profession can return to doing what we do best – counseling patients on staying healthy. We do that by working with our patients face to face every time they come into the pharmacy.

1 We make sure they are taking the right medicine for the most effective results.
   - Do mail order pharmacies worry about efficacy?
2 We work with their physicians to adequately choose the best drug regimen for that patient's need.
   --Do mail order pharmacies know the patients' physicians?
3 We ensure they don't have to deal with drug interactions or allergic reactions.
   --Do mail order pharmacies maintain adequate patient profiles to minimize the same risks?
4 We ensure they are taking the right dose at the right time
   --Do mail order pharmacies consult their patients?

5 We help people with chronic diseases live healthier lives and avoid more expensive healthcare costs.
--Do mail order pharmacies concern themselves with these issues?

I enjoy the bonds I've developed with my community. I have a desire to take care of my family, friends, and neighbors and someday I hope to use my education to help these people I care about. HB 1332 enables me to do that because this bill creates a real option for patients to choose to get their medications from the local pharmacy or through mail order – whatever they prefer.

The equal "copays and days of supply" in HB 1332 create an authentic "choice" for patients. Patients, who don't want to use mail order are often mandated to do so by their healthcare plan, or they are seduced into using mail order with fewer co-pays for a 90 day supply of their medications. Even if they want to go downtown and have a consultation with the pharmacist about their prescription, the financial incentive often drives them away from the local pharmacy. HB 1332 gives them the freedom of choice by allowing the local pharmacy to provide the same co-pays and days of supply. I think it is clear how, under current policies, mail order is killing small town pharmacies.

The co-pays and days of supply are directly related to mail order, so all references to mail order must remain in the bill to make it effective. It's not hard to grasp the impact of having thousands of people use mail order instead of their local pharmacy...the pharmacy will go out of business and the community will lose access to the professional expertise of a trained pharmacist. In addition, if enough pharmacies go out of business or come under the management of PBM's, competition in the market will vanish and any savings for the consumer will be lost. HB 1332, with the provisions for mail order, will make it possible to keep pharmacies open in small and large communities alike.

Not only do the tactics of PBM's, such as Prime Therapeutics, affect the policy holders of numerous employers across the state, they also have a direct impact on every person paying their taxes in the state of North Dakota. State employees are covered under Blue Cross Blue Shield, which currently enjoys about 80% of the market. State employees' health benefits are paid ultimately by the tax payers of North Dakota, some of which are pharmacy owners. It is unconscionable to me that you would allow PBMs the power to drive out small businesses with the aid of tax payer moneys. It is, ultimately, your job to make sure that taxes paid by North Dakotans are used to protect their best interests. Having state employees get their prescriptions filled through a mail order pharmacy in Texas (Prime Therapeutics) sends millions of dollars out of North Dakota to enhance someone else's economy. I would rather see those millions stay right here to support our economy!

You see Senators, I am not just here as a future pharmacist and potential small business owner, but as a Blue Cross customer who is finding my options diminishing. I am also a taxpayer who prefers to see my taxes used to serve me, not some corporation in another state. HB 1332 is public policy that will assist you in fulfilling your obligation as lawmakers, to protect the well-being of the people of this state.

HB 1332 holds the interests of North Dakota, its citizens, and its pharmacies. I support this bill and I request your support as well.

Community Action PARTNERSHIP

Helping People. Changing Lives.

January 31, 2005

REGION VIII
DICKINSON, ND

CASE MANAGEMENT/
FAMILY DEVELOPMENT
227-0131

CHILDREN SERVICES
COORDINATING COMMITTEE
227-0131

EMERGENCY/CLIENT
SERVICES
227-0131

FAMILY PLANNING
227-0131

HEAD START/EARLY
CHILDHOOD CENTER
227-3010
877-546-9420

HOUSING/HOME
REHABILITATION
227-0131

PRAIRIE ROSE CENTER
227-0135

SAFE COMMUNITIES
227-0131

WEATHERIZATION
227-0131

REGION I
WILLISTON, ND

CASE MANAGEMENT/
FAMILY DEVELOPMENT
572-8191

CHILDREN SERVICES
COORDINATING COMMITTEE
572-8191

EMERGENCY/CLIENT
SERVICES
572-8191

HOUSING/HOME
REHABILITATION
1-800-359-2243

SAFE COMMUNITIES
572-8191

WEATHERIZATION
774-3328

Representative George J. Keiser
State Capitol
600 East Boulevard
Bismarck, ND 58505-0360

Dear Chairman Keiser:

This letter is in support of HB 1332 relating to the regulation of pharmacy benefit management (PBM).

Over the last several years our health insurance premiums have increased for our agency significantly. The agency has approximately 60 employees enrolled in the group health plan, which also covers pharmacy. We have implemented some measures on our end to minimize premium increases; however, there are many areas we have no control over or knowledge of. One area is prescription drugs. Currently there are Pharmacy Benefit Managers (PBM) who generate millions of dollars for themselves at the expense of the insured, with very little if any accountability.

If this process continues to be left unchecked, insurance premiums will continue to rise, leaving even more individuals and families uninsured.

I urge your committee to send this bill to the full House with a do pass recommendation. If you have any questions, please feel free to call me. Thank you.

Sincerely,

Erv Bren
Executive Director

3050 Highway 22 North
Dickinson, ND USA 58601
1-888-steffes
Phone: 701-483-5400
Fax: 701-483-5402
E-Mail: jrothschiller@steffes.com

January 28, 2005

ND Legislators

Ref: HB 1332 – Pharmacy Benefit Managers legislation

In review of HB1332, we urge you to pass this legislation and make the "hidden" fees transparent to us as employers.

Steffes Corporation employs 150 individuals, of which 86% of full benefits. We are a self-funded plan and take "managed care" very serious. In fact, we communicate to our employees that our health care benefits are "NOT" a plan but a "program". This means we must all understand the impact of "managing" our personal health and in making wise choices.

HB1332 exposes the costs behind the scenes that we don't see from the Pharmacy Benefits Managers. We believe if these costs were transparent to us, we could manage our out of pocket costs to providers even better. If you wish to talk further with us on this subject, please feel free to call us at 1-888-783-3337.

Sincerely,

Joe Rothschiller
President

Fisher Industries

January 28, 2005

Representative George J. Keiser
State Capitol
600 East Boulevard
Bismarck, ND 58505-0360

RE: HB 1332

Dear Chairman Keiser:

I am in support of HB 1332 sponsored by Rep. Nancy Johnson. As an employer of more than 550 employees and having a self-funded health insurance plan for employees and their families I am concerned with the costs associated with prescription drugs.

The payment of prescription drug costs is a very complex issue and has significant costs to my firm. We as the plan sponsor do not have adequate information regarding our costs. Every quarter we receive a rebate check from Blue Cross Blue Shield of ND for discounts on drugs. We presently have to assume that we are receiving the correct rebate that we are entitled to receive. HB 1332 will allow us to see the bottom line costs that we are being charged and where discounts are being applied.

Please urge your committee to send this bill to the House with a do pass recommendation. If you have additional questions please feel free to contact me at 701.456.9184. Thank you for your time and consideration.

Sincerely,

Todd Tavis, SPHR
Human Resources Director

Support for HB 1332

- 325 business owners who are members of the state retailers association
- North Dakota Insurance Department
- AARP of North Dakota
- Letters of support attached – received following testimony in the House
- Drug Manufacturers