2011 HOUSE INDUSTRY, BUSINESS AND LABOR

HB 1418

2011 HOUSE STANDING COMMITTEE MINUTES

House Industry, Business and Labor Committee
Peace Garden Room, State Capitol

HB 1418
January 31, 2011
13740

☐ Conference Committee

Committee Clerk Signature

Explanation or reason for introduction of bill/resolution: A BILL for an Act to provide standards for audits of pharmacy records; and to provide a penalty.

Minutes:

Chairman Keiser: We will open the hearing on HB 1418. Support?

Daniel Duletski~Pharm D Student Intern of Pharmacy to represent the Board of Pharmacy: (see attached testimony 1).

Michael D Schwab~Executive Vice President of the North Dakota Pharmacists Association: (see attached testimony 2).

John Olson~Lobbist for H Edward Heckman, R PH-President & PAAS National Inc: (see attached testimony 3).

David Olig, R. Ph: (see attached testimony 4).

Vice Chairman Kasper: Can you explain a hard audit?

David Olig: This 3 day supply you see in my notes should be 30. Three days would be inappropriate for that amount of medication. You can set up those perimeters on the backside so that when we send that they say this must be a typo or you have something wrong as far as medications. They will send a note back that says you have a problem with this particular prescription and is this correct day supply. We do these all the time now but for whatever reason they are not doing them on a regular basis. It appears a set of parameters are set up so they don't want to do those things on a regular basis because I do believe it is a profitable line item for them. They can set up parameters to where we send it, they do the edit, and they send things back again and it is a four-second transaction.

Vice Chairman Kasper: It would be a matter of proper communications and proper computer programming to simply notify you that it should have been 30 instead of 3. If they know that 3 is wrong then they must know that 30 is right. The system is there they just aren't communicating with you.

David Olig: They have pharmacists on their staff. They know these clinical criteria. Yes they would know and could transmit that back. They simply choose not to.

Representative Vigesaa: The written notice of at least 14 business days, how do they notify you currently when they are going to do an audit?

David Olig: Through a registered letter. They will probably give you a list.

Representative Vigesaa: Are they coming in a lot shorter time period than 14 days at times?

David Olig: 14 days is probably reasonable. Other people might say different.

Representative Vigesaa: Limiting the audit to no more than 18 months back. How far are they currently going back on audits?

David Olig: I think at least 24 months. I don't have a problem with going beyond that if fraud, waste and abuse are found. Because these problems can be identified on the day of the transaction, to wait and go back 18 months is actually quite burdensome.

Chairman Keiser: Do they do desk audits versus audits in person?

David Olig: Yes they do desk audits. The desk audits end up showing up on a regular basis. The vast majority of them shouldn't because of the hard edit that I think should happen. We've made mistakes. We had an expensive injectable use post-op for anticoagulation therapy. It comes in a box of ten and there 4/10 milliliter per syringe. So when my technician filled the prescription she put in a 10 day supply and 10 syringes when in fact it should be 4. Right off the bat the hard edit should have tossed that out but it was our mistake. The desk audit should have caught it right away.

Chairman Keiser: What has been your experience when they have found a typographical error but everything else was ok? Do you have one or every case that deny?

David Olig: They deny virtually every case for typographical errors.

Chairman Keiser: 100% of the cases would have found the typographical error. You have not been able to get relief?

David Olig: I can't say 100%.

Representative M Nelson: We talk about waste, fraud, or abuse. If they actually believed that it was a 3 day supply would that not be waste, fraud, or abuse? Didn't they have to say no actually it is 30 days and by rights turn you into the pharmacy board?

David Olig: Absolutely but there is no reason to believe it would be a 30 day supply. That would be completely therapeutically inappropriate. Any common sense would say it is not correct.

Representative M Nelson: By not taking action they are really kind of agreeing with you that it was thirty days.

David Olig: Until they decided to take the money back.

Representative N Johnson: On page 2, line 24 of the bill, could you help me understand that?

David Olig: The current manuals from the large PBMs are anywhere from 60-125 pages long and they are beginning to set their own criteria as what is a valid or invalid prescription. What they are doing is superseding the board of pharmacy's regulations as far as what is a legal prescription in the state of North Dakota. That has become a major issue nationwide.

Representative Kreun: How many PBM's do you deal with in a year?

David Olig: There is probably 30-40.

Representative Kreun: Technically you could be audited by 40 different companies within any given time?

David Olig: Yes.

Representative Clark: Did you say how many audits you have to deal with every year?

David Olig: We are fortunate. I have only had 2 audits in 28 years.

Representative Clark: Is this typical?

David Olig: I don't believe so.

Representative M Nelson: What percentage of your pharmaceutical sales would be covered by a PBM?

David Olig: Today about 96%.

Representative N Johnson: When you say an audit of 2 in 28 years, are those 2 on-site audits or 2 desk audits and on-site audits?

David Olig: The desk audits are ongoing. If PBM sees something then they are pulling them up and looking at them. I think when they get to a particular point that triggers the on-site audit. My opinion is that it appears as though it has to be financially viable for them to come out and do this or they won't bother. That is how we get the 700 dollar recoupment.

Representative Clark: If proper software on the other end would discover these errors when they are transmitted to them electronically, wouldn't proper software on your end also disclose these errors? Is there no way to do this?

David Olig: I think that is probably true however our software doesn't tend those kinds of things as far as medication and recommended daily supply. The PBMs actually structure their claims processing software to do those types of things. Ours looks for allergies, drug-drug interactions, adverse reactions and those types of things. We have the clinical aspect set up but as far as daily supply no and there is probably a reason for that because there are times when we go beyond either below or above physicians or manufacturer's recommended daily doses. Those are verified with physicians or providers so that happens on a regular basis.

Representative Boe: When you refer to the software for the PBM, is that software that is available or is that something that would have to be created?

David Olig: It is already being done. If it weren't the audits wouldn't be started in the first place. That is how the desk audits are originated. They have set the criteria. They wouldn't come and tell me that I have 30 capsules for 3 day supply and that is inappropriate if they didn't already have it. All they have to do is respond to that inappropriate number. They just have to send a note back that says it is done already. Those types of communications are done on regular basis now it is just a matter of setting up the criteria for expanding that base. Their audit system already tracks that so it is a matter of responding.

Chairman Keiser: Further questions from committee members? David now you will see why they wanted you to go first. Anyone else here to testify?

Tony Welder~Partner-Prairie Pharmacy: (see attached testimony 5).

Vice Chairman Kasper: If you do an appeal, I heard somewhere that some appeals aren't even allowed. Can you do appeals with the PBMs with the ones that you are contracted with or are there appeals processes?

Tony Welder: Yes they are. The copy I left you was our kind of appeal without being legally written. It was written from the facts as we knew them. As I can remember there was no response to that so the very last day of December we wrote the check.

Vice Chairman Kasper: In all the years you have been in the pharmacy business and you have had audits, how many of them were like this audit you've described where they found things that you or one of your employees was willfully trying to do something in error? Has that ever happened to you in your career?

Tony Welder: I've been fortunate as well. We've always done things pretty well and we've not been audited a lot but I've never had an audit that proved that we've done anything wrong. It was always a simple error like I described here. Naturally after this we are careful about that day supply thing.

Vice Chairman Kasper: When these clerical errors have been found over the years, where in this case you had to pay money back even though as your statement says no extra cost to the patient, the plan, or the sponsors, how many times have you had to pay where there was no cost to the patient, plan, or sponsor percentage wise as opposed o where they said we understand it is a clerical error and we'll let you go?

Tony Welder: I've never heard that. We've always just paid it. The audits before have not been close to this amount. This for us is substantial. Given what I have explained it would have been pretty tough to fight and cost more time, effort, and legal expenses.

Vice Chairman Kasper: In your experience you've never been forgiven, if they found 100 dollars or 500 dollars or 2,700 dollars, that expense by the PBM because of a typo error or a clerical error. They have always said pay it?

Tony Welder: No, I have never had a refund from those amounts that I have paid or an offer. It was always if you don't pay, they have the power to withhold from future reimbursements.

Vice Chairman Kasper: So I'm saying that they do make you pay but they don't forgive it?

Tony Welder: I've never had any forgiven.

Representative N Johnson: How many desk audits or on-site audits have you had in your span?

Tony Welder: I don't know about the amount of desk audits.

Representative N Johnson: Have you had audit teams come in frequently?

Tom Welder: No.

Representative Vigesaa: I can certainly understand why insulin, eye drops, and inhalers could easily be used up before the prescription runs out. What do you do as a pharmacist when that customer comes in and needs more of that because they've missed their eye, applied too much insulin? Knowing full well that you are probably going to be audited and maybe have to pay back up to a year's worth of drugs, what do you do when that patient is standing in front of your counter?

Tony Welder: If that happened there would be a pharmacy out with that patient explaining and showing them how to do the eye drops more accurately. We don't like to see that happened either. It is an extra cost when it is wasted.

Representative Vigesaa: I imagine if you want to have good customer service you are probably going to give that patient another prescription and thereby setting yourself up for a possible audit. Would that be correct?

Tony Welder: I would probably allow that to happen once and know the audit would be coming somewhere down the road. I think we are all pretty careful about that and understanding that sometimes that happens to people and their medications.

Chairman Keiser: The tough question I have for you is I'm trying to relate the handout you gave us relative to the payment that was made and I'm struggling seeing how this bill would have changed any of those outcomes. An example would be subsection 4 a clerical or

record keeping error may not be considered fraud. So it is not fraud but it is still chargeable back to you based on this legislation as I read it. I don't know where you would go to get relief from that.

Tony Welder: I'm not sure I understand that completely either but as Dave Olig pointed out, it would be so simple to get that hard edit back. As soon as you hit that button and it was a one day supply but really it should be a thirty day supply, we should get that back. And of course we should be watching that closer too. I can guarantee you that my people here are watching that very close now.

Chairman Keiser: The example of the DEA number, this bill wouldn't change that. You are in error with the missing DEA number.

Tony Welder: Yes that has happened but a little common sense could work here. If the name of the physician doesn't match the DEA number, why couldn't we just be told that there is an error? We could correct that in a heartbeat and not hear about it a year later.

Chairman Keiser: Are there any other questions? Is there anyone else here to testify in support of HB 1418?

Mark Hardy, Pharm D: (see testimony 6).

Representative Amerman: When you say you have seen the audits increase up to 4 times in the last 2 years, it sends off a red flag. We now have the Federal Healthcare Reform Act, is there something in that federal thing that the PBM, down the road, might lose some money so now they increase audits just in case there is something in there that handcuff's them?

Mark Hardy: I am not aware of that. I don't have a good reason why we have seen the increase. I just don't know.

Representative Clark: Thrifty White has several drug stores. What is your total annual for these charge backs that go to PBMs?

Mark Hardy: As far as our total recovery dollars, I don't have that total. I have a specific company and that was Prime Therapeutics and their charge backs for 2010 were over 70,000 dollars. As far a total I don't have that for you. I can find that out.

Representative Clark: It would be interesting to know. That sounds like a lot of money especially if you have many PBMs to deal with. How often do these typographical go undiscovered? Wouldn't the patient come back and say you gave me 3 pills instead of 30? If they are discovered, is there an opportunity to correct that so you don't get hammered?

Mark Hardy: Typically your typographical errors are due to day supply. It is not so much as in your dispense quantity as that is something that is taken right off the prescription. As far as patients, yes if there was a mistake made of course a patient would let us know. A lot of times they go undetected for the simple fact that the co-pay is the same as what it should

have been before and the dispense quantity is the same. How many go undetected? I don't know. It seems like the big dollar amount ones do show up quite often on our audits.

Chairman Keiser: One of the issues you cited was a physicians dispense quantity is unreasonable for migraine medication even though there is no way to know. Migraine medication can be pretty amazing stuff. My wife gets migraines and it seems to me that her neurologist is very concerned about how much she is taking and he writes a prescription that is very clear because he wants to come back in the picture if it exceeds that number. Claiming a physician's dispense quantity is unreasonable, just in that particular case, if you gave out too many, I know that the physician is going to consider it unreasonable. How does that interplay between the physician and those kinds of drugs?

Mark Hardy: Typically on something like that a pharmacist doesn't really know how many migraines a patient is going to have. When you dispense a prescription like that, you don't know how many they are going to have in the next month. As far as refilling, it is something that is between the doctor and the patient and we are stuck in the middle. If what the PBM refers to as unreasonable quantity, it is something where we get the burden placed on us. It is not something that the prescriber has to answer to. In this specific example it was something that a PBM tried to take money back for a medication that was clearly dispensed and was clearly written for that quantity by the prescriber.

Vice Chairman Kasper: On page 4, starting on line 11, we are saying that the auditing entity shall provide a copy of the final report to the plan sponsor and it goes on to give information of the plan sponsor. Who do you consider the plan sponsor?

Mark Hardy: The plan sponsor if it is a self funded insurance, I deem that to be the employer of the patient.

Vice Chairman Kasper: I have a concern because the plan sponsor is not defined in the bill which I think there should possibly be an amendment. I have heard over the years, and we have had PBM in the 2005 session where we had the big battle about PBM regulation, employers know all this information and what is going on. In my experience I have yet to find an employer who knows anything about PBMs or audits or anything. I'm wondering if we could, without violating HIPAA, require the information has to go to the employer HIPAA protected as well as maybe the insurance company. If it is fully insured plan would you see any merit to the employer knowing what is going on?

Mark Hardy: I agree with you 100% that the employer should know what is going on in respect to their dollars that they are paying out for health insurance. That is why we want to put this in legislation so the responsible person knows where the money goes. Unfortunately we have no way of tracking that right now. From the testimony on the national scene, there weren't any trends seen that it is happening. We want to make sure the money is going in the right hands.

Chairman Keiser: Further questions from committee members? Is there anyone else here to testify in support of HB 1418? Is there any here to testify in opposition to HB 1418?

Stacey Fahrner~VP, Government Affairs for Prime Therapeutics: (see attached testimony 7)

Representative Gruchalla: You heard Mr. Hardy state that the audits have gone up 4 times in the last year. Do you have any reason why that happened?

Stacey Fahrner: Our audits have not gone up 4 times in the last year. We start out the year with the number audits that we want to do. It is just how we are able to account for the claims that come through to our health plans. In 2010, we did approximately 20. In 2011, we are going to do 22 or somewhere around there.

Vice Chairman Kasper: You indicated that one of the things you found in the abuses of your audits is what you said is over dispensing according to plan design. Can you explain what you mean by over dispensing?

Stacey Fahrner: I have a couple of examples. The pharmacy incorrectly enters 60 tablets for 10 days. The correct submission would have been 30 days for 30 tablets.

Vice Chairman Kasper: Let me ask you something right there. There was a typographical error. Maybe not an over dispensing error so do you consider that over dispensing if they dispense the right amount or is that just a typographical error that you allow them to correct?

Stacey Fahrner: In this instance it was dispensed.

Vice Chairman Kasper: So that was an actual error.

Stacey Fahrner: Right. The prescription ordered 1 tablet twice daily. The pharmacy submitted 120 tablets for 25 days which was then filled monthly for 3 consecutive months. The patients obtained 3 additional months of medication with fulfilling the co-payment obligation. I'll stress for you that the pharmacy benefit design is set up by an independent panel of experts called a pharmacy and therapeutics committee. They are not associated or employed by Prime. They set those up according to clinical rules.

Vice Chairman Kasper: In those instances you are citing the plan. The PBM was overbilled by the pharmacist and you paid a greater amount than you should have. Is that correct?

Stacey Fahrner: No. Well the patient did not come in for three additional refills.

Vice Chairman Kasper: So that might have been a fraudulent situation?

Stacey Fahrner: Fraud is hard to prove. I think that our assumption is that it is a mistake and not fraud. .

Vice Chairman Kasper: If you find in your audits where you think that it looks like a potential fraudulent situation, are you required to report that to anybody or are you required to enter into a prosecution yourself? How does that work?

Stacey Fahrner: We would work with that plan if we were seeing a disturbing pattern of errors. We would work on a corrective action plan to fix those errors. We don't assume something is fraud. Certainly if we had a smoking gun situation, yes we would have to report that.

Vice Chairman Kasper: You say you would with the plan. Do you mean you'd work with the pharmacist that was doing the dispensing because the plan had nothing to do with it.

Stacey Fahrner: I'm sorry I misspoke. We would work with the pharmacist. We would report the audit findings to the plan and then the plan has some say on whether or not we move forward with a corrective action plan or terminate from a network.

Vice Chairman Kasper: Out of the 100,000 dollars that you have indicated that you said needed recouping. Would that be where the pharmacist was overpaid based on what they should have been paid or are those areas where the numbers were transposed but you don't know for sure if the dispensing and payment was wrong? Are they combination of those?

Stacey Fahrner: Those are areas of non compliance. I think part of the problem is that Prime's definition of when the plan is harmed is different from the pharmacy's definition.

Vice Chairman Kasper: Do you not outline that in your manual what the definitions are?

Stacey Fahrner: Yes we do.

Vice Chairman Kasper: Do you and the pharmacist have a discussion that you are saying this is the way it ought to be and they say no it isn't? Are we assuming here what is going on? What are you finding?

Stacey Fahrner: Are you asking about our contracting process?

Vice Chairman Kasper: No I'm asking what your results are. If you are saying there is a misinterpretation of what things ought to be, is that communicated to the pharmacist?

Stacey Fahrner: We will sit down and have educational meetings with pharmacies that we are seeing a pattern of problems with to educate them on why we have the requirements we have and why we need them to comply. with education,

Vice Chairman Kasper: Do you find that a lot in North Dakota with the pharmacies that you audit here?

Stacey Fahrner: I think there were a couple instances last year. I don't think, given the number of pharmacies you have, which I think is upwards of 150, it is a common occurrence.

Vice Chairman Kasper: Did you find that the pharmacists were willing to cooperate and try to rectify any situations that you found?

Stacey Fahrner: I think in some cases they are. I think in some cases it is more difficult.

Vice Chairman Kasper: Is it often that they are not?

Stacey Fahrner: It is not very often that we have put a pharmacy on a corrective action plan.

Vice Chairman Kasper: Have you ever done that in North Dakota?

Stacey Fahrner: Yes.

Vice Chairman Kasper: How often would that be?

Stacey Fahrner: My understanding is that there were 2 last year.

Vice Chairman Kasper: Then do you have to notify the pharmacy board about that?

Stacey Fahrner: I don't know.

Chairman Keiser: On one page here you have in your testimony is another recurring issue was pharmacies submitting to Prime post-audit validation documents that were not recorded at the time of dispensing. How rigid a line do you draw on that and I will give you the analogy. I have been known to drive without a driver's license. It is not a good thing. I don't recommend it and if you get pulled over you will be given a ticket or if you don't have your insurance card with you which has also happened to me. In both those instances I have a period in which I can remedy it. I am in violation and I have to go get that and prove but I'm off the hook. It concerns me how this language reads and maybe I'm reading it incorrectly. It seems to me that when an audit is done with a pharmacy if there is clerical error, a doctor's code is wrong but the name is right and everything else is right, to what degree do they have a chance to come back and say look, we did make a mistake and the is the right code. It is the right doctor and the prescription is right and there is not a charge back. How often does that happen?

Stacey Fahrner: We allow post-audit documentation.

Chairman Keiser: But you said this was the issue. Another recurring issue was pharmacies submitting to Prime post-audit validation documents that were not recorded at the time of dispensing.

Stacey Fahrner: So what we are looking for is that the certain elements that need to validate the claim are recorded at the time of dispensing.

Chairman Keiser: But they didn't do it. So to what degree when you come back and say we did audit you and you are out of compliance do they get a chance to come back and say yes we were out of compliance and here is the information and all is forgiven.

Stacey Fahrner: I don't have those numbers but I can tell you that approximately 50% of the claims for recoupment are appealed and we never collect the full amount of the recoupment for the global claims that are audited in the state.

Representative M Nelson: When you said common errors identified in an audit process include instances where the pharmacist over dispensed drugs compared to what the health plan has agreed to pay for under the benefit plan. Isn't that the hard audits that the pharmacists were asking for to be put in place?

Stacey Fahrner: I am not an expert on hard edits. I do know that we have had conversations with CMS about implementing new hard edits for processes that they want put in. My understanding is that it is difficult to get the software change. I don't know that I can't be done.

Representative M Nelson: Wouldn't it be a benefit for your plan sponsors to catch all of those at the time of dispensing rather than catching some in an audit later on to save them if there is a question?

Stacey Fahrner: Sure and that is our goal with the daily claims review. To a certain extent we can't be expected to catch every error that the pharmacist makes. We have requirements that are clearly laid out for them when they contract through us. They are on our website. We have a list of common billing errors that they can check whenever they want. We have a call center so if they questions they can call. We are willing to sit down and have educational meetings with them to sort of walk them through what we need.

Representative M Nelson: If you come into that situation where it is outside what you have agreed to pay for but it is correct according to the prescription, what wins? If the prescription actually called for that much to be dispensed, maybe the pharmacist checked with the doctor and that was right and everything but it is outside what your plan agreed to pay for but you paid for it. What wins in that situation?

Stacey Fahrner: I'll construct an example. So the doctor said a 90 day supply and we only cover 30. Is that what you are talking about?

Representative M Nelson: No I think I'm talking about where it is normally where you would agree to pay for 60 pills for 30 days and 90 pills for 30 days was dispensed and prescribed.

Stacey Fahrner: That overrides. There are processes for overrides in the system. I don't know that I understand your example completely but if the prescription is changed, it needs to be noted at the time.

Representative M Nelson: I'm trying to figure out what the health plan has agreed to pay for and what real authority that has. If the health plan says normally this is just prescribed, say one pill a day, but a doctor says I want two pills a day, you didn't agree to pay for two pills a day with the pharmacy. Who really pays for what in that situation? You just pay for one pill and then it is the patient's responsibility to pay for any more or do you override? And if you pay for two now and later come back against the pharmacist and he can't

recover from the patient then now you have damaged him haven't you? If your plan isn't catching these errors, you're potentially leaving the pharmacist just hanging to get paid from anybody.

Stacey Fahrner: The benefit should come up at the time of claims submission. It is the other stuff that we can't check at the time of submission like does the MPI number match the name of the doctor. Those are the things we can't check.

Representative M Nelson: You can't check that at the time?

Stacey Fahrner: No that is reviewed later. On a daily claims review it would be reviewed immediately but it would be reviewed by a person.

Vice Chairman Kasper: You said in testimony that you have an online claims appeal process. Is that your only method of appeal? Is it online or is there a face-to-face?

Stacey Fahrner: That is how they get the appeal started. They would start by submitting the online claim or a paper description with an item by item where they disagreed with the audit findings. It would be reviewed and we would respond and at that point we would reconcile any claims that we agreed with them are not appropriate for recoupment. I think at that point it can also be elevated to the plan sponsor for a decision.

Vice Chairman Kasper: Once you make a decision is there another step where the pharmacist can go if they don't agree with your decision?

Stacey Fahrner: I don't know that.

Vice Chairman Kasper: You indicated early on in your testimony that this bill would make it difficult to do your job. Can you tell me what in this bill causes you a problem?

Stacey Fahrner: Right off the bat 40 scripts is not a very realistic number of scripts to look at in meaningful audit. To get to any meaningful level we would have to do audit after audit after audit. We would be there every 2 days except that the bill also limits the access to the pharmacy. You can't get in the first week of the month. The other issue is the notice requirements. Like I said we give at least 14 days for on-site audits and we are fine with that but there is no exceptions in here for fraud, waste, and abuse. If you truly suspect that there is fraud, waste, and abuse, you can't give a pharmacy a heads up that you are coming. The board of pharmacy requirement, I'll just say, they are not a payer. They are not responsible for keeping track of policy holder money so they set their requirements for different purposes than we do so having us limit our prescription elements to board of pharmacy elements is not very realistic for conducting a meaningful audit.

Vice Chairman Kasper: You said 40 is not enough. What would be enough?

Stacey Fahrner: We for our commercial audits, a desk top audit would probably be 100-150 claims. Center for Medicare and Medicaid Services audits are sometimes up to 500 claims.

Representative Frantsvog: Who pays for the audit? If I own a pharmacy and you call and say you are going to audit me do I get billed a fee for having this audit done?

Stacey Fahrner: You don't get bill by us but I'm sure there is a cost to you to having the audit done just like there is a cost to us when we get audited by our clients and the federal government.

Representative Frantsvog: I have a question on page 2 of your testimony in the second paragraph. In 2010, Prime conducted 20 audits in North Dakota and had identified approximately 100,000 in inaccurate claims. Is that 100,000 dollars that would be a responsibility of the pharmacies to pay to you?

Stacey Fahrner: That is before the appeals process.

Representative Frantsvog: So if the appeals were unsuccessful, you would get 100,000 dollars. Is that correct?

Stacey Fahrner: We do not get the 100,000 dollars. This is not a revenue source for us.

Representative Frantsvog: What do you do with the money then?

Stacey Fahrner: It goes back to the plan sponsor.

Representative Kreun: Why would they contract with you if they don't like your audit process? Why don't they get somebody else?

Stacey Fahrner: They can contract with whomever they want and most pharmacies contract with all of the big PBMs. To the extent we are associated with Blue Cross Blue Shield. I am sure that means a lot of additional business.

Representative Kreun: Why can't they do their own audit or hire their own auditors? Why would they sign a contract with you?

Stacey Fahrner: The audits are part of the provider agreement that we sign with the pharmacy.

Representative Kreun: So if you want to do business then with a health care company or pharmaceutical company you have to sign that audit with them in order to do business with that company?

Stacey Fahrner: It is a part of the provider agreement yes.

Representative Kreun: So then in all actuality they really don't have a choice to pick and choose an auditor for that particular pharmaceutical company.

Stacey Fahrner: Our auditors are employed by Prime. We don't have contract auditors.

Representative Kreun: There is an audit process to make sure that all the prescriptions are done properly by the pharmaceutical company. The audit is required by the pharmaceutical company.

Stacey Fahrner: The audit is required by the PBM.

Representative Kreun: If you don't use that audit company or yours with that company, then you may not get the contract to sell the drugs from that company.

Stacey Fahrner: Right.

Chairman Keiser: We are getting a little bit confused. The drug company is not involved per say.

Stacey Fahrner: The structure is that the health plan collects money from policy holders. A certain percentage of that comes to Prime for management of the pharmacy benefits. As part of our contract with the health plan, we negotiate networks with retail pharmacies to prescribe drugs. When the pharmacy negotiates and signs a contract with Prime, they agree to the audit terms that we have in place.

Representative Kreun: Who is selling the healthcare contract? You said the pharmaceutical company is not involved. So it is the healthcare contract? The health care company is requiring the contract?

Stacey Fahrner: Prime requires that they comply with our audit policy to be a member of our network. To be a member they need to sign a provider agreement.

Representative Kreun: They can't use another provider or another audit company then?

Stacey Fahrner: No our auditors are employed by Prime.

Representative Kreun: So the pharmacy has to use Prime for the audit process?

Chairman Keiser: Blue Cross Blue Shield has your policy and they use her company to audit their claims. So if you want your drugs covered and you go to your pharmacy, your pharmacy is going to call her PBM if you are on a Blue Cross Blue Shield plan.

Representative Kreun: You don't have another choice though?

Chairman Keiser: No and that is part of the Blue Cross Blue Shield package.

Representative N Johnson: You mentioned a little while ago that the money that is recouped goes back to the plan sponsors. How does it get back to the plan sponsors? Is it a check or a letter saying it is returned?

Stacey Fahrner: I can find that out for you. I know that they get a full accounting of what our recoupment is. I don't know that we cut them an actual check in that amount or if it's offset by some other expense.

Chairman Keiser: Opposition?

David Root~Represents Medco Health Solutions, Inc and Affiliates: (see attached testimony 8).

Representative N Johnson: I have a question about the board of pharmacy not dictating. Does your company kind of set our parameters that they can pick and choose?

David Root: It depends. One of the things we heard earlier on is that the purchasers of our services are ill informed or uneducated about what it is that they are purchasing and that is far from the truth. These are highly sophisticated consumers that are using highly sophisticated consultants in addition to their own knowledge, and that includes North Dakota, to determine what they want within their plan. So in some instances a plan may come to us and say can you help us create what we want to have that will constitute a valid script. In other instances they will bring to us what they want us to adjudicate and equals a valid script.

Vice Chairman Kasper: I'm in the insurance business and I sell health insurance and have for many years both fully insured and self funded. Let me just make a statement on yours that buyers are sophisticated and know all these things. It's been my experience in North Dakota that the buyer's in our state, with the exception of the very large ones, are very unsophisticated and know nothing about PBMs. Regarding your statement that you do negotiate, will you tell me about your negotiating process if you're negotiating with a pharmacist for a contract? How does that process work?

David Root: Typically what we like to do is work through PSAO. That in affect in its simplest terms is a trade association that a cluster of pharmacies will work with to negotiate contracts with insurers and in many cases also to work with purchasing agreements with wholesalers for the drugs for their pharmacy. If there are 50 pharmacies using a PSAO, we will go to the PSAO and we will work out an arrangement with them as far as those contracts are concerned. The contract would then be relevant for all the pharmacies within that PSAO. Then there are occasions where we have to do direct negotiations with a particular individual pharmacist or pharmacy. We obviously as a national player try very hard to work through the PSAOs because it is an easier to deal with as many people as possible

Vice Chairman Kasper: In you experience here in North Dakota for getting out there and in negotiation with an individual pharmacist, because I asked a pharmacist this morning if they had this PSAO to negotiate for the contract and I was informed that no because of antitrust laws they do not. They have to negotiate their own contracts. In North Dakota it might be different. How many times have you modified your standard contract with an individual pharmacist of North Dakota rather than saying here it is take it or leave it?

David Root: I don't know. I do know we have a standard contract and the pharmacies are presented with those contracts. I would also like to bring to the committee's attention to be specific to North Dakota, that North Dakota has prohibition on chains. There are very few chained pharmacies in the state. We have contractual obligations that we have to meet for

the payers with respect to access to pharmacies so do to the fact that there is not a prolific amount of competition in the state, our goal is to get as many pharmacies in North Dakota in our network in order to be compliant with the access requirements of our contract with our plan sponsors. This area is not like Washington D.C., Fairfax County, or New York where you have a pharmacy on every corner. You have three pharmacies on every corner so we have to work very hard for that.

Vice Chairman Kasper: Let me correct your statement about us having a prohibition on chains in North Dakota. We don't have a prohibition on chains. We have a prohibition of ownership. You could have a chain of 200 so long as the pharmacist owned 51%. What is it where we talked about fraud and the bill addresses fraud? What is the percentage of claims that you found in North Dakota that were out and out fraud over the last year or two?

David Root: I went back 5 years and didn't find any fraud. I think it is important for the committee to understand that Fraud is more than a word. Fraud has a legally defined definition. It is a legal standard. It is not our goal, going back to my comment about it not being designed to be a "got you" moment; it's not our goal to wonder through the countryside accusing people of fraud. They have to meet a very specific legal standard and it is a very high threshold. You have to prove intent. The fraud statutes in this language are one issue. Another issue is that there are mistakes, or mistakes made on purpose. Unfortunately the outcome of either of those is often an expenditure that shouldn't have taken place and so the audit catches those expenditures. Regardless of what you label the act, the outcome is the same.

Representative Nathe: In your testimony you insinuate that you have a problem with the two week notice and the 40 script audit and you insinuate in here that if this bill were to take change that it would increase fraud. My question is do you have any information that supports that from other states where a change like this has happened?

David Root: In the beginning of this the supporters of this language had indicated that there were between 9 and 11 states that had passed audit language and that is accurate however, I would say that none of those states have passed language with restrictions that are included in this. If you had a 40 script maximum, then all you would really have to do is fill the first 40 scripts. If I had to give you a 14 day notice that I was coming then for those 14 days you would fill those scripts legitimately and that would be all that I could look at. The unintended consequence of that language could very well be an on-site audit every third day to collect 40 scripts at a time to find a history of potential errors or fraud which we don't want to do but would obviously be a tremendous burden to everyone involved. The idea that you physically limit the number not only causes those problems but also has the ability of limiting us of finding a history of mistakes and if we are going to go back to that fraud word, often if you are going to prove fraud, the way you prove it might be over the course of a year or two years where you show a history of this drug being misapplied or overprescribed.

Vice Chairman Kasper: To verify what you said about fraud. You found nothing in North Dakota that was fraud over the last five years so from the perspective of your concern there with you testimony does use the word fraud quite often. I think maybe you solved that yourself. On an appeals process if a pharmacist doesn't like the result of an audit and by

the way can't you go back 18 months to audit and under a desk audit can't you audit five years back because it's all computerized?

David Root: Some pharmacies are computerized and some are not. The pharmacist has the records. All we have we they have are the computer records for what the pharmacy actually inputs at the time. They have the physical copies and we need to match the physical copies with what was put into the system. The bill allows us to go back 18 months and we typically go back anywhere from 2 to 3 years.

Vice Chairman Kasper: Does you company refund and contact the customer and give that customer the refund of the co-pay that the customer paid?

David Root: The co-pay is not part of that recoupment. We don't give it back and we don't take it.

Vice Chairman Kasper: As far as the number of scripts you think would be fair to audit to give you a sampling that you need, what number would be helpful for you to have in this bill?

David Root: It is impossible to put a number on that because it depends on the script. We have heard a number of cases and the committee had been tending, in the end, to focus on the focus tends to be on the high dollar prescriptions. This is an audit. This is a following of the money trail. They money is in those high dollar prescriptions so it would only make sense that those are the things are getting audited.

Vice Chairman Kasper: You indicated that plan sponsors decide what a valid script is. In my experience in North Dakota a plan sponsor has no clue what a valid script is because they are never involved in that level and that is why a PBM is there and that is why the doctor and pharmacist are there. When you make that statement are you referring to big companies?

David Root: What my intention to make sure everyone understood was that within our contract with the payer it clearly articulates what we will manage and one of those things is what constitutes a valid script. The payer is not the organization that takes the incoming script and lays it over the formula and says yes this is a valid script. That is our job as an administrator but they are well aware of what we are comparing the script to. It is their contract.

Vice Chairman Kasper: So you are giving that to the plan sponsor?

David Root: The plan sponsor is well aware of that information when the contract with us.

Vice Chairman Kasper: So you are providing it to the plan sponsor?

David Root: If the plan sponsor says they want to see the script then we present that to them along with any recouped moneys.

Vice Chairman Kasper: Is the plan sponsor the insurance company if it is fully insured?

David Root: Yes.

Vice Chairman Kasper: So the employer that pays the bill never sees it.?

David Root: What the insurance does with it, I don't know.

Representative Ruby: You indicated that the reason for the audits is that is the requirement by the sponsor. Do you recommend how many should be done or do they tell you how often they want you to?

David Root: The numbers are as varied as the number of contracts we have with plans.

Representative Ruby: It is those sponsors that are directing you to what they want.

David Root: Yes.

Representative Ruby: Has the number of audits in North Dakota gone up with your company?

David Root: No.

Representative Ruby: Do you believe that you are you getting the blame and taking the heat for caring out the contractual agreement of the sponsor?

David Root: Yes, on both counts. Parts of the plans are spending the money and they've asked us to keep track of it. The federal issue that the pharmacists face within their audits is that the federal audits require pharmacies to keep records for 10 years. A DEA audit can walk in and say they want to see the records from 10 years back. We as a PBM employ in house. Our audit division is part of our company. It is a service we provide. This bill will not alter the federal aspect.

Vice Chairman Kasper: Does your company have contracts that accept rebates from the manufacturers?

David Root: Our company does have contracts that accept rebates from manufactures and we also have contracts with payers that require 100% pass through. That would mean that any rebate dollar that we collect from that plan is then passed to the plan sponsor once we receive them. Rebates are risky be they are predicated on usage so if you don't have a particular population that has that disease, it is possible that you don't receive a significant portion of rebate dollars from the drug manufacturer that manufactures the prescription that address that disease.

Chairman Keiser: We had a number of 100,000 dollars that they recovered through a firm. How much did your firm recover last year?

David Root: I don't have the 2010 numbers. In 2009 we conducted approximately 500 desk audits and we recovered 63,782 dollars from pharmacies within the state.

Chairman Keiser: 163,000 dollars representing 97% of all the PBM business in the state, given the amount of prescriptions filled in the state, I don't know what that percentage is but it will be small. The question is, is it worth it? These plans aren't saving a lot and I know you want to prevent fraud but there was no fraud identified. The return on this investment and the cost to the pharmacies and your companies doesn't have big recovery.

David Root: If you look at those numbers in isolation, you are correct. However, these numbers represent an overall cumulative effort on our part to maintain and lower drug spend. Drug spend is going down or maintaining and one of the reasons is because of our aggressive use in generic opportunities

Chairman Keiser: Anyone else here to testify in opposition to HB 1418?

Mike Ayotte~Pharmacist and the Director of Government Affairs for CVS Caremark Corporation: (see attached testimony 9).

Chairman Keiser: It all sound good but we have a lot of pharmacists in the room and they are all saying they have problem. These are all good people. So how do we resolve this? Where is the halfway point here because what is happening is driving them crazy. Something has to be addressed.

Mike Ayotte: It's a fine line because as you can tell from the numbers we processed 554,000 retail claims in North Dakota last year. The problem is when you are being paid by somebody to guarantee a service is given they want to make sure things are done accurately. Pharmacy is a complex system. We are still paper based. I don't have a right answer yet. We have to continue to audit.

Chairman Keiser: Anyone else here to testify in opposition? Neutral testimony for HB 1418?

Melissa Hauer~General Counsel-North Dakota Insurance Department: (see attached testimony 10).

Chairman Keiser: I had the same concern about the definitions in this. The implication of what you said is there would be a fiscal note on this bill but I don't see one.

Melissa Hauer: That is correct. We have not received a request to fill out a fiscal note.

Chairman Keiser: So we would request a fiscal note. Any other questions? Anyone else here to testify in a neutral position? We will close the hearing on HB 1418 and Representative Frantsvog and Representative Gruchalla will make up a subcommittee.

2011 HOUSE STANDING COMMITTEE MINUTES

House Industry, Business and Labor Committee
Peace Garden Room, State Capitol

HB 1418
February 9, 2011
14243

☐ Conference Committee

Committee Clerk Signature

Explanation or reason for introduction of bill/resolution: A BILL for an Act to provide standards for audits of pharmacy records; and to provide a penalty.

Minutes:

Chairman Keiser: We will go to HB 1418. This provides a penalty. We do have a fiscal notes and I would like to point out that they are applicable, as you will see, because there has been a proposed amendment to take them out of the bill. The fiscal notes apply if the bill stands as it currently reads but if it is changed then there would obviously be implications on the fiscal note.

Representative Vigesaa: I want to say that both the pharmacy group and the people representing the PBMs were very helpful in making the amendments that we have before you today. We are not in total agreement between the two parties but both sides did a lot of compromising so I appreciate their efforts. I passed out amendments and I also had Legislative Council do a draft of the bill the changes included. I can walk through those amendments also.

Chairman Keiser: That would be helpful and I would like to point out that Rep. Vigesaa had an engrossed version prepared for the committee members that is color coded. When you are working in subcommittees you can ask for that.

Representative Vigesaa: What you will see as we go through the bill is that what is in green is the new language. The red that is over struck is coming out. On page one the definition of plan sponsor was added. On page two subsection one in subsection B, instead of pharmacists licensed in this state of North Dakota it can be any state. I might say that it was fine with both parties. Under C the time period that they can look back went from eighteen to twenty-four months. We did remove the limit of the prescriptions that can be looked at in an audit and that was agreeable by both parties.

Chairman Keiser: Did both parties agree to the twenty-four?

Representative Vigesaa: Yes both parties did. Both parties agreed to remove the limit on the amount of prescriptions and both parties agreed to eliminate the first five business days of each month that could be included in the audit. On page three you know that we have had, in this the committee the goal is to take out language that says that somebody shall

adopt rules. We took out the insurance commissioner in this bill completely and if you recall in testimony there were three areas where the pharmacies thought that they were being audited and a lot of the recoupment was coming from eye drops, insulin, and topical products because the consumer has those and applies them but sometimes they fall short of the product before the prescription is up. Rather than having the commissioner adopt rules we asked them to put it into the code so it is right in there that in those three areas this would apply. That was the pharmacists' language. On page four if you see a subsection that has been completely eliminated, that was agreed to by both parties.

Chairman Keiser: Let's take these as you are going. When you say the pharmacists put that in, did the PBM group disagree with this then?

Representative Vigesaa: Concerning the rules with the eye drops, insulin, and topical products?

Chairman Keiser: Correct.

Representative Vigesaa: With the pharmacists' language the PBMs did not agree to that particular section. On page four, the language that is stricken there in eight and nine was agreed to by both parties. Then we go to section three and you see that we have moved the days. I talked to an attorney about using the business days because we have used that in a lot of our language and they felt that once it gets to thirty and beyond you don't use business so when you see the one-hundred twenty days and the sixty days, that is proper. If you get within thirty then business days is often used. The number one there has the preliminarily audit report must be delivered to the pharmacy within one-hundred twenty days. We are giving both parties more time to either deliver the audit and also to provide documentation to substantiate findings in the audit. That was agreeable by both parties. You will see that we have stricken some language in the remaining part of that section. Section four with the applicability of this act, the pharmacists' request was to have it begin at the beginning of the next biennium so after July 31, claims adjudicated after that date would be applicable to this law.

Chairman Keiser: On page four, the strike on subsection six, those were both agreed to?

Representative Vigesaa: If I remember correctly they were. As I said the pharmacists requested this date of July 31, and the PBM group wanted it to be upon contract renewal which could be as many as three years out. The pharmacies felt that it would give the PBM auditing groups three years to go in and do it the way they have been doing it. They felt if we are going to make this change we need to make it right at the biennium change.

Chairman Keiser: When the pharmacists agreed to this, did this mean that they would be changing their business practice in some way in this delayed period so the audits would work differently?

Representative Vigesaa: I think the concern was primarily making the act effective when a bill normally becomes in law which is August 1. They wanted it to be effective when a new bill usually takes effect rather than delaying the implementation for each pharmacist by just when the contract would renew. It makes it consistent across the board for each

pharmacist. On the bottom of page five you will see that it doesn't apply to state Medicaid programs.

Chairman Keiser: Who wanted that?

Representative Vigesaa: I think that was agreed to by both parties. Lastly a penalty clause and we took out the insurance commissioner. It is simply any person violating this act is guilty of a class B misdemeanor. Without the insurance commissioner in the equation, if a pharmacy feels that this act has been violated then they need to work through their own state's attorney on a civil suit against the PBM. A class B misdemeanor for a corporation I believe is up to a 10,000 dollar fine. There was a lot of cooperation from both sides here. I don't think the PBMs are necessarily 100% pleased with this but this is the way that I hope the committee can send it out. I would move the amendments.

Representative Frantsvog: Second.

Chairman Keiser: Further discussion on the amendments? I want to compliment you and your subcommittee. It seems that given the task at hand you have addressed a lot of the concerns of the parties. Further discussion on the amendments? Seeing none all those in favor? Opposed? Motion carries.

Voice vote: Motion carries.

Chairman Keiser: We now have the bill before us as amended.

Representative Vigesaa: I will move a do pass as amended on HB 1418.

Representative Kasper: Second.

Chairman Keiser: Further discussion? Seeing none we will take the roll.

Representative Vigesaa: I don't know the procedure but I would like the request a new fiscal note.

Chairman Keiser: I will make that request.

14 YEAS 0 NAYS 0 ABSENT DO PASS as Amended
CARRIER: Rep. Vigesaa

FISCAL NOTE

Requested by Legislative Council
02/11/2011

Amendment to: HB 1418

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.*

	2009-2011 Biennium		2011-2013 Biennium		2013-2015 Biennium	
	General Fund	Other Funds	General Fund	Other Funds	General Fund	Other Funds
Revenues						
Expenditures						
Appropriations						

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

2009-2011 Biennium			2011-2013 Biennium			2013-2015 Biennium		
Counties	Cities	School Districts	Counties	Cities	School Districts	Counties	Cities	School Districts

2A. **Bill and fiscal impact summary:** *Provide a brief summary of the measure, including description of the provisions having fiscal impact (limited to 300 characters).*

This bill provides standards that insurers would have to abide by when they audit the claims that pharmacies send to them. The bill places the responsibility to enforce these standards on the Insurance Commissioner.

The amendments remove this responsibility.

B. **Fiscal impact sections:** *Identify and provide a brief description of the sections of the measure which have fiscal impact. Include any assumptions and comments relevant to the analysis.*

To carry out Section 5 of the act the Department would need to hire a full-time attorney and a full-time investigator.

The amendments to the bill remove the responsibility of enforcing the audit standards of the bill from the Insurance Commissioner. After this requirement is removed, this bill will have no fiscal impact on the Department.

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.*

This bill will not affect revenues unless a penalty is assessed by the Commissioner for violation of the act. Penalties up to $10,000 may be assessed.

The amended bill will have no impact on revenues.

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.*

This bill will increase expenditures. The Department would need to hire a full-time attorney and a full-time investigator to carry out this act. The Department estimates $341,797 would be needed for salary and fringe benefits as well as $271,550 for operating expenses.

These expenses would be funded out of the Insurance Regulatory Trust Fund.

The amended bill will have no impact on expenditures.

C. **Appropriations:** *Explain the appropriation amounts. Provide detail, when appropriate, for each agency and fund affected. Explain the relationship between the amounts shown for expenditures and appropriations. Indicate whether the appropriation is also included in the executive budget or relates to a continuing appropriation.*

This bill would require an increase in appropriations. The Department would need two new FTEs with an appropriation of $341,797 for salary and fringe benefits and $271,550 for operating expenses. The total additional appropriation needed is $613,347.

The amended bill will have no impact on appropriations.

Name:	Larry Martin	**Agency:**	Insurance Department
Phone Number:	701-328-2930	**Date Prepared:**	02/11/2011

FISCAL NOTE

Requested by Legislative Council
02/01/2011

Bill/Resolution No.: HB 1418

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.*

	2009-2011 Biennium		2011-2013 Biennium		2013-2015 Biennium	
	General Fund	Other Funds	General Fund	Other Funds	General Fund	Other Funds
Revenues						
Expenditures				$613,347		$613,347
Appropriations				$613,347		$613,347

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

2009-2011 Biennium			2011-2013 Biennium			2013-2015 Biennium		
Counties	Cities	School Districts	Counties	Cities	School Districts	Counties	Cities	School Districts

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This bill provides standards that insurers would have to abide by when they audit the claims that pharmacies send to them. The bill places the responsibility to enforce these standards on the Insurance Commissioner.

B. **Fiscal impact sections:** *Identify and provide a brief description of the sections of the measure which have fiscal impact. Include any assumptions and comments relevant to the analysis.*

To carry out Section 5 of the act the Department would need to hire a full-time attorney and a full-time investigator.

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.*

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Name:	Larry Martin	**Agency:**	Insurance Department
Phone Number:	328-2930	**Date Prepared:**	02/07/2011

11.0658.01002
Title.02000

Prepared by the Legislative Council staff for
Representative Vigesaa
February 8, 2011

VK
2/9/11
1082

PROPOSED AMENDMENTS TO HOUSE BILL NO. 1418

Page 1, line 19, after "5." insert ""Plan sponsor" means the employer in the case of an employee benefit plan established or maintained by a single employer, or the employee organization in the case of a plan established or maintained by an employee organization, an association, joint board of trustees, committee, or other similar group that establishes or maintains the plan.

6."

Page 2, line 4, replace "this" with "any"

Page 2, line 5, remove "or conducted by"

Page 2, line 6, remove "the state board of pharmacy"

Page 2, line 7, replace "eighteen" with "twenty-four"

Page 2, line 9, replace "eighteen" with "twenty-four"

Page 2, remove line 11

Page 2, line 12, replace "e." with "d."

Page 2, line 12, replace "seven" with "five"

Page 2, line 14, replace "f." with "e."

Page 2, line 17, replace "g." with "f."

Page 2, line 20, replace "h." with "g."

Page 3, line 11, remove "The insurance commissioner shall adopt rules establishing parameters of audits."

Page 3, replace lines 12 and 13 with "The parameters of an audit must comply with consumer-oriented parameters based on manufacturer listings or recommendations for the following:

a. The day supply for eye drops must be calculated so that the consumer pays only one 30-day copayment if the bottle of eye drops is intended by the manufacturer to be a thirty-day supply.

b. The day supply for insulin must be calculated so that the highest dose prescribed is used to determine the day supply and consumer copayment.

c. The day supply for a topical product must be determined by the judgment of the pharmacist based upon the treated area."

Page 3, line 19, remove "which must"

Page 3, remove lines 20 through 23

Page 3, line 24, remove "to the pharmacy"

Page 3, line 27, replace "thirty" with "one hundred twenty"

Page 3, line 29, replace "thirty" with "sixty"

Page 4, remove lines 8 through 10

Page 4, line 11, replace "7." with "6."

Page 4, line 11, after the second "the" insert "plan"

Page 4, line 11, remove "of the plan"

Page 4, line 13, remove "and the copayment must be returned directly to the patient."

Page 4, remove line 14

Page 4, line 15, remove "auditing entity"

Page 4, line 18, replace "December 31, 2010" with "July 31, 2011"

Page 4, line 19, replace "investigative audit that involves" with "audit, review, or investigation that is initiated based upon alleged"

Page 5, after line 15, insert:

"4. This Act does not apply to state medicaid programs."

Page 5, replace lines 18 and 19 with "Any person violating this Act is guilty of a class B misdemeanor."

Renumber accordingly

Date: Feb 9, 2011

Roll Call Vote # 1

2011 HOUSE STANDING COMMITTEE ROLL CALL VOTES

BILL/RESOLUTION NO. 1418

House **House Industry, Business and Labor** Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number 11.0658.01002

Action Taken: ☐ Do Pass ☐ Do Not Pass ☒ Amended ☐ Adopt Amendment

Motion Made By Rep. Vigesaa Seconded By Rep. Frantsvog

Representatives	Yes	No	Representatives	Yes	No
Chairman Keiser			Representative Amerman		
Vice Chairman Kasper			Representative Boe		
Representative Clark			Representative Gruchalla		
Representative Frantsvog			Representative M Nelson		
Representative N Johnson					
Representative Kreun					
Representative Nathe					
Representative Ruby					
Representative Sukut					
Representative Vigesaa					

Total Yes _____ No _____

Absent _____

Floor Assignment _____

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

MOTION CARRIES

Date: Feb 9, 2011

Roll Call Vote # 2

2011 HOUSE STANDING COMMITTEE ROLL CALL VOTES

BILL/RESOLUTION NO. 1418

House **House Industry, Business and Labor** Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken: ☒ Do Pass ☐ Do Not Pass ☒ Amended ☐ Adopt Amendment

Motion Made By Rep. Vigesaa Seconded By Rep. Kasper

Representatives	Yes	No	Representatives	Yes	No
Chairman Keiser	✓		Representative Amerman	✓	
Vice Chairman Kasper	✓		Representative Boe	✓	
Representative Clark	✓		Representative Gruchalla	✓	
Representative Frantsvog	✓		Representative M Nelson	✓	
Representative N Johnson	✓				
Representative Kreun	✓				
Representative Nathe	✓				
Representative Ruby	✓				
Representative Sukut	✓				
Representative Vigesaa	✓				

Total Yes 14 No 0

Absent 0

Floor Assignment Rep. Vigesaa

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

REPORT OF STANDING COMMITTEE

HB 1418: Industry, Business and Labor Committee (Rep. Keiser, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (14 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). HB 1418 was placed on the Sixth order on the calendar.

Page 1, line 19, after "5." insert ""Plan sponsor" means the employer in the case of an employee benefit plan established or maintained by a single employer, or the employee organization in the case of a plan established or maintained by an employee organization, an association, joint board of trustees, committee, or other similar group that establishes or maintains the plan.

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Page 2, line 20, replace "h." with "g."

Page 3, line 11, remove "The insurance commissioner shall adopt rules establishing parameters of audits."

Page 3, replace lines 12 and 13 with "The parameters of an audit must comply with consumer-oriented parameters based on manufacturer listings or recommendations for the following:

a. The day supply for eye drops must be calculated so that the consumer pays only one 30-day copayment if the bottle of eye drops is intended by the manufacturer to be a thirty-day supply.

b. The day supply for insulin must be calculated so that the highest dose prescribed is used to determine the day supply and consumer copayment.

c. The day supply for a topical product must be determined by the judgment of the pharmacist based upon the treated area."

Page 3, line 19, remove "which must"

Page 3, remove lines 20 through 23

Page 3, line 24, remove "to the pharmacy"

Page 3, line 27, replace "thirty" with "one hundred twenty"

Page 3, line 29, replace "thirty" with "sixty"

Page 4, remove lines 8 through 10

Page 4, line 11, replace "7." with "6."

Page 4, line 11, after the second "the" insert "plan"

Page 4, line 11, remove "of the plan"

Page 4, line 13, remove "and the copayment must be returned directly to the patient."

Page 4, remove line 14

Page 4, line 15, remove "auditing entity"

Page 4, line 18, replace "December 31, 2010" with "July 31, 2011"

Page 4, line 19, replace "investigative audit that involves" with "audit, review, or investigation that is initiated based upon alleged"

Page 5, after line 15, insert:

"4. This Act does not apply to state medicaid programs."

Page 5, replace lines 18 and 19 with "Any person violating this Act is guilty of a class B misdemeanor."

Renumber accordingly

2011 SENATE INDUSTRY, BUSINESS AND LABOR

HB 1418

2011 SENATE STANDING COMMITTEE MINUTES

Senate Industry, Business and Labor Committee
Roosevelt Park Room, State Capitol

HB 1418
March 14, 2011
Job Number 15379

☐ Conference Committee

Committee Clerk Signature Ella Lisbeth

Explanation or reason for introduction of bill/resolution:

An Act to provide standards for audits of pharmacy records

Minutes: Testimony Attached

Chairman Klein: Opened the hearing.

Representative Kasper: Introduces the bill. He said the purpose of the bill is Pharmacy benefits Managers are the entities that were created years ago and the original intent of a PBM was to be a record keeper for prescription drugs. He stated that it checks that the drug is covered under your insurance carrier and they authorize the payment of the bill. He said that in the beginning they were good cooperate citizens but as time has gone on there has areas of abuse that the pharmacist in our area and around the nation have said we need to have some corrective action legislatively about the rules and regulations regarding how the PBM's do their audits with pharmacist's. This is what the bill addresses a PBM auditing of prescriptions that a pharmacist provides to the consumer of our State. He said they did amend the bill and he feels it is a good piece of legislation.

Representative Vigesaa: He said that he chaired the subcommittee and had three meetings with each party. He said both sides were willing for the most part to negotiate. They didn't come to total agreement.

Howard C. Anderson, Jr, R.Ph. Executive Director of the Board of Pharmacy: Testimony Attached (1).

Michael Schwab, Executive Vice President of the North Dakota Pharmacists Association: Written Testimony (2).

Chairman Klein: Said that the fact that they worked as a subcommittee on the amendments to get them where they wanted and asked if through the negotiations they got where they wanted to.

Michael: Said that he they were supplied with amendments and he believe they made concessions and eight or nine things were changed.

Senator Andrist: Asked about the process of the getting a prescription is filed. He doesn't know how the PBM's can come back and say that the pharmacists prescribed too much.

Michael: He said that his understanding is that most of the PBM's operate in that manner.

Senator Andrist: Asked if he finds a significant difference in PBM's are there good guys and bad guys or are they all a challenge to your business.

Michael: He said that some do a better job than others. He shared an issue that he had with them.

Senator Andrist: Asked when an audit is done do they get to keep that money, it doesn't go back to the insurance company.

Michael: He said he understands it depends on the relationship with the insurance company and the PBM.

Senator Andrist: Said that it seems to him to be a huge conflict of interest.

John Olson, Pharmacy Services Cooperation: He handed out a letter from H. Edward Heckman, R.Ph. (3). He went over the letter.

Tony Welder, Partner, Prairie Pharmacy: Testimony Attached (4).

Senator Schneider: Asked how frequently the onsite audits happen.

Tony: Said that some have regular audits.

Senator Schneider: Asked if regular means one or two times a year.

Tony: He said they are irregular. They don't have a warning when they happen.

Senator Andrist: Asked in your opinion are the people doing the audits paid a finder's fee or are the PBM's paid a fee.

Tony: He couldn't say if that is true. He doesn't have firsthand knowledge of that.

David Olig, R. Ph.: Testimony Attached (5).

Senator Andrist: Asked if finding problems with specific PBM's.

David: He said there are transparent PBM's and there are some that are not transparent. The nontransparent ones follow the money because we are talking about millions of dollars.

Senator Laffen: Asked if the multimillion dollars all coming from the pharmacist back to the PBM's just through these claims or is there another revenue stream.

David: He said there are all kinds of revenue streams for the PBM's. The data said they recovered seventy four million dollars in the interventions that H. Edward Heckman has done. That is what has been attempted to be taken away from the pharmacist and he stepped in and stopped the unilateral taking away of funds from the pharmacist to the PBM's. He said it seems to be as soon as they get to a certain number the audit stops.

Senator Laffen: Asked if he knew of two ways they get paid one from the claim that comes back from your pharmacy and the other is they get paid for the audit.

David: Said that if it is a contracted service than the contracted service that provides the audit will actually get paid either, that is one of the things that is in the bill that they will not get paid for a percentage of what they are trying to recoup. The audit services of how they are paid they are either in house services, contractually or by subsidizing some of this improper recoupment.

Senator Andrist: Asked if there was a way to find out if the auditors and the PBM's are doing with the money recovered from you. He said it seems to him if they are partners in the business they should be able to audit them.

David: He said first they are not partners. We have contracts that are, "take it or leave it". He said the contract is between the PBM and the sponsor.

Mark Hardy, Pharmacist: Testimony Attached (6).

Senator Laffen: Said that in his testimony he said that if a supply of medication was entered in by mistake, his assumption is that the dosage didn't change.

Mark: Said that is what happens the patient didn't get it anymore than they would of and the plan sponsor wasn't charge no more than they should be and the patient's co pay was the same.

Patrick Ward, Medco Health Solutions: Testimony Attached (7), in opposition to the bill.

Senator Andrist: Asked if they have evidence to specific fraud in North Dakota.

Pat: Said he didn't know if they have found specific fraud in North Dakota.

David Root, Medco Health Solutions: He said that there are no fraud cases in North Dakota. He said the pharmacy is given time to provide documentation to the auditing entity to determine the validity of those scripts, that is recognized in the bill. He said after they find the mistake that item is stricken from the audit report. That is not money that is recovered. He said that they are there as a product of a contract with a plan sponsor. He said they request that they follow their payment to see that it is being put to what they agreed to cover. He said the PBM doesn't say no the plan says no, they are the ones that have to deliver that message. It is all based on the design of the plan. He said in the State of North Dakota they are regulated as a non resident pharmacy and they hold a TPA license. The money that they collect is not a source of revenue; it is a service they provide. They are paid an administrative fee on the contract they have.

Senator Nodland: Asked when he is talking about administration fees, you are paid a fee to do the audits but it has nothing to do with the fees collected there are no percentage, no commission, nothing there.

David: He said that they have learned that there are payers that will put into their contract that they would request the auditing entity keep a percentage of that recovery and they use that as leverage to drive a lower price for something else within the administrative contract for the PBM, so they are leveraged much the same way as the pharmacist are leveraged in a negative way. He said that is a trend that is growing as they have more payers involved in the federal system and more concerns that center on fraud, waste and abuse.

Senator Andrist: He said what he is hearing is the auditing is providing a finder's fee. He asked why they don't pay bigger finder's fees so you don't have to pay anything up front. He said he is having a hard time understanding why this isn't an uncompetitive business practice.

David: He said if it was contained in the contract.

Senator Laffen: Asked what Medco's business volume was in North Dakota.

David: He said that in 2009 they did 1.4 million retail scripts in the state and the audit would be conducted against those scripts. He said they did 555 desk audits no onsite audits. He said they recovered 63,782 dollars.

Stacey Fahrner, Vice president of Government Affairs for Prime Therapeutics: Testimony Attached (8).

Senator Murphy: Asked if most of the insurance coverage in North Dakota is provided by her company and what percentage of pharmacies they cover in North Dakota.

Stacey: Said they probably cover 98-100%.

Senator Murphy: Said that if it is that overriding, what do you think you could do along with the pharmacists, to make negotiations a little bit more amenable to all sides if anything?

Stacey: Said they contract with a third part to do those negotiations with them, she has never sat in on one.

Senator Laffen: Asked if a pharmacy doesn't like the contract and says I just can't sign this contract, they still write prescriptions, but do they not get reimbursed from Blue Cross Blue Shield.

Stacey: Said that patients can go wherever they want. They would still be able to fill those scripts for that patient but they would be out of our network. Which means they wouldn't incentivize people to go to that pharmacy, it is cheaper to go to an in network pharmacy.

Senator Laffen: Said so the cost for that patient would go up?

Stacey: Yes and for the payer.

Senator Andrist: Asked about the structure of the company and if they represent a large number of the Blues'.

Stacey: Said that they are owned by twelve Blue Cross Blue Shield nonprofit plans.

Senator Andrist: Said only one which is North Dakota and you are a for profit company?

Stacy: Yes they are for profit they are privately owned and not publically traded.

Senator Andrist: Said that that these companies are not stuck with them, and asked if they had ownership in them.

Stacy: Said that they own them.

Questions

Rod St. Aubyn, Blue Cross Blue Shield of North Dakota: Said that it was alluded to that BC/BS owns its PBM, they are a small owner in the Prime Therapeutics. They process claims everyday and want to have a more transparent PBM. That is one of the reasons that several of the Blues' went together. In terms of profit, he is not aware that they get any profit it is put back into the PBM for services in terms of IT and other things, he could stand corrected. He gave an example and went over the part of the bill he has a problem with.

Senator Andrist: Said that he it is a huge red flag when somebody is in a nonprofit and starts creating for profit subsidiary, as large as you are couldn't you do a better job at setting up your own PBM and provide your own formulary.

Rod: Said it is not a subsidiary of them, it is a contracted service and just an investment.

Senator Andrist: Said but you own part of it.

Rod: Said a very small part but it isn't a subsidiary and they also own real estate. He said it is all part of the investments that they have and it is part of their reserves.

Questions

Robert Harms, CVS Caremark: He spoke to the issues he saw with the bill and shared the testimony of Mike Aott, North Dakota Director of Government Affairs for CVS Pharmacy. Testimony Attached (9). He said that he wanted to cover three things, a quick overview of the PBM industry. He said in terms of money to address some of the comments made. He said they are not talking about tens a millions of dollars in the audit process that is not in North Dakota, it is tens of thousands at most. He understands the concerns the pharmacists have in going through the audit process that involves nits. He went over the PBM system and how it works. He said that the PBM's save health care dollars and they are a for profit industry but very affective in keeping Americas health care cost down.

Questions

Jack McDonald, Prime Therapeutics: He said they need to keep matters in prospective. He said these are not problems that are necessarily problems in North Dakota but nationally. He said they need to sort out what is happening in North Dakota and what is happening nationally. He said there is always a middle ground and both parties are working hard to solve the problem.

Comment: There was a rebuttal, did not get the name.

Chairman Klein: Closed the hearing.

2011 SENATE STANDING COMMITTEE MINUTES

Senate Industry, Business and Labor Committee
Roosevelt Park Room, State Capitol

HB 1418
March 14, 2011
Job Number 15390

☐ Conference Committee

Committee Clerk Signature Eva Lutetl

Explanation or reason for introduction of bill/resolution:

An Act to provide standards for audits of pharmacy records

Minutes: Discussion

Chairman Klein: Said he is looking for continued discussion on 1418. He asked if there was any information to search out. There has been discussion on additional amendments and he will continue to visit with the interested parties. He said there was a lot of work done in the house. He believes the issue is that PBM's are a big business, for profit corporations that we allowed to establish in 2005 the entail PBM regulation. He said there is a concern because they determine what the pharmacy can charge as a fair price. They tried to figure out a way to bring down the cost of the ever rising health care.

Senator Andrist: Said he would offer a do pass. This is a bill that would never be here if there were not some problems with PBM's to begin with. He said if nothing else, sending a message to PBM's to tell them they are going too far.

Senator Laffen: He said he struggled a bit on how the PBM's worked as they were going through this. He said that the bill is just on the way they are audited by the PBM's. He said it is difficult to negotiate with the big companies; they have all the control and usually are a take it or leave it. He said these rules don't seem that orneriest to him, just in the way they audit.

Senator Schneider: Said that it did sound like the opponents were working on this legislation with the proponents before it was kicked out of the house.

Chairman Klein: Said he wanted to get a feel from the group and not ready to vote yet.

Senator Larsen: He said that he understood it was already in code but just a clarification of how it is to be administered and it is not anything big. It is just holding them accountable.

Senator Laffen: Said that Pharmacies in North Dakota aren't they owned 51% by a person that is at that pharmacy.

Chairman Klein: Said that would be the case in a huge percentage although the CVS folks and the Thrifty White's are owned by themselves because they have a program for the employees to own the company.

2011 SENATE STANDING COMMITTEE MINUTES

Senate Industry, Business and Labor Committee
Roosevelt Park Room, State Capitol

HB 1418
March 21, 2011
Job Number 15740

☐ Conference Committee

Committee Clerk Signature Eva Lobel

Explanation or reason for introduction of bill/resolution:

An Act to provide standards for audits of pharmacy records

Minutes: Discussion and Vote

Chairman Klein: Said that there has been discussion on amendments and changes. He spoke with the folks who brought the bill in they believe the bill is fine in the way it came over from the house.

Senator Nodland: Moved a do pass on Engrossed Bill 1418.

Senator Andrist: Seconded the motion.

Senator Schneider: Asked if the committee considered the amendments brought in by Jack McDonald, he said he understood that he had been working with the pharmacists on that.

Chairman Klein: He said they said they liked the bill the way it is.

Roll Call Vote: Yes-7 No-0

Senator Klein to carry the bill

2011 SENATE STANDING COMMITTEE MINUTES

Senate Industry, Business and Labor Committee
Roosevelt Park Room, State Capitol

HB 1418
March 29, 2011
Job Number 16104

☐ Conference Committee

Committee Clerk Signature Eric Luibakk

Explanation or reason for introduction of bill/resolution:

An Act to provide standards for audits of pharmacy records

Minutes:

Further Discussion on a proposed amendment, Attached

Chairman Klein: Said that it isn't his intent to do anything to 1418, it has been passed it passed unanimously. He said he did promise the concerned individual that they would have discussion and that if the committee thought it was worthy he would attempt to find another vehicle for his amendment. He did not print out the amendment but his concern is the way the language is written. He reads from the proposed amendment, Attached (1).

Senator Laffen: Said if I remember right we passed this just as it was and didn't make any amendments, this would be done if we left this one alone, going to the Governor.

Chairman Klein: Said this bill is done and will be going to the Governor. What I would attempt to do is find a secondary source to put this amendment on. If we believe this is a major issue that we had missed out on we would address it.

Senator Larsen: Said he thinks on this bill his concern was that when the audit happens his company has to send the audit information to all of the policy holders. If he has a policy holder with Minot public schools, that everybody that is on that policy gets an audit report. He asked if that was one of the amendments that he was talking about and then the other amendment was if there is there a discrepancy where does the money go for the overpriced stuff, does it go to the individual policy holder or does it go to the Minot public policy?

Chairman Klein: Said that according to what the individual believes it would require the distribution of the final audit and that recoupment back to the employer in a fully insured plan. I don't know if the Minot program is self insured or fully insured. His concerns are that the employers aren't liable for those claims and do not pay the claims directly and are not typically eligible for the refunds. He also said that would be an accounting issue. There is some discussion that they already have some sort of mechanism in place, I believe when there is a rebate that has to be redistributed they've found a way to do that. We can keep this alive for a little while yet.

Senator Nodland: Asked when an audit is being preformed does it say now that they have to be notified, I thought it was only the people that were audited.

Chairman Klein: Said in a recoupment if they find that that there was an audit and they recovered some money. He said when they are negotiating between the employer and insurer they would have to put in there, if requested by the third party payer.

Senator Andrist: Asked if he was proposing to change this bill, you are talking about attaching this provision to another bill someplace.

Chairman Klein: He said he would need the support of the committee to have management work with him on this and I suggested that I would bring this back.

Senator Larsen: Said that when they were working on this no one provided any amendments.

Chairman Klein: Said he provided no written testimony and no amendments. He closed the meeting.

2011 SENATE STANDING COMMITTEE MINUTES

Senate Industry, Business and Labor Committee
Roosevelt Park Room, State Capitol

HB 1418
March 30, 2011
Job Number 16168

☐ Conference Committee

Committee Clerk Signature Eva Lubelt

Explanation or reason for introduction of bill/resolution:

An Act to provide standard for audits of pharmacy records

Minutes: Further Discussion and Proposed Amendment

Chairman Klein: Asked if there was any discussion on 1418.

Senator Andrist: Said that we passed out 1418 and I still think it is a pretty good bill. I don't think it doesn't hurt to let it work for a couple of years and nothing is ever final.

Senator Laffen: Asked if they voted on the floor for this already.

Chairman Klein: Said that 1418 passed unanimously. He said it could be addressed in the future.

Senator Nodland: Said that he feels the same as Senator Andrist. If they need to fix it they can do it in two years from now.

Senator Laffen: Said he would defer to you, if you think we need to do something I would support it.

Senator Schneider: Said he felt the same.

Chairman Klein: Said we talked about it and always willing to listen.

Senator Murphy: Said I think the reason it passed unanimously is because we recommended it. I don't think anybody that voted on it would understand all the language. I would say if you want to do this you probably have a better idea than anyone on what should be done in this situation.

Chairman Klein: Said wherever it wines up I will give the committee a verbal notice it is on whatever bill, so you will know because the House will know and will make a decision. He said he has gotten direction and closed the hearing.

Date: 3/21/11
Roll Call Vote # 1

2011 SENATE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. Engrossed HB 1418

Senate Industry, Business and Labor Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken: ☑ Do Pass ☐ Do Not Pass ☐ Amended ☐ Adopt Amendment

☐ Rerefer to Appropriations ☐ Reconsider

Motion Made By Senator Nodland Seconded By Senator Andrist

Senators	Yes	No	Senators	Yes	No
Chairman Jerry Klein	✓		Senator Mac Schneider	✓	
VC George L. Nodland	✓		Senator Philip Murphy	✓	
Senator John Andrist	✓				
Senator Lonnie J. Laffen	✓				
Senator Oley Larsen	✓				

Total (Yes) 7 No 0

Absent 0

Floor Assignment Senator Klein

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

REPORT OF STANDING COMMITTEE

HB 1418, as engrossed: Industry, Business and Labor Committee (Sen. Klein, Chairman) recommends **DO PASS** (7 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). Engrossed HB 1418 was placed on the Fourteenth order on the calendar.

2011 TESTIMONY

HB 1418

testimony 1

BOARD OF PHARMACY
State of North Dakota

Jack Dalrymple, Governor

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House Bill No 1418 – Audit of Pharmacy Records
House Industry, Business & Labor Committee
Peace Garden Room – State Capitol Bldg
2:30 PM – Monday - January 31st , 2011

Chairman Keiser and members of the House Industry, Business & Labor Committee thank you for the opportunity to discuss House Bill #1418 today. Since I had a schedule conflict and could not actually attend this hearing myself, I have asked Daniel Duletski, our PharmD Student Intern to represent the Board of Pharmacy.

At the Board of Pharmacy January 2011 Meeting each Board Member stressed that they would like to do something similar to what is found in House Bill 1418 to resolve some of the problems they see in the Pharmacy Auditing Business. Each Board Member has seen specific instances in their own practices.

The Board of Pharmacy has also seen a few instances which have come to our attention via patients who felt that the pharmacy was treating them unfairly. Upon analysis it turned out that the pharmacy was attempting to comply with audit requirements of the PBM Audit companies and in some cases this resulted in additional co-pays being charged to their patients. One such incident occurred when a patient was being dispensed an eye-drop called Xalatan and the pharmacy was stating that the bottle of eye-drops was a 42 day supply. The pharmacy and patient had obtained information from the manufacturer that it was supposed to be a 30 day supply. But, Pharmacy Audit Assistance Services, their consulting company advised them that they were seeing PBM Audits requiring a 42 day supply on these eye-drops, because if you counted the drops, one drop a day, this amounted to a 42 day supply. Therefore, this patient was charged 2 co-pays, because they paid one co-pay for each month. With much work and contacting, we were able to resolve the issue for this patient. However, the audit practices are endemic and pharmacies are being advised that to avoid having money taken back from them in similar cases such as these. Also, we do not hear from every patient who has been negatively impacted.

When the Pharmacist Association came to us proposing this bill, we asked that the specific instances that we had identified from patients be included in the bill. I believe the legislative council took those examples out and Michael Schwab is prepared to offer amendments to you that would put them back in Bill #1418 again.

Howard Anderson

From: Sue Nelson (Pharmacy) [SNelson@famhealthcare.org]
Sent: Thursday, January 27, 2011 1:58 PM
To: Howard Anderson
Subject: [BULK]
Importance: Low

The PBMs are up to it again. Now they are requesting that we present evidence of good standing for the pharmacy and pharmacist in charge that is no older than 30 days. They must stay up nights thinking of this stuff. I have my compliance report from Sept 2010 and my new license so if you can just send me a response regarding these I will print out your E Mail and throw it in the packet. How ridiculous!

I will send all of that in a separate E Mail without my comments☺. Hope you are fine, Howard. Sue

Susan Wolf Nelson, RPh, Pharmacy Director
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testimony 2

NDPhA
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House Industry, Business and Labor Committee
Rep. George Keiser – Chairman
HB 1418 - Monday, January 31, 2011 – 2:45

Chairman and members of the committee, my name is Michael D. Schwab, Executive Vice President of the ND Pharmacists Association. We are here today to support HB 1418. This legislation is nothing new. There are a number of states that have passed similar Pharmacy Benefit Manager (PBM) audit legislation. I believe there are 12 states that already have passed PBM audit legislation. According to our National Alliance of State Pharmacy Association's, as of December 17, 2010, reports indicate at least 13 additional states are currently introducing PBM audit related legislation during 2011 and there is currently federal PBM audit legislation being worked on. Chairman and members of the committee, this bill is simply asking for "fairness" and is needed to take the powers of prosecutor, judge and jury out of the hands of PBM's when it comes to pharmacy audits.

Today, you are going to hear from pharmacists who encounter and deal with PBM audits at their practice setting. You will hear why "fairness" legislation like HB 1418 is needed. We are not here asking for more money and we definitely are not here to protect those who commit fraud, waste or abuse. Section 4 of this legislation is basically devoted to outlining fraud, waste or abuse provisions. If a pharmacy is committing fraud, waste or abuse, we fully support turning them over to the appropriate regulatory board and action must be taken.

We are asking you to pass legislation just like many others states have already done and ask you to be mindful that numerous other states are currently looking to implement similar PBM audit provisions this year alone.

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Rationale for Audit Provisions

Below, I highlighted some provisions and provided additional testimony for the record. I also wanted to help give you a better understanding of the legislation in front of you.

1. Section 2 – Page 2 – Letter a: *"If conducting an onsite audit, give the pharmacy a written notice at least fourteen business days before conducting an initial audit."*

A PBM audit of a pharmacy typically involves the PBM reviewing numerous selected prescription records and supporting documents. Sufficient advance notice of an audit allows the pharmacy to retrieve the needed prescriptions and claim records for that PBM prior to the auditor physically arriving at the pharmacy. This advance notice allows the pharmacist to keep the pharmacy open and continue to serve patients while the auditor is reviewing the needed records. Similarly, the IRS and others, provide individuals with advance notice of an audit to give them sufficient time to gather the needed records and information and routinely postpones audits for these purposes.

2. Section 2 – Page 2 – Letter b: *"If the audit involves clinical or professional judgment, ensure the audit is conducted by or in consultation with a pharmacist licensed in this state and employed by or contracted with the pharmacy benefits manager or conducted by the state board of pharmacy."*

Pharmacists are licensed by each individual state in which they practice and the relevant rules and regulations governing the practice of pharmacy frequently vary depending on the particular state. Requiring that any consultant pharmacist in an audit is licensed in the state in which the audit is being conducted ensures that the consultant is cognizant of and familiar with the specific standards of practice and the requisite nuances of the pharmacy statutes and regulations of that state.

3. Section 2 – Page 2 – Letter c: *"Limit the audit to no more than 18 months from the date that the claim was submitted to or adjudicated by the entity. A claim may not be reviewed that is older than 18 months from the date of the audit, unless a longer period is permitted under federal law. "*

Keep in mind that the pharmacy claims that are being audited by the PBM are ones that have already been approved by the PBM when they were initially submitted. Therefore, the pharmacy has been proceeding on the assumption that these are "clean claims" and have not "set aside" the reimbursement received from the PBM for these claims based on the fact that there could be a discrepancy. Please note, if an audit uncovers or involves fraud, waste or abuse, Section 4 of the bill states this Act does not apply.

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4. Section 2 – Page 2 – Number 2: *"An audit may not allow a recoupment to be assessed for items on the face of a prescription not required by rules adopted by the state board of pharmacy with respect to patient hard copy prescription forms for controlled and uncontrolled drugs."*

The nature and content of record keeping required of pharmacies and pharmacists is regulated by State Boards of Pharmacy and federal regulation. For example, State Boards of Pharmacy currently regulate content and format of prescription labeling and the Drug Enforcement Administration (DEA) regulates the record keeping required for controlled substances. PBMs that require recordkeeping in excess of that required by state or federal law are infringing upon the regulatory authority of these government entities. In addition, pharmacies typically deal with multiple PBMs. If each PBM were to layer additional recordkeeping requirements over those currently required by state and federal law, this system quickly becomes unmanageable.

5. Section 2 – Page 2 – Letters g-h: *"Allow the pharmacy to use the records, including a medication administration record, of a hospital, physician, or other authorized practitioner to validate the pharmacy record and delivery. Allow the pharmacy to use any legal prescription, including medication administration records, electronic documents, or documented telephone calls from the prescriber of the prescriber's agents, to validate claims in connection with prescriptions and refills or changes in prescriptions."*

These provisions would simply allow pharmacists to submit supporting documentation or affidavit's of healthcare practitioners (i.e., prescribing physicians) to clarify possible questions regarding the details of a prescription and the actual drug and amount thereof dispensed. There have been reports in which PBMs have not allowed pharmacists to use these valid contributions of other healthcare providers to justify their actions and pharmacists have simply been financially penalized.

6. Section 2 – Page 2 – Number 3: *"A finding or overpayment or underpayment may be based only on the actual over payment or underpayment and not on a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs. A calculation of an overpayment may not include dispensing fees, unless a prescription was not dispensed or the prescriber denied authorization. The entity conducting the audit may not use extrapolation in calculating the recoupment or penalties for audits."*

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Extrapolation is a highly questionable statistical technique in which a small representative sample--in this case a few prescriptions-- is extracted from the total number of prescriptions filled for the particular PBM. The number of errors detected in the small sample is then extrapolated across the entire pool of examples to arrive at a questionably inflated number of discrepancies and corresponding penalties. Extrapolation has been widely criticized as an auditing technique and a number of states have passed legislation to prohibit its use (AK, FL, GA, MO, NM, TN, MD, and ID).

7. Section 2 – Page 3 – Number 4: *"A clerical or recordkeeping error may not be considered fraud, but may be subject to recoupment. A person is not subject to any criminal penalty for a clerical or recordkeeping error without proof of intent to commit fraud. "*

When talking about clerical or recordkeeping errors, we are talking about typographical errors or computer errors. PBMs justifiably audit pharmacies in order to detect any improper payment by the PBM on behalf of the plan or consumer. However, many times PBMs fine or penalize pharmacies for even the slightest typographical errors even in the absence of any evidence of intent to defraud or in the absence of any financial harm to the PBM, the plan sponsor or the patient. These provisions would ensure that the pharmacy is only penalized for those mistakes that resulted in actual harm, financial or otherwise, to any interested party. These provisions would remove the incentive for the PBM to penalize pharmacies for inadvertent errors when no harm, financial or otherwise, resulted to any interested party. If a prescription is filled for "31 days" and the prescription was supposed to be filled for "30 days," the PBM should be entitled to take back the "extra day supply" but not the whole 30 day prescription. Hard Edits - are an example of where the PBM and pharmacy could be working together to better efficiencies, recordkeeping and accuracy. Members of the ND Pharmacists Association during their annual convention in 2008 formally requested PRIME Therapeutics engage in discussions to implement "hard edits" to help alleviate clerical errors. Again, in 2009, during a BC/BS Pharmacy Advisory Committee which PRIME has representation on, pharmacists requested hard edits be considered. Even though reasonable, these discussions have never seemed to materialize.

8. Section 2 – Page 3 – Number 8: *"An entity conducting an audit shall establish a written appeals process which must include appeals of preliminary reports and final reports and provide that if either party is not satisfied with the appeal, that party may seek mediation."*

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Currently, PBMs may recoup or retain future payments (some do and some don't) to a pharmacy based on the results of an audit that they perform without allowing the pharmacy the right to appeal or question the audit findings. When one considers that audit recoupment's frequently, involve significant amounts of money, the request for the implementation of an audit appeals process is not an unreasonable one. Similarly, Individuals subject to an IRS audit as well as most other types of audits with potentially significant financial implications are legally entitled to appeal the decision.

9. Section 3 – Page 4 – Number 7: *"An auditing entity shall provide a copy of the final report to the sponsor of the plan for which claims were included in the audit. Any funds recouped must be returned to the plan sponsor and the copayment must be returned directly to the patient."*

It is worth asking, are monies recovered or recouped from pharmacies ever returned to the plan sponsor? Many times, plan sponsors are not aware that the PBM is auditing pharmacies and are similarly unaware that the PBM is extracting recoupments for prescriptions filled under their plan. This provision would simply provide plan sponsors with needed information about the actual operation of their pharmacy benefits plan.

In conclusion, some comments you might hear today from the opposition to this bill might include, (1) these kinds of issues can be resolved through contract negotiations and this legislation is not needed. Let me reassure you, contract negotiations between pharmacies and PBM's are basically non-existent. Feel free to ask the pharmacists here today how many times they have been successful in negotiating contracts with PBM's. Pharmacies are basically given "take-it" or "leave-it" contracts. (2) You might here this legislation is going to do nothing more than allow more fraud, waste or abuse to take place. As you know, as an Association of pharmacists, we do not condone fraud, waste or abuse. This bill explicitly outlines fraud, waste or abuse provisions and any pharmacy conducting such should be dealt with appropriately. If anything, Section 4 of this legislation sends a message to pharmacies, we will not stand for any fraud, waste or abuse. (3) Opposition might also try to make the case, this legislation will increase premiums. We do not see the math or how that broad statement even adds up. Besides, they shouldn't be counting on the pharmacies to pad their pockets and fundamentally should

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not be allowed to take monies back when there has been no financial harm to the plan sponsor, patient or the PBM.

We are open to any and all discussions relating to the passing of HB 1418. We would like to offer a couple of amendments for consideration. The amendments are attached for your review and consideration. Thanks for your time and attention today. I would like to call on John Olson, who would like to add a few comments and introduce a few pharmacists who can provide you with more details and examples of what they see at their practice locations.

Respectfully Submitted,

Mike

Michael D. Schwab
NDPhA - EVP

HB 1418 – Amendments for consideration

Section 2 – Page 3
Strikeout number 5 lines 11-13.
Replace with...

5. Audit parameters must not exceed the following rules.
    a. Consumer-oriented parameters based on manufacturer listings or recommendations:
        i. Day supply for eye drops, so that the consumer pays only one 30 day copayment when the bottle of eye drops is intended by the manufacturer to be a 30 day supply.
        ii. When calculating the day supply for insulin, the highest dose prescribed should be used to determine the day supply and patient copayments.
        iii. When calculating the day supply for topical products, because of the uncertainty about the size of the area to be treated, the pharmacist's judgment shall take precedence.

Section 4
Applicability
Insert # 4

4. This Act does not apply to State Medicaid programs.

testimony 3

PAAS National, Inc.
Expert Third-Party Contract and Audit Advice
160 Business Park Circle • Stoughton, WI 53589 • 608-873-1342 • Fax: 608-873-4009

TO: MR. MICHAEL SCHWAB
EXECUTIVE VICE PRESIDENT
NORTH DAKOTA PHARMACISTS ASSOCIATION

FROM: H. EDWARD HECKMAN, R.Ph.
PRESIDENT

DATE: JANUARY 27, 2011

RE: PHARMACY PRESCRIPTION CLAIMS AUDITS

PAAS National® Statement on Pharmacy Audits to the North Dakota Legislature

My name is H. Edward Heckman. I am a Pharmacist and the President and Owner of PAAS National® (pronounced "*pass*"), also known as the Pharmacy Audit Assistance Service – a company I founded in 1993 (www.paasnational.com). PAAS National® is an advocacy that has assisted community pharmacies in over 18,000 prescription claims audits. We have 4,500 members who are community pharmacies located in all 50 states. We have helped pharmacies recover more than $74 million in inappropriate audit chargebacks, which in most cases had been unilaterally redacted from them.

At the request of the North Dakota Pharmacy Association I provide expert written testimony in regard to the unjustly predatory practices of some Pharmacy Benefits Managers (PBMs) with their pharmacy prescription claims audits. While there is a need for a bill which would regulate pharmacy audits in this state, PAAS National® recognizes the importance of actions to curtail fraud, waste and abuse. I want to be clear that PAAS National® vigorously supports state and national measures to reduce and eliminate health care fraud waste and abuse. My testimony does nothing to weaken the government's efforts in these regards. Often however, pharmacy auditors prey on independent pharmacies as easy targets and pilfer the pockets of legitimate pharmacy owners by citing errors representing little more than technical discrepancies of no financial consequence having no effect upon patient care or outcomes.

Clerical or scrivener's errors do not necessarily indicate fraud or even an overpayment on a prescription claim. However, auditors often look for scribbles or scratches made as the doctor hurriedly fills out prescriptions for their patient, crossing out or writing over a date, strength, or quantity of a prescription. Pharmacists then have a corresponding duty to accurately interpret such orders and determine if contacting a prescriber is necessary to clarify an order. Pharmacists shoulder a serious responsibility to protect the safety of their patients and to assure that any medications prescribed are correct and appropriate to treat the patient's condition.

Unfortunately pharmacy auditors hired by some Pharmacy Benefits Managers (PBMs) take a different approach. Any scratch or scribble on a prescription is labeled as an unauthorized change or alteration nullifying the prescription, even when it is clearly not the case. Auditors target primarily high dollar claims often $500 or more, searching for the slightest imperfection and then recover the payment previously made to the pharmacy. In the spirit of a fair audit, documentation should be requested by the auditor from the prescribing physician to determine if the pharmacist dispensed the prescription correctly and if the payment was appropriate. In our experiences this is not always the case.

Another example from a popular Pharmacy Benefits Plan in North Dakota, "Prime Therapeutics" is found in their 2010 [Pharmacy] Provider Manual, on page 25 which states,

> *"Documentation that is required to be available at the time of dispensing will not be accepted post-audit."*

Prime Therapeutics uses this provision as a reason to refuse nearly any documentation to address audit discrepancies. Redactions for discrepancies are then taken from future remittances owed to the pharmacy, even though the pharmacy may not agree with Prime Therapeutics' claim and does not grant specific permission to take the money from them. These are unilateral decisions. The PBM is the judge and jury. A pharmacy's only remedy to such predatory practices is expensive litigation.

A typical scenario is for Prime Therapeutics or any other PBM to audit a pharmacy and deem flaws in just 6 prescriptions at $500 each. Then they deny the pharmacy a fair right to due process to appeal or challenge such discrepancies and the pharmacy is left with a $3,000 audit bill with the money extracted from future payments. The pharmacist knowing full well that the prescriptions in question were legitimate—meaning the doctor prescribed the medication and the patient received the medication—must choose whether to hire an attorney to litigate the case in the PBM's home state (which is anywhere other than North Dakota) or surrender without recourse. Faced with a reality of spending much more for defense than the cost of the penalty, the pharmacy always bows to the PBM. A pharmacy's profit margin on expensive brand prescription medications is usually 10% or less. On $3,000 of prescriptions the pharmacy's out of pocket expense to purchase the medications would be $2,700 and the PBM takes all the money back even though the patients received the prescriptions. Just to break even on the out-of-pocket costs of the medication on the six discrepant prescriptions, the pharmacy would need to fill 54 prescriptions at $500 each.

Keep in mind the PBM makes no claims that the patient did not receive the prescription. The pharmacy purchased the medication and dispensed it to the patient.

Another unfair audit discrepancy that occurs is with prescriptions labeled "Use or Take as Directed." The PBMs argue that "as directed" instructions are a method for patients to obtain excessive quantities of drugs beyond their plan's supply limits. While there may be instances of legitimate PBM concerns with "as directed" prescriptions, when a doctor and patient conspire to obtain larger days supplies and quantities of medication than the plan permits; these situations are isolated. There are many legitimate reasons for "as directed" on the label. There are instances when the amount of medication fluctuates

and must be titrated from one dose to the next. Such is a common practice for diabetic patients using insulin whose blood sugars may fluctuate—yet auditors claim discrepancies and redact payments. There are other drugs that the manufacturer's packaging if far more detailed and instructive than the limited number of words that can fit on a prescription label. Medications pre-packaged in their own dispensing systems, such as birth control tablets that are in a dispenser with clear labeling. And some antibiotics a such as Azithromycin packaged and more commonly known as "Z-Paks" come from the manufacturer on punch cards clearing labeled with instructions. The course of therapy with Azithromycin is six tablets taken over five days—two tablets on day one, and then one tablet daily for each of the next four days until gone. The manufacturer's packaging is a well designed punch-card containing clear labeling to assure that any patient who can read and pay attention can successfully take the right dose of medication at the right time. This type of manufacturer packaging is also known as compliance packaging, and goes far beyond the words that fit on a prescription label. Below is a rendering of typical Azithromycin packaging that visually illustrates my point.

Punch Tablets from the Card	Take 5 days until all tablets are gone	Instructions
○ ○	DAY ONE	Take two tablets
○	DAY TWO	Take one tablet
○	DAY THREE	Take one tablet
○	DAY FOUR	Take one tablet
○	DAY FIVE	Take one tablet

Believe or not, some PBMs, in particular CVS-Caremark, recapture payments made to pharmacies for Azithromycin prescriptions labeled "Take as directed." Again, pharmacies are often left with no chance for an appeal. People outside of the community pharmacy industry suggest that such practices are a form of extortion and opine "there should be a law against that!" This is the heart of the reason I offer my expert testimony to the Legislature.

PBMs such as Medco, CVS-Caremark, Express Scripts, Prime Therapeutics, Med Impact, Argus and a host of others are unregulated. This is amazing considering that the rest of the health care industry is wrought with regulations, licenses and oversight.

PBMs have created their own for-profit cottage industry from prescription claims audits. Some auditors are incented by receiving a percentage of money recouped. In many instances the money recovered in an audit is kept by the PBM and not returned to the plan sponsor, even though it technically belongs to the plan sponsor. In addition, during the eighteen years since PAAS started, I cannot recall one instance of patient co-pays being refunded to the patients even though the PBM recovered them from an audit. How can it be that PBM's can keep money that was never theirs in the first place? Fair legislation could prevent PBMs from operating their "for profit" cottage industry for their own benefit and require them to return all money recouped from legitimate audit discrepancies to plan sponsors and patients.

PAAS National® supports the need for pharmacy audits. However, audits must be conducted in a fair and balanced manner, allowing for a fair appeal and payment for all services rendered within the plan member's benefit limitations.

Today, it is the Legislators' responsibility to judge such practices for themselves and to take the necessary steps to prevent these unfair activities. The North Dakota Legislature can make a difference to improve health care quality and efficiency by establishing a fair playing field while not obstructing the elimination of fraud, waste and abuse.

Thank you for the opportunity to provide written testimony.

H. Edward Heckman

testimony 4

HB 1418

Chairman Keiser and committee members of the Industry, Business and Labor Committee:

I would like to share some examples of a recent audit done at our pharmacy in Fargo.

1. A medication that is filled for a migraine headache medication that is, through a typographical error, given a 3 day supply. The medication is refilled repeatedly in 21-30 day intervals on 7 different occasions. The PBM at audit stated: There was an invalid days supply based on manufacturers guide lines and recouped more than $700 on this prescription alone. In this case there was NEVER a premature refill nor was the patient over utilizing the medication. The appeal was denied. There are numerous examples such as this.
2. The concept of "Hard Edits" has been discussed with one of the largest PBM's in our region. This was discussed with this PBM during one of our recent pharmacy conventions as well as formally in meetings with them. To date the expansion of this concept has been denied. Adding these hard edits would eliminate many if not most of these types of audit claims. This process is already being applied in many areas of claim adjudication. If it weren't, the audit process would not have a place to start from. The recouping of these funds appears to be opportunistic and profitable for the PBM's.
3. PBM's are a multi Billion dollar portion of the health care industry. They are the only provider of service, in this magnitude, that has virtually no oversight as to their current operations but do have a very profound effect on pharmacy practice, patient care and escalating medication costs.

Respectfully submitted:

David Olig, R.Ph.
Fargo, ND

testimony 5

PRAIRIE PHARMACY
4731 13TH Avenue SW
Fargo, North Dakota 58103

Tony Weldon

Prime Therapeutics
1305 Corporate Center Drive
Eagan, MN 55121
Attention: Chelsea Nash
Senior Pharmacy Compliance Analyst

Dear Chelsea,

Enclosed are copies of the results of our recent audit. I have been out of state, and just received these a few days ago.

As I look over the individual claims, it is obvious that most of the errors were in the days supply. It's hard to define why those happened, but all staff members have been alerted to be more aware of that critical number and that should not be an issue in the future. In fairness to them, different PBM's have different ways of defining a "unit," some wanting a different definition of the unit size. E.g. some want an eye drop unit to be identified as 5, as in 5 ml, and others want it defined as 1, or a complete dispensing unit.

I scrutinized the list to determine when we filled and refilled those prescriptions and it appears that none were filled too soon or more often than allowed.

The DEA numbers have been corrected.

While we are not asking for a review of all the prescription fills on the list, we are appealing the most expensive prescription charge backs. I have marked those with a circle. Since I am not at the Fargo site, I have notified our pharmacist in charge, Bruce Herold, to be prepared to furnish copies of the prescriptions. Is it acceptable for those to be faxed, or should I have him FedEx them to you?

Thank you for your attention to this matter. I do appreciate it.

Sincerely,

Tony Welder, R. Ph. (one of the owners)
Direct line 701-258-2270
Email tonywelder@dakotarx.com
705 E. Main Avenue
Bismarck, ND 58501

testimony 5

Testimony PBM, IBL Comm 1-31-11

January 31, 2011

HB 1418

Chairman Keiser and members of the Industry, Business and Labor Committee:

On December 31, 2008, Prairie Pharmacy in Fargo wrote a check to Prime Therapeutics in the amount of $2,459.92 for chargebacks, the amount Prime claimed we owed them for incorrect submission of claims.

Prime Therapeutics did an audit of some prescriptions in September of 2008.and found the following:

One physician DEA number was incorrect

Most chargebacks were for incorrect days supply. Here are some examples of why that happens

1. Insulin users frequently change doses as necessary for the control of their diabetes and is determined by testing of their blood glucose level. Since we must bill for the days supply when filling the insulin prescription it is difficult to determine the exact number of days supply for that prescription.

2. Eye drops are also difficult. While we can calculate how many drops is in a container, frequently a patient may miss the eye and the drop is running down their cheek.

3. Inhalers may be used "as necessary" for their asthma condition, so the days supply has to be an educated guess.

4. Various PBM's formerly may have required different claim methods for amount dispensed at our audit time. For example, one

may require 5, as in 5 milliliters as the dispensed amount, others may require "1" as the complete pre-packaged amount dispensed. This has now been standardized.

After we received the report, the DEA number was corrected and all staff were alerted to be more aware of the days supply issue.

In the end, on reviewing all the prescriptions audited, we found there weren't any that were actually filled too soon or more often than allowed, so there was no extra cost to the patient, plan or the sponsors.

We paid the chargeback because of the time, effort and probably the expense that would have been involved to challenge the issue.

Respectfully submitted.

Tony Welder, Partner, Prairie Pharmacy.

testimony 6

HB 1418 PBM Audit Reform Testimony

Mark Hardy, PharmD

Chairman Kaiser and members of the House Industry, Business and Labor Committee, for the record my name Is Mark Hardy a registered pharmacist from Neche, ND. I work for Thrifty White Drug. I would like to urge the committee to give HB 1418 a DO PASS recommendation.

Pharmacists from North Dakota are bringing this piece of legislation in response to the exponential increase in predatory and unfair PBM audit practices which we are experiencing. Let me be clear we are not scared of an audit and welcome these to ensure fraudulent prescriptions are not being filled. We are looking for these audits to be fair and not an aggressive mechanism for these PBMs to take back payments. I would like to give you a few of the trends which Thrifty White has seen in regards to audit practices.

1. We have seen the number of audits increase up to four times what we experienced just two years ago. Thrifty White has had to hire additional staff to specifically deal with this increase.
2. The amount of money in claims they determine should be charged back has seen over a 5 fold increase in the last 2 years. For one PBM alone, the chargeback went from over $15,000 in 2008 to over $70,000 in 2010.
3. The average price per claim audited is $614.52. Our average prescription price currently is $52.08. For one of our more common PBMs, Prime Therapeutics the average price of an audited claim is $944.40
4. The overall percentage of generic prescription claims audited by these PBMs is 21.4% while our average generic dispensing rate over all stores is 74%.
5. The number of prescriptions examined per audit has increased and in some cases they want to look at over 200 prescriptions per audit
6. PBMs are giving pharmacies shorter notice times of upcoming audits and schedule them during typical busy days.

Along with these trends, we have also seen outrageous examples of where a PBM determines a claim to be charged back. Here are just a few of the examples of these crooked behaviors.

1. Claiming a prescription is invalid because a NPI number of a prescriber is not written on the prescription. Having this number on a prescription is not a requirement by the State Board of Pharmacy.
2. Not accepting a Medication Administration Record (MAR) from a nursing home as proof a prescription was received.
3. Taking money back on creams and ointments due to what the PBM refers to as inadequate day supply. Even though it is impossible to determine how large an area a patient needs to apply the medication.
4. PBM taking claim money back for insulin prescriptions due to directions written by prescriber to "use per sliding scale." Patient was never refilling earlier than needed and the prescription accurately reflected the physician's directions.

5. Claiming a physician's dispense quantity is unreasonable for a migraine medication even though there is no way to know how many headaches a patient may have in a month.

An audit is very time consuming and requires preparation and extra labor. This is why the legislation includes mandates on prior notice.

In the case of a determined discrepancy in day supply, a PBM will take back claim payments where no financial harm is done to the plan or the patient. An example is if a 30 day supply of medication was entered in as a 20 day supply due to hitting a wrong key, this claim will be recouped by the PBM. Even with documentation that the patient did not get it any sooner than 30 days, the PBM determines this as reason for a chargeback.

We have consistently tried to get PBMs to put real-time messaging in to help catch these typographical errors. They do not take any action on this even though this would be an easy process to implement for them and would appear to be a win-win for both sides. The audit practices have influenced pharmacist's dispensing habits and this can ultimately negatively impact patients.

In closing, I hope this give you our perspective on this increasingly abusive practice by the PBM industry on pharmacies. It is my understanding in the past this auditing was done in a more fair and reasonable way and involved common sense to determine if claims were adjudicated correctly. Unfortunately this has changed and due to the increasingly abusive practices we are looking for your support to help set some parameters to follow as we move forward. I hope for your support in passage of HB 1418 and I would be more than happy to answer any questions.

Respectfully submitted,
Mark Hardy
mhardy@thriftywhite.com

testimony 7

January 31, 2011

House Industry, Business & Labor Committee – HB 1418

CHAIRMAN KEISER & MEMBERS OF THE COMMITTEE:

I am Stacey Fahrner, Vice President of Government Affairs for Prime Therapeutics. Prime is a pharmacy benefit management (PBM) company owned by 12 non-profit Blue Cross Blue Shield companies. We manage pharmacy benefits for approximately 18 million covered lives.

I am here today to answer your questions and provide some clarity on Prime's audit processes and policies as you consider House Bill 1418. Prime's mission is to provide high quality yet cost effective pharmacy benefits. We are one of the few full service PBMs that operate through a transparent business model, meaning that we provide our health plan clients with a full accounting of income and expenses. An effective audit process is an essential part of maintaining a high-value pharmacy network and decreasing exposure to fraud, waste, and abuse.

I'll start with a description of our audit processes. Like all businesses, Prime is audited by our clients and by the government. Our clients include the state and federal government, with the Medicare program and CMS – the Centers for Medicare and Medicaid services – being the largest. Both the public and private clients expect, and are entitled to, an accounting of their expenditures on pharmacy benefits to ensure that their policy holders receive the full value of their premium dollars. Likewise, federal and state governments must ensure the accuracy of pharmacy claims financed through public tax dollars. To fulfill those obligations, Prime must audit the pharmacies we do business with.

Prime performs daily claims reviews for pharmacy claims over a certain dollar threshold. Daily claims reviews allow us to address most errors or inaccuracies before a payment is made and helps to reduce frequency of additional audits as well as avoid future claims recoupment.

In addition, desktop and on-site audits are performed periodically to verify the integrity of submitted claims and payments to the pharmacy. For desktop audits, we notify pharmacies of the claims in question and a description of the required documentation. Pharmacies are given 14 business days to respond.

Pharmacies are given at least 14 days advance notice of an on site audit. Notices include information on the audit timeframe as well as required documentation. In addition to claim verification, on site audits allow us to observe the pharmacy's physical environment and identify any safety or drug storage issues.

(OVER)

Prime provides a written audit report of all desktop and on site audit findings with 30 days. Pharmacies have 30 days to submit an appeal.

In 2010, Prime conducted 20 audits in North Dakota and has identified approximately $100,000 in inaccurate claims. Common errors identified in the audit process include instances where the pharmacist over dispensed drugs compared to what the health plan has agreed to pay for under the benefit plan. This practice circumvents the plan benefit design and in many cases allows the patient to obtain additional medicines without refilling their medications at the proper time. Some pharmacies did not retain adequate records to properly validate that the prescriptions written by physicians were filled for that physician's patient. Another recurring issue was pharmacies submitting to Prime post-audit validation documents that were not recorded at the time of dispensing. Prime also identified instances in which the patient was given the wrong dose or the wrong directions for administration, which raises important safety concerns.

Prime works with our health plan clients to view pharmacy benefits as an investment. A patient who is well managed on drug therapy is less likely to incur unnecessary medical expenses. Prime considers pharmacists an essential part of that mission. To that end, we are continually working to develop new product offerings, such as more robust medication therapy management programs, through which we will more heavily rely on pharmacists to deliver high-quality counseling and other services to members.

New services represent additional reimbursements and billing interactions between pharmacies and PBMs. Likewise, in the post-health reform era we will see dramatic increases in tax-payer funds in the commercial market, increased access to the health system and, finally, an aging population will result in an overall increase in the need for drug therapies. As these changes are implemented, it is more important than ever for PBMs to be good stewards of health plan, policy holder, and government funds.

While we acknowledge that the vast majority of pharmacists are honest, the problem of fraudulent claims is a growing concern, and PBMs must be diligent in limiting our exposure. The federal government estimates that as much as 10% of total health expenditures, over $200 billion a year, are lost to fraudulent activities.

This concludes my testimony. Thank you for your time and consideration. I am happy to answer any question you have.

testimony 8

North Dakota HB 1418
House IBL Hearing – January 31, 2011
Comments by David Root
Medco Health Solutions, Inc., and Affiliates.

Chairman Keiser and members of the House IBL Committee, my name is David Root and I represent Medco Health Solutions, Inc., and Affiliates, which is a Pharmacy Benefits Management Company, or PBM. I am here today before you to express our opposition to HB 1418. We believe that this legislation interferes with freedom of contract within the pharmacy benefit structure, would increase the cost of the pharmacy benefit to the insurer and the patient because of possible mistakes or errors resulting in overcharges being missed, and runs counter to the contractual wishes of those that pay for the pharmacy benefit.

Medco Health Solutions, Inc. and Affiliates is a leading health care company that is advancing innovations in the practice of pharmacy. We provide comprehensive, high quality, affordable prescription drug care to over 65 million Americans. We currently manage the prescription drug benefit for approximately 17% of the North Dakota population. We are licensed in this state as a non-resident and third party administrator.

Medco covers approximately 110,900 lives in North Dakota, representing about 17% of the population of the state. In 2009 Medco adjudicated 1.4 million retail scripts in the state. Out of those 1.4 million scripts Medco conducted approximately 555 desk audits in North Dakota. During the course of any given year 60% to 70% of Medco audits country wide are desk audits. *A desk audit can often be as simple as a phone call to verify an issue.*

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. Our clients include such health care purchasers as:

Fortune 500 corporations & smaller employers
Local, state, and federal employee and retiree groups
Blue Cross & Blue Shield plans
Labor Unions
Insurance carriers and managed care plans.

We believe this legislation, although it appears to help pharmacies, could have the unintended consequence of opening the door to fraud, abuse, and wasteful spending in health care. Health plans and employers with pharmacy benefit plans rely on audits of their network pharmacies to recoup monies incorrectly paid for claims with improper quantity, improper days supply, improper coding, duplicative claims, and other irregularities. Health plans and employers should have the right to ensure that the pharmacy claims that they are paying for are legitimate. In a time of rising health care costs, preventing fraudulent activity is an important tool to keeping health care costs down. This legislation severely restricts the ability of health plans and employers to make sure they are getting what they pay for.

Auditing is part of the cost of doing business. That goes for any type of business – pharmacies should not be an exception to the rule.

Legislation that requires entities to provide pharmacies/pharmacists with an advanced notice of two weeks before an audit would give individuals ample time to hide evidence of mistakes or fraudulent activities or evade authorities altogether.

Similarly, limiting the number of prescriptions available to audit to 40 would also impede the ability of auditors to detect fraudulent prescriptions. Such a major restriction would allow pharmacies acting illegally to beat the system easily and not be caught.

Pharmacy Benefit Managers (PBMs) look for errors, irregularities, and suspicious patterns over time. Claims are compared with historical information as well as claims submitted by similarly situated pharmacies. Substantial changes in the volume of claims or the dollar amount of claims from particular pharmacies can indicate fraudulent activity.

In addition to detecting fraud, audits also have a patient safety aspect. Auditors ensure that pharmacies are complying with Board of Pharmacy rules including the proper storage of prescription drugs or posting of required signs.

Audit and appeals procedures are already contained in contracts between PBMs and pharmacies. PBMs also supply pharmacies/pharmacists with provider manuals, which contain information about audits and examples of fraud, waste, and abuse. Additionally, some PBMs also distribute provider tip sheets quarterly, which may contain additional information related specifically to what audits entail.

Our goal is to work with our network pharmacies and our third party payers to eliminate waste and mistakes and make sure only those drugs prescribed and necessary are paid for by the plans.

We urge a Do Not Pass on HB 1418.

BOARD OF PHARMACY
State of North Dakota

Jack Dalrymple, Governor

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Fargo
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Wahpeton, Treasurer

House Bill No 1418 – Audit of Pharmacy Records
Senate Industry, Business & Labor Committee
Roosevelt Room – State Capitol Bldg
10:15 AM – Monday - March 14th, 2011

Chairman Klein and members of the Senate Industry, Business & Labor Committee thank you for the opportunity to discuss House Bill #1418 today.

At the Board of Pharmacy January 2011 Meeting each Board Member stressed that they would like to do something similar to what is found in House Bill 1418 to resolve some of the problems they see in the Pharmacy Auditing Business. Each Board Member has seen specific instances in their own practices.

The Board of Pharmacy has also seen a few instances which have come to our attention via patients who felt that the pharmacy was treating them unfairly. Upon analysis it turned out that the pharmacy was attempting to comply with audit requirements of the PBM Audit companies and in some cases this resulted in additional co-pays being charged to their patients. One such incident occurred when a patient was being dispensed an eye-drop called Xalatan and the pharmacy was stating that the bottle of eye-drops was a 42 day supply. The pharmacy and patient had obtained information from the manufacturer that it was supposed to be a 30 day supply. But, Pharmacy Audit Assistance Services, their consulting company advised them that they were seeing PBM Audits requiring a 42 day supply on these eye-drops, because if you counted the drops, one drop a day, this amounted to a 42 day supply. Therefore, this patient was charged 2 co-pays, because they paid one co-pay for each month. With much work and contacting the companies involved, we were able to resolve the issue for this patient (see attached copies). However, the audit practices are endemic and pharmacies are being advised that to avoid having money taken back from them in similar cases such as these, they must affix these ridiculous days supply numbers. Also, we do not hear from every patient who has been negatively impacted, so cannot help them, except legislatively.

Additionally, the Board of Pharmacy asked that the provisions on page 4, line 20 and after be included in this bill so that no one got the impression that they could avoid unprofessional conduct, or get away with fraudulent activities, by this legislation. We also clearly mentioned that the auditing company would be required to report suspected fraud or violations of the law to the licensing board.

We see multiple instances, and I have included an email I just received Thursday, January 27th from one of our pharmacists, pointing out one of the practices of a PBM, Express Scripts, asking for additional information and in my opinion adding costs unnecessarily to the system. If a pharmacy or pharmacist has a valid license issued by the State Board of Pharmacy, that should be considered as evidence that they are able to practice their profession according to the laws and rules of the State of North Dakota.

Another instance came in just the other day and I have included a copy of my letter pointing out that you make the laws in North Dakota and we enforce them, not the auditors.

Howard C. Anderson, Jr, R.Ph.
Executive Director

July 25, 2009

RECEIVED
JUL 29 2009

Dear Mrs Anderson,

This letter is to give you permission to ask questions and get information on my behalf from my prescription plan and also from the following places regarding Travatan Z. Rx #

My member ID number is

1. First Health Part D (from Coventry Health Care)
   First Health Life & Health
   Insurance Company P.O Box 7763
   London, Ky. 40742-7763 phone 1-866-865-0662
2. Ye olde Medicine Center. Cavalier & Park Rivers ND. phone 701-265-3332
3. Paas
4. Medicare
5. I am also enclosing the letter from Alcon.

It does not make sense to preclude such an exact amount of eye drops when even a very skilled pharm would not be ~~abble~~ able to do this; and because they say you should get 4.3 drops they are allowed to change double the Co pay.

Last year and the first part of this year they did not do this.

Thank you for your help.

Agnes M. Heuchert
St. Thomas N. Dak 58276
Phone

Ms. Agnes M. Heuchert
Saint Thomas, ND 58276-9736

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State of North Dakota

John Hoeven, Governor

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Granville
Gayle D. Ziegler, R.Ph.
Fargo
William J. Grosz, Sc.D., R.Ph.
Wahpeton, Treasurer

October 27, 2009

First Health Part D (from Coventry Health Care)
First Health, Life and Health Insurance Company
P.O. Box 7763
London, KY 40742-7763

Dear First Health:

I have a complaint from one of our North Dakota patients, Ms. Agnes M. Heuchert of 8538 145th Ave NE, St. Thomas, ND 58276. Ms. Heuchert had a prescription for Travatan Z filled at Ye Olde Medicine Center in Cavalier and Park River, North Dakota. Ms. Heuchert tells us that Ye Olde Medicine Center was advised by you and PAAS consultants that a 40 day supply should be listed when filling the prescription for her Travatan Z in a 2.5 ml bottle. You can see from the explanation of Ms. Heuchert on the attached letter authorizing you to talk with us about her medical care that she is unable to obtain a 40 day supply; and in addition, the 40 day supply necessitates a double co-payment on her part.

It seems reasonable that a 2.5 ml supply should be listed by the pharmacy as a 30 day supply and paid for by the insurance company, as such. You will note the attached letter from Alcon Research Limited indicating that it is reasonable to assume that there is a little overfill in the bottle to compensate for the loss of a few drops by the older individual trying to instill them in their eye.

Obviously the pharmacy does not wish the payment for this prescription to be taken away from them on an audit, and thus relies on the insurance company's previous audit experience communicated to them by the PAAS consultants.

Please clear this up for us, Ye Olde Medicine Center, PAAS, and Ms. Heuchert, so that a reasonable accommodation may be made by the pharmacy in filling Ms. Heuchert's prescriptions without charging her two co-pays for medication that does, and is reasonably expected, to last her for one month.

Sincerely,

Howard C. Anderson, Jr., R.Ph.
Executive Director

HCA/bn
CC: Ye Olde Medicine Shoppe, Inc.-Cavalier; PAAS Member Services; Medicare Part D Complaint Services; ND Insurance Commissioner; Ms. Agnes Heuchert
Enclosure

Alcon®
RESEARCH, Ltd.
6201 South Freeway TC-37
Fort Worth, Texas 76134

Ms. Agnes Heuchert
8538 145th Ave. NE
St. Thomas, ND 58276

22 June 2009

Re: TRAVATAN® Z Estimated Average Drops per Label Fill (estimation as per use by a patient)

Dear Ms. Heuchert:

Thank you for your unsolicited inquiry regarding the available drops per label fill in Alcon's product, TRAVATAN® Z (travoprost ophthalmic solution) 0.004%.

TRAVATAN® Z is approved for the treatment of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension. The recommended dosage is one drop in the affected eye(s) once daily in the evening. Per our telephone discussion, TRAVATAN® Z as supplied in a 2.5mL quantity will have sufficient fill for one month of practical use.

Drop usage for the duration as listed above corresponds to the labeled amount of product only, and does not account for any overfill which may or may not be present within a specific bottle. Overfill volumes may be subject to variation.

Drops per fill data is not provided, as it does not always correspond to the number of drops that a patient may actually instill that will be of therapeutic value. The number of drops obtained from each bottle will vary from patient to patient. Patients may not reliably deliver each drop contained in a packaged unit to the eye. This is especially true for persons who are not experienced or are infrequent users of eye drops, or those persons who are elderly and/or have physical or visual disabilities that might limit their ability to successfully administer the eye drops. Drop size administration can be highly variable. Human factors such as hand strength, shakiness of hands, dexterity, method of squeezing the bottle and the bottle-angle during administration contribute significantly to the variability that can occur from one patient to the next.

Decisions regarding off-label use of medication are always made at the treating physician's discretion. Off-label dosing will cause variations in the length of time that the product will last.

For additional information, please refer to the full product label.

Sincerely,

Janis Fiocchi, MS, CCOA
Medical Information Services
Telephone: 1-800-757-9785
Fax: 1-800-757-9786
Email: medical.information@alconlabs.com

The information given in this email is provided in response to an unsolicited request for information, as a professional courtesy, and neither purports, nor is intended to be related to individual health care. To the extent that any off-label use is discussed therein, Alcon does not endorse or condone such procedures and disclaims any liability for unanticipated outcomes arising from such use. Therefore, each user should make an informed medical decision as to how and to what extent the information is used.

Subject: PAAS National

Laurie,

Here is the information you requested—you should also like the letter from Alcon to the patient.

Hope this helps—have a great weekend!!

Deb Saeger, CPhT

Audit Analyst

PAAS National, Inc.

160 Business Park Circle

Stoughton, WI 53589

P: (888) 870-7227

F: (608) 873-4009

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Wahpeton, Treasurer

March 8, 2011

Aetna Pharmacy Management
Attn: Quality Review Appeal Unit
300 Highway 169 South – Suite 600
Minneapolis, MN 55426

Dear Aetna Pharmacy Management,

The North Dakota State Board of Pharmacy would like to clarify controlled prescription requirements in reference to Central Avenue Pharmacy and discrepancies identified by ACS Audit & Compliance Solutions for Aetna regarding missing DEA numbers.

According to North Dakota State Board of Pharmacy Rules and Laws the requirements for a prescription order for controlled drugs include: the name and address of the patient, date of issuance, name of the drug, quantity, strength, adequate directions for use, the prescriber's name, indication of refill authorization, 'brand necessary' reminder legend, the DEA number and signature of the prescriber. North Dakota law does not specify the location of this information on the prescription so long as it is complete. Therefore in accordance with North Dakota law the prescriber's DEA number may be located on either the front or back of the prescription.

If a pharmacist receives a controlled prescription order that does not contain the prescriber's DEA number the pharmacist may add the number on either side of the prescription. In addition to the DEA number, a pharmacist may alter the following on a schedule II medication prescription: the patient's address (upon verification), addition or change of the dosage form, drug strength, quantity, directions for use or issue date after consultation and agreement with the prescriber. As long as the pharmacist is working within these rules, verifying the prescriber's intentions are being fulfilled and the patient is being taken care of, the North Dakota State Board of Pharmacy recognizes the prescription as being valid and in compliance with North Dakota law,

It is the role of the North Dakota State Board of Pharmacy to regulate and control the dispensing of prescription drugs and the practice of pharmacy for the protection of the health, welfare and safety of the citizens of the state. We request that third party payers concentrate on paying claims for health care services and leave enforcement of North Dakota rules and laws, up to the Board of Pharmacy.

Sincerely,

Howard C. Anderson Jr., R.Ph.
Executive Director

Marissa Clarin
Pharm.D. Candidate 2011

(2)

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Senate Industry, Business and Labor Committee
Senator Jerry Klein - Chairman
HB 1418 – Monday 10:15

Chairman and members of the committee, my name is Michael D. Schwab, Executive Vice President of the ND Pharmacists Association. We are here today to support HB 1418. You have heard already, this legislation passed 14-0 out of the House IBL committee and passed 92-2 on the floor of the House. We agreed to a number of amendments during Subcommittee work on the House and support HB 1418 as introduced in the Senate.

This legislation is nothing new. There are a number of states that have passed similar Pharmacy Benefit Manager (PBM) audit legislation. I believe there are 12 states that already have passed PBM audit legislation. According to our National Alliance of State Pharmacy Association's, as of December 17, 2010, reports indicate at least 13 additional states are currently introducing PBM audit related legislation during 2011 and there is currently federal PBM audit legislation being worked on. Chairman and members of the committee, this bill is simply asking for "fairness" and is needed to take the powers of prosecutor, judge, and jury out of the hands of PBM's when it comes to pharmacy audit practices.

Today, you are going to hear from pharmacists who encounter and deal with PBM audits at their practice setting. You will hear why "fairness" legislation like HB 1418 is needed. We are not here asking for more money and we definitely are not here to protect those who commit fraud, waste or abuse. Section 4 of this legislation is basically devoted to outlining fraud, waste or abuse provisions. If a pharmacy is committing fraud, waste or abuse, we fully support turning them over to the appropriate regulatory board and action must be taken.

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We are asking you to pass legislation like many others states have already done and ask you to be mindful that numerous other states are currently looking to implement similar PBM audit provisions this year alone.

Rationale for Audit Provisions

Below, I highlighted some provisions and provided additional testimony for the record. I also wanted to help give you a better understanding of the legislation in front of you.

1. Section 2 – Page 2 – Letter a: *"If conducting an onsite audit, give the pharmacy a written notice at least fourteen business days before conducting an initial audit."*

A PBM audit of a pharmacy typically involves the PBM reviewing numerous selected prescription records and supporting documents. Sufficient advance notice of an audit allows the pharmacy to retrieve the needed prescriptions and claim records for that PBM prior to the auditor physically arriving at the pharmacy. This advance notice allows the pharmacist to keep the pharmacy open and continue to serve patients while the auditor is reviewing the needed records. Similarly, the IRS and others provide individuals with advance notice of an audit to give them sufficient time to gather the needed records and information and routinely postpones audits for these purposes.

2. Section 2 – Page 2 – Letter b: *"If the audit involves clinical or professional judgment, ensure the audit is conducted by or in consultation with a pharmacist licensed in any state and employed by or contracted with the pharmacy benefits manager."*

Requiring a licensed pharmacist conduct or be consulted in an audit ensures there is someone who is cognizant of and familiar with the specific standards of practice and the requisite nuances of the pharmacy statutes and regulations.

3. Section 2 – Page 2 – Letter c: "*Limit the audit to no more than 24 months from the date that the claim was submitted to or adjudicated by the entity. A claim may not be reviewed that is older than 24 months from the date of the audit, unless a longer period is permitted under federal law. "*

Keep in mind that the pharmacy claims that are being audited by the PBM are ones that have already been approved by the PBM when they were initially submitted. Therefore, the pharmacy has been proceeding on the assumption that these are "clean claims" and have not "set aside" the reimbursement received from the PBM for these claims based on the fact that there could be a

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discrepancy. Please note, if an audit uncovers or involves fraud, waste or abuse, Section 4 of the bill states this Act does not apply.

4. Section 2 – Page 2 – Number 2: *"An audit may not allow a recoupment to be assessed for items on the face of a prescription not required by rules adopted by the state board of pharmacy with respect to patient hard copy prescription forms for controlled and uncontrolled drugs."*

The nature and content of record keeping required of pharmacies and pharmacists is regulated by State Boards of Pharmacy and federal regulation. For example, State Boards of Pharmacy currently regulate content and format of prescription labeling and the Drug Enforcement Administration (DEA) regulates the record keeping required for controlled substances. PBMs that require recordkeeping in excess of that required by state or federal law are infringing upon the regulatory authority of these government entities. In addition, pharmacies typically deal with multiple PBMs. If each PBM were to layer additional recordkeeping requirements over those currently required by state and federal law, this system quickly becomes unmanageable.

5. Section 2 – Page 2 – Letters g-h: *"Allow the pharmacy to use the records, including a medication administration record, of a hospital, physician, or other authorized practitioner to validate the pharmacy record and delivery. Allow the pharmacy to use any legal prescription, including medication administration records, electronic documents, or documented telephone calls from the prescriber of the prescriber's agents, to validate claims in connection with prescriptions and refills or changes in prescriptions."*

These provisions would simply allow pharmacists to submit supporting documentation or affidavit's of healthcare practitioners (i.e., prescribing physicians) to clarify possible questions regarding the details of a prescription and the actual drug and amount thereof dispensed. There have been reports in which PBMs have not allowed pharmacists to use these valid contributions of other healthcare providers to justify their actions and pharmacists have simply been financially penalized.

6. Section 2 – Page 2 – Number 3: *"A finding or overpayment or underpayment may be based only on the actual over payment or underpayment and not on a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs. A calculation of an overpayment may not include dispensing fees, unless a prescription was not*

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dispensed or the prescriber denied authorization. The entity conducting the audit may not use extrapolation in calculating the recoupment or penalties for audits."

Extrapolation is a highly questionable statistical technique in which a small representative sample--in this case a few prescriptions-- is extracted from the total number of prescriptions filled for the particular PBM. The number of errors detected in the small sample is then extrapolated across the entire pool of examples to arrive at a questionably inflated number of discrepancies and corresponding penalties. Extrapolation has been widely criticized as an auditing technique and a number of states have passed legislation to prohibit its use (AK, FL, GA, MO, NM, TN, MD, and ID).

7. Section 2 – Page 3 – Number 4: *"A clerical or recordkeeping error may not be considered fraud, but may be subject to recoupment. A person is not subject to any criminal penalty for a clerical or recordkeeping error without proof of intent to commit fraud. "*

When talking about clerical or recordkeeping errors, we are talking about typographical errors or computer errors. PBMs justifiably audit pharmacies in order to detect any improper payment by the PBM on behalf of the plan or consumer. However, many times PBMs fine or penalize pharmacies for even the slightest typographical errors even in the absence of any evidence of intent to defraud or in the absence of any financial harm to the PBM, the plan sponsor or the patient. These provisions would ensure that the pharmacy is only penalized for those mistakes that resulted in actual harm, financial or otherwise, to any interested party. These provisions would remove the incentive for the PBM to penalize pharmacies for inadvertent errors when no harm, financial or otherwise, resulted to any interested party. If a prescription is filled for "31 days" and the prescription was supposed to be filled for "30 days," the PBM should be entitled to take back the "extra day supply" but not the whole 30 day prescription. Hard Edits - are an example of where the PBM and pharmacy could be working together to better efficiencies, recordkeeping and accuracy. Members of the ND Pharmacists Association during their annual convention in 2008 formally requested PRIME Therapeutics engage in discussions to implement "hard edits" to help alleviate clerical errors. Again, in 2009, during a BC/BS Pharmacy Advisory Committee which PRIME has representation on, pharmacists requested hard edits be considered. Even though reasonable, these discussions have never seemed to materialize.

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8. Section 2 – Page 3 – Number 8: *"An entity conducting an audit shall establish a written appeals process."*

Currently, PBMs may recoup or retain future payments (some do and some don't) to a pharmacy based on the results of an audit they perform without allowing the pharmacy the right to appeal or question the audit findings. When one considers that audit recoupment's frequently involve significant amounts of money the request for the implementation of an audit appeals process is not an unreasonable one. Similarly, individuals subject to an IRS audit as well as most other types of audits with potentially significant financial implications are legally entitled to appeal the decision.

9. Section 3 – Page 4 – Number 7: *"An auditing entity shall provide a copy of the final report to the plan sponsor for which claims were included in the audit. Any funds recouped must be returned to the plan sponsor (the employer group)."*

It is worth asking, are monies recovered or recouped from pharmacies ever returned to the plan sponsor? Many times, plan sponsors are not aware that the PBM is auditing pharmacies and are similarly unaware that the PBM is extracting recoupments for prescriptions filled under their plan. This provision would simply provide plan sponsors with needed information about the actual operation of their pharmacy benefits plan.

In conclusion, some comments you might hear today from the opposition to this bill might include, (1) these kinds of issues can be resolved through contract negotiations and this legislation is not needed. Let me reassure you, contract negotiations between pharmacies and PBM's are basically non-existent. Feel free to ask the pharmacists here today how many times they have been successful in negotiating contracts with PBM's. Pharmacies are basically given "take-it" or "leave-it" contracts. (2) You might here this legislation is going to do nothing more than allow more fraud, waste or abuse to take place. As you know, as an Association of pharmacists, we do not condone fraud, waste or abuse. This bill explicitly outlines fraud, waste or abuse provisions and any pharmacy conducting such should be dealt with appropriately. If anything, Section 4 of this legislation sends a message to pharmacies, we will not stand for any fraud, waste or abuse. (3) Opposition might also try to make the case, this

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legislation will increase premiums. We do not see the math or how that broad sweeping statement even adds up. Besides, they shouldn't be counting on the pharmacies to pad their pockets and fundamentally should not be allowed to take back money when there has been no financial harm to the plan sponsor, patient or the PBM. (4) Finally, you might hear this legislation was introduced to restrict audits. This legislation surely doesn't prevent or restrict audits from happening. This legislation simply provides provisions that will bring about "fairness" to the auditing processes being conducted by PBMs.

We are open to discussions related to the passing of HB 1418. Thanks for your time and attention today. I would like to call on John Olson, who would like to add a few comments and introduce a few pharmacists who can provide you with more details and examples of what they see at their practice locations.

Respectfully Submitted,

Mike

Michael D. Schwab
NDPhA - EVP

(3)

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Expert Third-Party Contract and Audit Advice
160 Business Park Circle • Stoughton, WI 53589 • 608-873-1342 • Fax: 608-873-4009

TO: MR. MICHAEL SCHWAB
EXECUTIVE VICE PRESIDENT
NORTH DAKOTA PHARMACISTS ASSOCIATION

FROM: H. EDWARD HECKMAN, R.Ph.
PRESIDENT

DATE: JANUARY 27, 2011

RE: PHARMACY PRESCRIPTION CLAIMS AUDITS

PAAS National® Statement on Pharmacy Audits to the North Dakota Legislature

My name is H. Edward Heckman. I am a Pharmacist and the President and Owner of PAAS National® (pronounced "*pass*"), also known as the Pharmacy Audit Assistance Service – a company I founded in 1993 (www.paasnational.com). PAAS National® is an advocacy that has assisted community pharmacies in over 18,000 prescription claims audits. We have 4,500 members who are community pharmacies located in all 50 states. We have helped pharmacies recover more than $74 million in inappropriate audit chargebacks, which in most cases had been unilaterally redacted from them.

At the request of the North Dakota Pharmacy Association I provide expert written testimony in regard to the unjustly predatory practices of some Pharmacy Benefits Managers (PBMs) with their pharmacy prescription claims audits. While there is a need for a bill which would regulate pharmacy audits in this state, PAAS National® recognizes the importance of actions to curtail fraud, waste and abuse. I want to be clear that PAAS National® vigorously supports state and national measures to reduce and eliminate health care fraud waste and abuse. My testimony does nothing to weaken the government's efforts in these regards. Often however, pharmacy auditors prey on independent pharmacies as easy targets and pilfer the pockets of legitimate pharmacy owners by citing errors representing little more than technical discrepancies of no financial consequence having no effect upon patient care or outcomes.

Clerical or scrivener's errors do not necessarily indicate fraud or even an overpayment on a prescription claim. However, auditors often look for scribbles or scratches made as the doctor hurriedly fills out prescriptions for their patient, crossing out or writing over a date, strength, or quantity of a prescription. Pharmacists then have a corresponding duty to accurately interpret such orders and determine if contacting a prescriber is necessary to clarify an order. Pharmacists shoulder a serious responsibility to protect the safety of their patients and to assure that any medications prescribed are correct and appropriate to treat the patient's condition.

Unfortunately pharmacy auditors hired by some Pharmacy Benefits Managers (PBMs) take a different approach. Any scratch or scribble on a prescription is labeled as an unauthorized change or alteration nullifying the prescription, even when it is clearly not the case. Auditors target primarily high dollar claims often $500 or more, searching for the slightest imperfection and then recover the payment previously made to the pharmacy. In the spirit of a fair audit, documentation should be requested by the auditor from the prescribing physician to determine if the pharmacist dispensed the prescription correctly and if the payment was appropriate. In our experiences this is not always the case.

Another example from a popular Pharmacy Benefits Plan in North Dakota, "Prime Therapeutics" is found in their 2010 [Pharmacy] Provider Manual, on page 25 which states,

> *"Documentation that is required to be available at the time of dispensing will not be accepted post-audit."*

Prime Therapeutics uses this provision as a reason to refuse nearly any documentation to address audit discrepancies. Redactions for discrepancies are then taken from future remittances owed to the pharmacy, even though the pharmacy may not agree with Prime Therapeutics' claim and does not grant specific permission to take the money from them. These are unilateral decisions. The PBM is the judge and jury. A pharmacy's only remedy to such predatory practices is expensive litigation.

A typical scenario is for Prime Therapeutics or any other PBM to audit a pharmacy and deem flaws in just 6 prescriptions at $500 each. Then they deny the pharmacy a fair right to due process to appeal or challenge such discrepancies and the pharmacy is left with a $3,000 audit bill with the money extracted from future payments. The pharmacist knowing full well that the prescriptions in question were legitimate—meaning the doctor prescribed the medication and the patient received the medication—must choose whether to hire an attorney to litigate the case in the PBM's home state (which is anywhere other than North Dakota) or surrender without recourse. Faced with a reality of spending much more for defense than the cost of the penalty, the pharmacy always bows to the PBM. A pharmacy's profit margin on expensive brand prescription medications is usually 10% or less. On $3,000 of prescriptions the pharmacy's out of pocket expense to purchase the medications would be $2,700 and the PBM takes all the money back even though the patients received the prescriptions. Just to break even on the out-of-pocket costs of the medication on the six discrepant prescriptions, the pharmacy would need to fill 54 prescriptions at $500 each.

Keep in mind the PBM makes no claims that the patient did not receive the prescription. The pharmacy purchased the medication and dispensed it to the patient.

Another unfair audit discrepancy that occurs is with prescriptions labeled "Use or Take as Directed." The PBMs argue that "as directed" instructions are a method for patients to obtain excessive quantities of drugs beyond their plan's supply limits. While there may be instances of legitimate PBM concerns with "as directed" prescriptions, when a doctor and patient conspire to obtain larger days supplies and quantities of medication than the plan permits; these situations are isolated. There are many legitimate reasons for "as directed" on the label. There are instances when the amount of medication fluctuates

and must be titrated from one dose to the next. Such is a common practice for diabetic patients using insulin whose blood sugars may fluctuate—yet auditors claim discrepancies and redact payments. There are other drugs that the manufacturer's packaging if far more detailed and instructive than the limited number of words that can fit on a prescription label. Medications pre-packaged in their own dispensing systems, such as birth control tablets that are in a dispenser with clear labeling. And some antibiotics a such as Azithromycin packaged and more commonly known as "Z-Paks" come from the manufacturer on punch cards clearing labeled with instructions. The course of therapy with Azithromycin is six tablets taken over five days—two tablets on day one, and then one tablet daily for each of the next four days until gone. The manufacturer's packaging is a well designed punch-card containing clear labeling to assure that any patient who can read and pay attention can successfully take the right dose of medication at the right time. This type of manufacturer packaging is also known as compliance packaging, and goes far beyond the words that fit on a prescription label. Below is a rendering of typical Azithromycin packaging that visually illustrates my point.

Punch Tablets from the Card	Take 5 days until all tablets are gone	Instructions
○ ○	DAY ONE	Take two tablets
○	DAY TWO	Take one tablet
○	DAY THREE	Take one tablet
○	DAY FOUR	Take one tablet
○	DAY FIVE	Take one tablet

Believe or not, some PBMs, in particular CVS-Caremark, recapture payments made to pharmacies for Azithromycin prescriptions labeled "Take as directed." Again, pharmacies are often left with no chance for an appeal. People outside of the community pharmacy industry suggest that such practices are a form of extortion and opine "there should be a law against that!" This is the heart of the reason I offer my expert testimony to the Legislature.

PBMs such as Medco, CVS-Caremark, Express Scripts, Prime Therapeutics, Med Impact, Argus and a host of others are unregulated. This is amazing considering that the rest of the health care industry is wrought with regulations, licenses and oversight.

PBMs have created their own for-profit cottage industry from prescription claims audits. Some auditors are incented by receiving a percentage of money recouped. In many instances the money recovered in an audit is kept by the PBM and not returned to the plan sponsor, even though it technically belongs to the plan sponsor. In addition, during the eighteen years since PAAS started, I cannot recall one instance of patient co-pays being refunded to the patients even though the PBM recovered them from an audit. How can it be that PBM's can keep money that was never theirs in the first place? Fair legislation could prevent PBMs from operating their "for profit" cottage industry for their own benefit and require them to return all money recouped from legitimate audit discrepancies to plan sponsors and patients.

PAAS National® supports the need for pharmacy audits. However, audits must be conducted in a fair and balanced manner, allowing for a fair appeal and payment for all services rendered within the plan member's benefit limitations.

Today, it is the Legislators' responsibility to judge such practices for themselves and to take the necessary steps to prevent these unfair activities. The North Dakota Legislature can make a difference to improve health care quality and efficiency by establishing a fair playing field while not obstructing the elimination of fraud, waste and abuse.

Thank you for the opportunity to provide written testimony.

H. Edward Heckman

Testimony PBM, IBL Comm 03-14-11

March 14, 2011

Mr. Chairman and members of the Senate Industry, Business and Labor Committee:

On December 31, 2008, Prairie Pharmacy in Fargo wrote a check to Prime Therapeutics in the amount of $2,459.92 for chargebacks, the amount Prime claimed we owed them for incorrect submission of claims.

In September of 2008 Prime Therapeutics did an audit of some prescriptions filled at Prairie Pharmacy and found the following:

One physician DEA number was incorrect

Most chargebacks were for incorrect days supply. One of the prescriptions was $1,490. Some of the other more expensive prescriptions were for insulin. Here are some examples of why that happens

1. Insulin users change doses frequently as necessary for the control of their diabetes and that dose is determined by testing of their blood glucose level. Since we must bill for the days supply when filling the insulin prescription it is difficult to determine the exact number of days supply for that prescription.

2. Eye drops are also difficult. While we can calculate how many drops in a container, frequently a patient may miss the eye and the drop is running down their cheek.

3. Inhalers may be used "as necessary" for their asthma condition, so the days supply has to be an educated guess.

4. At that audit time, various PBM's may have required different claim methods for amount dispensed at our audit time. For example, one may require 5, as in 5 milliliters as the dispensed amount, others may require "1" as the complete pre-packaged amount dispensed. This has now been standardized.

After we received the report, the physician DEA number was corrected and all staff were alerted to be more aware of the days supply issue.

In conclusion, this is the important part. On reviewing all the prescriptions audited, we found there were none that were filled too soon or more often than allowed, so there was no extra cost to the patient, the plan or the sponsors.

We paid the chargeback because of the time, effort and probably the expense that would have been involved to challenge the issue.

Respectfully submitted.

Tony Welder, Partner, Prairie Pharmacy.

HB 1418

Recommend DO PASS as previously amended by House IBL committee, WITHOUT further amendment.

Chairman Klein and Members of the ND Senate Industry, Business and Labor Committee:

I would like to share some examples from a recent audit done at our pharmacy in Fargo.

1. A medication that is filled for a migraine headache medication that is, through a typographical error, given a 3 day, instead of a 30 day supply at the time of adjudication. The medication is refilled 7 times over a 6 month period. There was never a premature refill nor was the patient over utilizing the medication. Our appeal was denied and $718.77 was recouped on this prescription alone. There was no financial harm to the plan sponsor or patient.
2. Insulin prescriptions have become a real hot button for PBM's because of physicians writing" use as directed" when patients are on varying doses. We put in a 30 day supply for a prescription of insulin when it actually was a 25 day supply based on the prescribed dose. The PBM recouped $65.56 on this single Rx. There was no financial harm to the patient or plan sponsor.
   Another example of this is a prescription for insulin was filled as a 30 day supply under the directions of use as directed. The prescription was filled on 3 different dates from 30-40 days apart. Again no financial harm to the plan sponsor or patient and $393.84 was recouped on this prescription. The PBM states that use as directed is not an acceptable direction for a patient. There is a line between being a claims processor and the practice of medicine and or pharmacy and the PBM's are now crossing it on a regular basis.
3. The concept of "hard edits" has been discussed with one of the largest PBM's in the region. This was discussed directly with the PBM at one of our recent ND Pharmacy conventions as well as at a meeting with the insurance company and the PBM. To date the expansion of this process in online prescription processing has been denied. This process is already being applied in reverse or the prescriptions in question would never show up on an audit trail. The recouping of these funds appears to be opportunistic if not predatory and profitable for the PBM's. It may be that this recoupment is actually the funding mechanism for the PBM's contractually required auditing process.
4. PBM's are a multibillion dollar portion of the health care industry. They are the only provider of service, in this magnitude, that has virtually no oversight as to their current operations but do have a very profound effect on pharmacy practice, patient care and escalating medication costs.

Respectfully submitted:

David Olig, R.Ph.

HB 1418 PBM Audit Reform Testimony

Mark Hardy, PharmD

Chairman Klein and members of the Senate Industry, Business and Labor Committee, for the record my name Is Mark Hardy a registered pharmacist from Neche, ND. I work for Thrifty White Drug. I would like to urge the committee to give HB 1418 a DO PASS recommendation.

Pharmacists from North Dakota are bringing this piece of legislation in response to the exponential increase in predatory and unfair PBM audit practices which we are experiencing. Let me be clear we are not scared of an audit and welcome these to ensure fraudulent prescriptions are not being filled. We are looking for these audits to be fair and not an aggressive mechanism for these PBMs to take back payments. I would like to give you a few of the trends which Thrifty White has seen in regards to audit practices.

1. We have seen the number of onsite audits increase up to four times what we experienced just two years ago. We also experienced an increase of desk audits to 2,300 for 2010 which is an increase of nearly 1,000 audits from the previous year. Thrifty White has had to hire additional staff to specifically deal with these increases.
2. The amount of money in claims they determine should be charged back has seen over a 5 fold increase in the last 2 years. For one PBM alone, the chargeback went from over $15,000 in 2008 to over $70,000 in 2010.
3. The average price per claim audited is $614.52. Our average prescription price currently is $52.08. For one of our more common PBMs, Prime Therapeutics the average price of an audited claim is $944.40
4. The overall percentage of generic prescription claims audited by these PBMs is 21.4% while our average generic dispensing rate over all stores is 74%.
5. The number of prescriptions examined per audit has increased and in some cases they want to look at over 200 prescriptions per audit
6. PBMs are giving pharmacies shorter notice times of upcoming audits and schedule them during typical busy days.

Along with these trends, we have also seen outrageous examples of where a PBM determines a claim to be charged back. Here are just a few of the examples of these crooked behaviors.

1. Claiming a prescription is invalid because a NPI number of a prescriber is not written on the prescription. Having this number on a prescription is not a requirement by the State Board of Pharmacy.
2. Not accepting a Medication Administration Record (MAR) from a nursing home as proof a prescription was received.
3. Taking money back on creams and ointments due to what the PBM refers to as inadequate day supply. Even though it is impossible to determine how large an area a patient needs to apply the medication.

4. PBM taking claim money back for insulin prescriptions due to directions written by prescriber to "use per sliding scale." Patient was never refilling earlier than needed and the prescription accurately reflected the physician's directions.
5. Claiming a physician's dispense quantity is unreasonable for a migraine medication even though there is no way to know how many headaches a patient may have in a month.

An audit is very time consuming and requires preparation and extra labor. This is why the legislation includes mandates on prior notice.

We also have seen no consistent time frames with audits. An example of this is a Prime Therapeutics audit that took place in our Grand Forks store. This audit was done on June 17, 2010. We still have not received a preliminary report back on this audit.

In the case of a determined discrepancy in day supply, a PBM will take back claim payments where no financial harm is done to the plan or the patient. An example is if a 30 day supply of medication was entered in as a 20 day supply due to hitting a wrong key, this claim will be recouped by the PBM. Even with documentation that the patient did not get it any sooner than 30 days, the PBM determines this as reason for a chargeback.

We have consistently tried to get PBMs to put real-time messaging in to help catch these typographical errors. They do not take any action on this even though this would be an easy process to implement for them and would appear to be a win-win for both sides. The audit practices have influenced pharmacist's dispensing habits and this can ultimately negatively impact patients.

In closing, I hope this give you our perspective on this increasingly abusive practice by the PBM industry on pharmacies. It is my understanding in the past this auditing was done in a more fair and reasonable way and involved common sense to determine if claims were adjudicated correctly. Unfortunately this has changed and due to the increasingly abusive practices we are looking for your support to help set some parameters to follow as we move forward. I hope for your support in passage of HB 1418 and I would be more than happy to answer any questions.

Respectfully submitted,
Mark Hardy
mhardy@thriftywhite.com

TESTIMONY IN OPPOSITION TO ENGROSSED HB 1418
SENATE IBL COMMITTEE
Monday, March 14, 2011, 10:15 a.m.

Good Morning Chairman Klein and Members of the Senate IBL Committee.

My name is Patrick Ward. I am an attorney with Zuger Kirmis & Smith here in Bismrack. I represent Medco Health Solutions, a pharmacy benefits manager, in opposition to Engrossed HB 1418. Medco covers approximately 111,000 lives in North Dakota or about 17% of the population. In 2009, Medco adjudicated 1.4 million retail scripts in the state.

This audit issue is not a local issue. This is a national agenda priority for the National Community Pharmacy Association. If you asked our pharmacists probing questions about the number of PBM audits they have faced, you will find that it is very few. They would like to be among the first to pass strong limitations on PBM audits to win favor with their national group and export the bill to other states. That is the real reason this bill is here, because they are "hearing stories" at their national meetings.

The facts are that the leading PBM's in North Dakota do very few on site audits. In fact, my client Medco did none in 2009. The market share leader, Prime Therapeutics, which works with BCBS, did only 20 in 2010. CVS did 8. This is a solution looking for a problem. Dave Olig from Fargo testified in the House that he had been audited 2 times in 28 years, Tony Welder, who has stores in Bismarck and Fargo, said a handful in 40 years. Thrifty White has over 80 stores, most of them in Minnesota, and the audits done last year requested only $70,000 in repayments, or less than $1000 per store.

No one likes to be audited. It is inconvenient and a distraction. However, most people are not good record keepers. I am told pharmacists are not immune to this affliction. My law firm has insurance clients that audit our bills or have them audited. We do not like it but it is a fact of life in this modern world. They tell us how to practice law and we resent that.

No one likes an IRS audit or the possibility of one...but it is the fear of an audit that makes people more careful and causes them to be more accurate and keep better records. I can only imagine what my tax documentation would look like if not for fear of an audit. Fortunately, the IRS usually does not audit paupers.

If you take away or limit the opportunity to audit, is fraud likely to decrease? Will pharmacists keep better records? Our local pharmacists will tell you they are honest or not likely to cheat, but the voters may soon do away with their legislatively protected oligopoly in the next election. Will the pharmacists with the big box stores and chains follow this same "code of honor".

The proponents will tell you that fraud is an exception to this bill in section 4. How do you uncover fraud if you cannot check the numbers and practices once in a while?

PBM's have contracts with plan sponsors that require them to do audits to catch fraud, waste, and mistakes in their network pharmacies. If you take the tools from the tool box, will it advance efforts to eliminate health care fraud and waste?

PBM audits are "plan specific" and not "state specific". They look for compliance with formulary and other plan specific issues. They are interstate and not intrastate.

This bill is not necessary in North Dakota and cannot put limits on the federal Medicare and Medicaid audits or audit practices that it seems designed to address. For example, none of our PBM's use extrapolation, that is a federal practice requirement. Federal audits will go on, and rightfully so.

A recent Grand Forks Herald article, discussing a state audit report to a legislative oversight committee, said the following:

> "North Dakota is the only state without a Medicaid fraud unit because of a federal waiver the state attained in 1994 after asserting the program had minimal fraud. The audit said the unit within the department that investigates fraud allegations for possible prosecution "is not currently conducting adequate investigations and, as a result, is not referring cases for further investigation and prosecution,"
>
> Additionally, auditors say the department (of Human Services) treats overbilling incidences as errors and simply asks for repayment when some of the incidences could be possible fraud cases, according to the report.

North Dakota does not need this bill. We urge a Do NOT Pass on Engrossed HB 1418.

North Dakota Only State Lacking Special Anti-Fraud Unit

By Jaimie Oh | October 25, 2010

A state audit presented to a North Dakota legislative oversight committee suggested the state's Department of Human Services doesn't pay enough attention to preventing Medicaid fraud, according to a *Grand Forks Herald* news report.

North Dakota is the only state without a Medicaid fraud unit because of a federal waiver the state attained in 1994 after asserting the program had minimal fraud. The audit said the unit within the department that investigates fraud allegations for possible prosecution "is not currently conducting adequate investigations and, as a result, is not referring cases for further investigation and prosecution," according to the report.

Additionally, auditors say the department treats overbilling incidences as errors and simply asks for repayment when some of the incidences could be possible fraud cases, according to the report.

In response, the department said it would increase efforts to spot Medicaid fraud.

Read the *Grand Forks Herald* news report about the North Dakota fraud audit.

(8)

PRIME THERAPEUTICS®

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Prime Therapeutics Testimony in Opposition to Engrossed HB 1418

Senate IBL Committee, March 14th, 2011

Chairman Klein and Members of the IBL Committee:

I am Stacey Fahrner, Vice President of Government Affairs for Prime Therapeutics. Prime is a pharmacy benefit management (PBM) company owned by 12 non-profit Blue Cross Blue Shield companies. We manage pharmacy benefits for approximately 18 million covered lives.

Prime Therapeutics continues to oppose HB 1418. Wasteful spending in health care is a growing concern, and I urge the committee to carefully consider the impact of legislating decreased accountability of retail pharmacies. Ultimately it will be consumers of North Dakota who pay for this through higher drug prices.

In addition to fraud deterrence, pharmacy audits are essential in controlling drug spending by helping us to indentify improper billing practices, safety errors such as wrong dosages or administration instructions, and inadequate formulary compliance. Our only opportunity to verify pharmacy claims against the physician scripts sent to pharmacies is through the audit procedure. In short, if we can't see these issues, we can't correct them.

While the pharmacists paint a picture of PBM audits as both constant and onerous, Prime audits only approximately 10 percent of North Dakota pharmacies every year. Last year we conducted approximately 20 audits. The majority of those were randomly selected and conducted to ensure the quality of our retail network. Two, however, were initiated through our member complaint hotline.

Furthermore, pharmacies are never surprised by our requirements in the audit process. Prime makes every effort to explain the purpose and intent of our policies. Our billing requirements, document retention requirements, and audit procedures and policies are publicly available and are known to pharmacies during the contract negotiation process. In addition, we have made available to all pharmacies in our network a list of common billing errors to avoid.

HB 1418 would place broad new restrictions on pharmacy access and ability to collect overpayments for our commercial clients and their members. Of particular concern is the requirement that payors (PBMs

(OVER)

and insurers) accept the "usual and customary price" for compound drugs. Because compound drugs are unique to the patient, contain several active ingredients, and are created by the pharmacist, they are not assigned a National Drug Code, which serves as the basis for all claims submission. While some payors either refuse to cover compound drugs or require patients to submit claims for reimbursement, Prime and our clients continue to provide coverage at the point of sale. Our billing requirements for compound drugs are clearly laid out in our provider manual. HB 1418 would undermine our contractual agreements and essentially allow pharmacists to set their own reimbursement rates for compound drugs. Again, overuse and over billing of compound drugs will hurt patients in North Dakota by increasing their out of pocket costs or ultimately decreasing payor willingness to provide coverage for those drugs.

Finally, I urge the Committee to take note that the burden of this legislation will fall disproportionately on commercial health benefit plans (employers and employees) in North Dakota. Health care is a complex industry and proper business practices and records retention are essential. Nothing in this bill relieves the pharmacy from Medicare and Medicaid data validation, record retention, and audit requirements. Federal programs account for at least half of the total pharmacy claims.

I ask the Committee to not pass HB 1418.

Thank you

March 15, 2011

SENATE I, B & L:

ATTACHED ARE PROPOSED HB 1418 AMENDMENTS WE DISCUSSED Monday w/ PHARMACISTS.

I BELIEVE THERE ARE MANY AREAS OF AGREEMENT. WE WILL CONTINUE DISCUSSIONS TODAY.

JACK McDonald

11.0658.02000

FIRST ENGROSSMENT

Sixty-second

Legislative Assembly

of North Dakota

ENGROSSED HOUSE BILL NO. 1418

Introduced by

Representatives Kasper, N. Johnson, Keiser, Vigesaa

Senators Wardner, Klein

A BILL for an Act to provide standards for audits of pharmacy records; and to provide a penalty.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1.

Definitions.

For the purposes of this Act:

1. "Entity" means a managed care company, an insurance company, a third-party payer, a pharmacy benefits manager, or any other organization that represents an insurance company, a third-party payer, or a pharmacy benefits manager.

2. "Insurance company" includes any corporation, association, benefit society, exchange, partnership, or individual engaged as principal in the business of insurance.

3. "Managed care company" is an entity that handles both health care and health care financing.

4. "Pharmacy benefits manager" means a person that performs pharmacy benefits management and includes any other person acting for such person under a contractual or employment relationship in the performance of pharmacy benefits management for a managed care company, nonprofit hospital or medical service organization, insurance company, third-party payer, or health program administered by a state agency.

5. "Plan sponsor" means the **health plan in the case of a fully insured plan or (this definition may need to be redone consistent with 26.1-27.1-01)** employer in the case of an employee benefit plan established or maintained by a single employer, or the employee organization in the case of a plan established or maintained by an employee

organization, an association, joint board of trustees, committee, or other similar group that establishes or maintains the plan.

6. "Third-party payer" means an organization other than the patient or health care provider involved in the financing of personal health services.

SECTION 2.

Pharmacy benefits manager audit - Rules.

1. An entity conducting an audit of a pharmacy shall:

a. If conducting an onsite audit, give the pharmacy a written notice at least fourteen business days before conducting an initial audit.

b. If the audit involves clinical or professional judgment, ensure the audit is conducted by or in consultation with a pharmacist licensed in any state and employed by or contracted with the pharmacy benefits manager.

c. Limit the audit to no more than twenty-four months from the date that the claim was submitted to or adjudicated by the entity. A claim may not be reviewed that is older than twenty-four months from the date of the audit, unless a longer period is permitted under federal law.

d. Refrain from conducting the **onsite** audit during the first five business days of the month unless otherwise consented to by the pharmacy.

e. Refrain, **unless granted permission from the Pharmacist,** from entering the pharmacy area where patient-specific information is available and remain out of sight and hearing range of the pharmacy customers. The pharmacy shall designate an area for auditors to conduct their business.

f. Allow the pharmacy to use the records, including a medication administration record, of a hospital, physician, or other authorized practitioner to validate the pharmacy record and delivery.

g. Allow the pharmacy to use any legal prescription, including medication administration records, electronic documents, or documented telephone calls from the prescriber or the prescriber's agents, to validate claims in connection with prescriptions and refills or changes in prescriptions.

2. An audit may not allow a recoupment to be assessed for items on the face of a prescription not required by rules adopted by the state board of pharmacy with respect to patient hard copy prescription forms for controlled and uncontrolled drugs.

3. **Notwithstanding any terms and conditions of a third party payer contract the following may occur:**

a. A finding of overpayment or underpayment may be based only on the actual overpayment or underpayment and not on a projection based on the number of

patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs.

b. A calculation of an overpayment may not include dispensing fees, unless a prescription was not dispensed or the prescriber denied authorization.

c. ~~In the case of~~ Unless continued and uncorrected, ~~an~~ errors that ~~hasve~~ no financial harm to the patient or plan, the pharmacy benefits manager may not assess ~~any chargeback.~~ The pharmacy benefits manager may not assess any chargeback for errors that have no financial harm to the patient or plan unless such errors are continued and uncorrected.

d. The entity conducting the audit may not use extrapolation in calculating the recoupment or penalties for audits.

e. Any recoupment may not be deducted against future remittances and must be invoiced to the pharmacy for payment.

f. An entity performing an audit may not receive payment based on a percentage of the amount recovered unless required by the third party payer contract.

g. Interest may not accrue during the audit period, which begins with the notice of audit and ends with the final audit report.

4. A clerical or recordkeeping error may not be considered fraud, but may be subject to recoupment. A person is not subject to any criminal penalty for a clerical or recordkeeping error without proof of intent to commit fraud.

5. The parameters of an audit must comply with ~~consumer-oriented parameters based on~~ manufacturer listings or recommendations and current clinical guidelines for the following:

a. The day supply for eye drops must be calculated so that the consumer pays only one 30-day copayment if the bottle of eye drops is intended by the manufacturer to be a thirty-day supply.

~~b. The day supply for insulin must be calculated so that the highest dose prescribed is used to determine the day supply and consumer copayment.~~

c. The day supply for a topical product must be determined by the judgment of the pharmacist based upon the treated area.

6. Unless an alternate price or billing procedures ~~is~~ are published in a provider contract and signed by both parties, the usual and customary price charged by a pharmacy for compounded medications is considered to be the reimbursable cost.

7. An entity conducting an audit shall utilize the same standards and parameters in auditing a pharmacy the entity uses with other similarly situated pharmacies.

8. An entity conducting an audit shall establish a written appeals process.

SECTION 3.

Audit reports - Disclosure - Distribution of recouped funds - Review of auditor.

1. A preliminary audit report must be delivered to the pharmacy within one hundred twenty days after the conclusion of the audit.

2. A pharmacy must be allowed at least sixty days following receipt of the preliminary audit to provide documentation to address any discrepancy found in the audit.

3. A final audit report must be delivered to the pharmacy within ninety days after receipt of the preliminary audit report or final appeal, whichever is later.

4. Unless the audit recoupment for a single audited site is in excess of $20,000, ~~N~~no chargeback, recoupment, or other penalty may be assessed until the appeal process has been exhausted and the final report issued.

5. An entity shall remit any money due to a pharmacy or pharmacist as a result of an underpayment of a claim within thirty days after the appeals process has been exhausted and the final audit report has been issued.

6. ~~Unless otherwise directed by a contractual agreement~~ Aan auditing entity shall, if requested by the third party payer contract, provide a copy of the final report to the plan sponsor for which claims were included in the audit. Any funds recouped must be returned to the plan sponsor, if required by the third party payer contract.

SECTION 4.

Applicability.

1. This Act applies to claims adjudicated after July 31, 2011.

2. This Act does not apply to any audit, review, or investigation that is initiated based upon alleged fraud, willful misrepresentation, or abuse, including:

a. Insurance fraud as defined in chapter 26.1-02.1.

b. Billing for services not furnished or supplies not provided.

c. Billing that appears to be a deliberate application for duplicate payment for the same services or supplies, billing both the beneficiary and the pharmacy benefits manager or payer for the same service.

d. Altering claim forms, electronic claim records, or medical documentation to obtain a higher payment amount.

e. Soliciting, offering, or receiving a kickback or bribe.

f. Participating in any scheme that involves collusion between a provider and a beneficiary or between a supplier and a provider which results in higher costs or charges to the entity.

g. Misrepresenting a date or description of services furnished or the identity of the beneficiary or the individual who furnished the services.

h. Billing for a prescription without a prescription on file in a situation in which an over-the-counter item is dispensed.

i. Dispensing a prescription using an out-of-date drug.

j. Billing with an incorrect national drug code or billing for a brand name when a generic drug is dispensed.

k. Failing to credit the payer for a medication or a portion of a prescription that was not obtained by the payer within fourteen days unless extenuating circumstances exist.

l. Billing the payer a higher price than the usual and customary charge of the pharmacy to the general public.

m. Billing for a product without proof that the purchaser purchased the product.

3. Any case of suspected fraud or violation of law must be reported by an auditor to the licensing board.

4. This Act does not apply to state medicaid programs.

SECTION 5.

Penalty.

Any person violating this Act ~~or found to have performed or caused to perform any acts in Section 4 of this act~~ is also guilty of a ~~class B misdemeanor~~ class B misdemeanor.~~ LAWYERS FILL IN~~

Proposed Amendments to Engrossed House Bill No. 1418

The problem with page 4, lines 14-16, is that it would require the distribution of the final audit and recoupment back to an employer in a fully insured plan. Employers are NOT liable for claims, do not pay direct claims, and as such are not typically eligible such refunds. The health plan, under a fully insured plan, assumes all risks and all underwriting gains. The employer/employee assumes no risk and instead purchases guaranteed coverage immaterial of the amount of claims versus premiums. The way the language is written in lines 14-16 would be more appropriate for a self-funded plan. However, self funded plans are regulated by the federal government and not the state, so this provision can not apply to self-funded plans.

The proposed amendments would allow for the distribution of the recoupment and the audit report to the employer if it is specified in the contract between the employer and the insurer.

Proposed Amendments

Page 4, line 14, after "shall" insert ", if requested by the third party payer contract,"

Page 4, line 16, after "sponsor" insert ", if required by the third party payer contract"