MICROFILM DIVIDER

OMB/RECORDS MANAGEMENT DIVISION
SFN 2053 (2/85) 5M

ROLL NUMBER

1116

DESCRIPTION

2001 HOUSE HUMAN SERVICES

HB 1116

2001 HOUSE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. HB 1116

House Human Services Committee

❑ Conference Committee

Hearing Date January 23, 2001

Tape Number	Side A	Side B	Meter #
Tape 2	X		0 to end
Tape 2		X	0 to end
Tape 3		X	2095 to 3430

Committee Clerk Signature Connie Easton

Minutes:

Chairman Price, Vice Chairman Devlin, Rep. Dosch, Rep. Galvin, Rep. Klein, Rep. Pollert, Rep. Porter, Rep. Tieman, Rep. Weiler, Rep. Weisz, Rep. Cleary, Rep. Metcalf, Rep. Niemeier, Rep Sandvig.

Chairman Price: Opened hearing on HB 1116

Dave Zentner: Director of Medical Services for the Department of Human Services. (See written testimony.)

Chairman Devlin: You talk about prior authorization for drugs, but as I read the language of the bill itself is there anything that a medical provider in North Dakota, from an ambulance driver on up, that wouldn't be covered under this bill the way it's drafted?

Dave Zentner: The concern of the department was where the legislature wanted to fall on this issue, because it would appear there was some question about our ability to do prior authorization without asking the legislature. We are at least asking for permission.

Rep. Devlin: How often has the DOUR Board met in the last year?

Dave Zentner: It has not met for some time. We are in the process of hiring an Pharmacist.

Rep. Devlin: Because the pharmacist left you, what medical background would someone in your department need to make decisions?

Dave Zentner: We are replacing him with another Pharmacist who will be on board.

Vice Chairman Price: There was some concern among some of the administrative rules committee that we don't see the cost. Some of the other states find this very expensive, how can you do this with the same amount of staff? How can you do it so much cheaper?

Dave Zentner: We are very efficient and we have very good people. We are willing to take that chance without adding anymore staff.

Vice Chairman Devlin: There are some concerns that you can nickel and dime yourself to death, and in this particular case we could say "yes, there is some savings in this", but there also savings from people who spend less time in the hospital, may didn't have to have the surgery they would have had to before the new level of drugs came out. How would you factor that into what you're presenting to us?

Dave Zentner: When we build our budget, we look at each individual services and if they are trending down, we are going to recog[illegible]hat when we present the budget. My concern is whether your paying for a $200 a month drug and a $40 a month drug will do the same job.

Vice Chairman Devlin: We were under the impression the DUR Board was the natural place for this thing to work, and I'm shocked the board didn't meet at all in the year 2000.

Dave Zentner: It was due to staff turnover and waiting for new data.

Rep. Sandvig: Could you tell us who was on the DUR Board for the department?

Dave Zentner: I do not have that information, but can provide that for you. It is made up of pharmacists and physicians.

Rep. Sandvig: You said that the department gets a rebate from the drug companies. Why then is it such a problem to have those drugs paid for?

Dave Zentner: There isn't really a problem.

Rep. Sandvig: Don't you think the doctor that is describing the drug knows what is best for the patient.

Dave Zentner: There are thousands of drugs out there, and doctors aren't always aware of what's available.

Rep. Sandvig: I've talked to some pharmacists and they say the form they will be filling out will be a paper work nightmare. What isn't this burden put on the department?

Dave Zentner: We are seeking information so that we can make a decision on what drug is appropriate.

Chairman Price: Why would pharmacist be required to fill out as opposed to physicians who prescribe the drug?

Dave Zentner: They have the information readily available. They are a better source to provide the information.

Chairman Price: Don't you think that if the physician has the form in front of him at the point that they saw the patient, that it would trigger in their brain to even think of the possibility of a different drug?

Dave Zentner: That is a possibility. We just know that our experience in working with pharmacists and physicians that placing it with the pharmacist is probably the most efficient way.

Rep. Sandvig: I'm still having a little bit of problem with the idea that the physicians don't know what is best for their patient. They are trained in that. Your saying $180,000 in general funds, why does the department always seem to be balancing their budget on the backs of the poor people?

Dave Zentner: I don't do this as necessarily balancing our budget on the backs of recipients. What we're saying here is if the most expensive drug is the drug that should be used, we will pay for that. If something else that is a lesser cost can do the job, we want to do that.

Rep. Porter: The paper work involved and the phone contacts between the pharmacist and the physicians, and the checking of prescriptions, and looking over the authorization list, all this extra burden we are putting on the pharmacist, how do they recoup their costs for doing this work?

Dave Zentner: We do pay a fee for overtime they provide a prescription.

Rep. Porter: Line 8 where it encompasses now all medical services and the department is going to micro manage different areas, you listed four or five different areas that you currently prior authorize on, how expansive is this list going to get as you look at this new authority?

Dave Zentner: Not much longer, I can tell you that. The areas that we chose are those we think get our best savings for our dollars. What we do prior authorize is of a limited nature. We are not looking to adding to the burden.

Rep. Porter: In this particular bill form, why wasn't the limits put in place for the medical services to limit to what you felt was necessary rather than a cart blanche approach of just listing everything that exists in medicine?

Dave Zentner: My biggest concern was that based on the administrative rules committee there was indication that the department needed to, because this was a public policy issue, have prior authorization approved by the legislature.

Rep. Niemeier: In the area of medical services would you be apt to ask for authorization on things like diagnostic tests, and does the 30 day time frame apply to these services as well as drug usage?

Dave Zentner: We're only looking at three classes of drugs. It does not apply to diagnostic testing.

Rep. Niemeier: But you could under this legislation?

Dave Zentner: That is correct. It does give us authority to implement prior authorization. What I'm trying to ascertain is what does the legislature want and expect of the department in relationship to prior authorization.

Rep. Niemeier: Would the 30 day amendment that you propose apply to medical services as well?

Dave Zentner: No, this is specific to the drug prior authorization and is designed to give the medical people the time to look into the issue. It really provides up to 37 days for them to document the needs and show us the drugs are used appropriately.

Vice Chairman Devlin: The committee was very concerned that the department did not have authority under the law to prior authorize drugs. We told them that they should bring this to the legislature because that is a policy making decision.

Rep. Klein: How are the savings and expenditures are here already before we've passed the bill.

Dave Zentner: When we submitted the executive budget to OMB, that was one of the areas that was shown as a possible cost savings.

Rep. Sandvig: You said there are 26 states that prior authorize the same drug, what are the other states doing to cut costs?

Dave Zentner: Most states think there are issues of usage and that prior authorization can save some dollars.

Rep. Sandvig: You must have assumed the bill would automatically be passed if you didn't include the medical cost of these drugs in your budget.

Chairman Price: What are the statistics for other state's that use prior authorization?

Dave Zentner: I don't have those, but I can check with other states.

Rep. Niemeier: What was the rationale behind choosing three classes of drugs?

Dave Zentner: These were high end drugs and were going up at a much greater pace. They looked at the utilization information.

Cal Rolfson: Attorney practicing in Bismarck and Legislative Consultant for the Pharmaceutical Research and Manufacturers of America (PhRMA). I appear in opposition of HB 1116. (See written testimony.) Pharmaceuticals are recognized as one of the most cost-effective and least invasive health care resources available, state Medicaid departments already receive considerable assistance from the pharmaceutical industry for drug expenditures, prior authorization programs interfere with the provision of appropriate and necessary medical care, prior authorization programs often result in increased expenditures, contrary to the savings projections anticipated during development, prescription and nonprescription medications vary considerably and should not be viewed as equally effective alternatives for the management of illnesses.

Vice Chairman Devlin: We didn't take the position whether it was good or bad, our only consideration regarding administrative rules was whether they have the authority to do it.

Chairman Price: Mr. Rolfson, you give a number of examples on page 4, are any of those types of drugs that you reference of the three classes that the department proposing to prior authorize?

Calvin Rolfson: I think Kelly would be the one to answer that question.

Kelly Marshall: Works for Pharmacia Corporation. The three classes they are recommended aren't included in that. By allowing access to drugs, you're probably saving money in a lot of different avenues. When you prior authorize you look at the fact that you are getting in between the physician and the patient.

Rep. Klein: How long will it take for less expensive drugs to get expensive if the persons going to be prescribing them there cost is going to be going up. How long will it take before they get as expensive as the other drugs. Seems to me they would catch up sooner or later.

Kelly Marshall: I think in terms of less expensive drugs a lot of times you're talking about generic equivalent. In which case they wouldn't get more expensive. Again you have to weigh that against the cost of more effective, more expensive drugs versus the cost of not treating.

Rep. Niemeier: Generic drugs have certainly become a popular alternative. Is there a difference in how generic and other drugs are developed?

Kelly Marshall: No. We go through 15 years on average to develop a drug. When a drug goes off patent, other companies can manufacture the drugs. So they don't have to do the research to develop the drug.

David Peske: Director of Governmental Relations for the ND Medical Association. (See written testimony.) HB 1116 would give the Department of Human Services discretion to require prior authorization for (1) medical services, and (2) certain outpatient drugs under Medicaid. The North Dakota Medical Association opposes HB 1116, and opposed a similar proposal made last year by the department before the Legislative Council's Administrative Rules Committee,

relating specifically to outpatient drugs. Until the department better utilizes the DUR Board and its intended scope, HB 1116 is premature in granting the department the ability to impose prior authorization. For these reasons, the North Dakota Medicaid Association urges a DO NOT PASS on HB 1116.

Chairman Price: Closed hearing on HB 1116.

Chairman Price: I will reopen the hearing on HB 1116.

Galen Jordre: Executive Vice President, North Dakota Pharmaceutical Association. Our primary concern is that all of our patients receive the medication that is most appropriate for what they need. We are not supportive of the prior authorization program as the primary means of controlling utilization of prescription drugs. We would prefer to see more aggressive use of the DUR board to outline specific utilization problems and then direct educational programs outlining treatment protocols to both prescribers and pharmacists who work with Medicaid patients.

Rep. Niemeier: We're talking about basing the need for this action, partly on the fact that prescription drugs have skyrocketed. We all have an idea why this has happened, but I'd like to hear yours.

Galen Jordre: First we are utilizing more prescription drugs because, in many cases, they are the appropriate therapy. I'm sure development costs are higher, there is better screening, new products with less side affects are coming out, and they do things that the old drugs did not do. they do save a lot of other areas.

Rep. Niemeier: When you talk about greater utilization, we always used to think that products were cheaper in volume. How do you respond to that?

Galen Jordre: The drug companies do have the cost of investments and research.

Chairman Price: Close the hearing on HB 1116.

COMMITTEE WORK:

Chairman Price: HB 1116.

Vice Chairman Price: Mr. Zentner had a legitimate concern is that if we take the bill the way it is an kill it, they are never going to be able to preauthorize anything. I wouldn't mind seeing us amend everything out of this bill except the prior authorization of drugs, and then vote that up or down. I was just being sensitive to his concern.

Chairman Price: (Discussed changes in the amendment.)

Vice Chairman Price: Changes would be on line 7 will read "prior authorization required for medical assistance coverage" and then take out the three words of "medical services and" would all come out. So it would be "prior authorization required for medical assistance coverage of outpatient drugs". After the drugs I would take out the rest of line 8 and all of line 9 up until the period.

Chairman Price: So we're looking at the amendments that we just read, plus the proposed amendments from the Department of Human Services? So it is all one amendment at this point.

Rep. Dosch: Should part of this amendment be that we recommend the department use the DUR Board to the best of their ability.

Chairman Price: All those in favor of this amendment signify by saying Aye. All in agreement.

Rep. Pollert: This is going to basically force the department to take a look at how they are going to save some money on the drugs.

Chairman Price: For a $65,000,000 budget, they are looking at saving $180,000.

Rep. Galvin: Motion for a DO NOT PASS.

Rep. Sandvig: Second.

Chairman Price: Any other discussion. Seeing none the clerk will take the roll for a **DO NOT PASS AS AMENDED.**

13 YES 0 NO 1 ABSENT CARRIED BY REP. DEVLIN

FISCAL NOTE

Requested by Legislative Council
01/26/2001

Bill/Resolution No.:

Amendment to: HB 1116

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.*

	1999-2001 Biennium		2001-2003 Biennium		2003-2005 Biennium	
	General Fund	Other Funds	General Fund	Other Funds	General Fund	Other Funds
Revenues				($419,700)		($479,965)
Expenditures			($180,300)	($419,700)	($206,975)	($479,965)
Appropriations						

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

1999-2001 Biennium			2001-2003 Biennium			2003-2005 Biennium		
Counties	Cities	School Districts	Counties	Cities	School Districts	Counties	Cities	School Districts

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

This bill would allow the Department of Human Services to require prior authorization of medical services before providing medical assistance coverage of outpatient drugs. This would be accomplished by the usage of less costly prescription drugs than those currently prescribed and the use of over the counter medications.

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.*

Impact of this bill reduces grant costs and therefore the federal reimbursement is also reduced as reflected above.

   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.*

If this bill is not passed the increase in costs would include $419,700 of federal funds and $180,300 of general funds for a total increase of $600,000. The above noted anticipated savings would not be realized. These savings in expenditures are **included** in the grants line item of the Department's budget.

   C. **Appropriations:** *Explain the appropriation amounts. Provide detail, when appropriate, of the effect on the biennial appropriation for each agency and fund affected and any amounts included in the*

executive budget. Indicate the relationship between the amounts shown for expenditures and appropriations.

The Executive Budget for the Department of Human Services **includes** the anticipated savings listed above - $419,700 of federal funds and $180,300 of general funds. The Executive Budget for the Department includes in total $79,115,722 for drug expenditures. If this bill does not pass, the appropriation for drug expenditures in the Department will need to be increased to $79,715,722, as the savings noted will not be realized.

Name:	Brenda M. Weisz	**Agency:**	Department of Human Services
Phone Number:	328-2397	**Date Prepared:**	01/29/2001

FISCAL NOTE

Requested by Legislative Council
12/18/2000

Bill/Resolution No.: HB 1116

Amendment to:

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.*

	1999-2001 Biennium		2001-2003 Biennium		2003-2005 Biennium	
	General Fund	Other Funds	General Fund	Other Funds	General Fund	Other Funds
Revenues				($419,700)		($479,965)
Expenditures			($180,300)	($419,700)	($206,975)	($479,965)
Appropriations						

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

1999-2001 Biennium			2001-2003 Biennium			2003-2005 Biennium		
Counties	Cities	School Districts	Counties	Cities	School Districts	Counties	Cities	School Districts

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

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Name:	Brenda Welsz	**Agency:**	Department of Human Services
Phone Number:	328-2397	**Date Prepared:**	12/20/2000

18126.0101
Title.0200

Adopted by the Human Services Committee
January 23, 2001

VR
1/24/01

HOUSE AMENDMENTS TO HB 1116 **HOUSE HS** **1-25-01**

Page 1, line 2, replace "medical assistance-covered services and" with "outpatient"

Page 1, line 7, replace "**medical services**" with "**outpatient**"

Page 1, line 8, remove "**and**" and remove "The department may require prior authorization of medical services before"

Page 1, line 9, remove "providing medical assistance coverage of medical services."

Page 1, line 13, replace "seven-day" with "thirty-day"

Page 1, line 14, after the period insert "The department shall provide medical assistance coverage of an additional seven-day supply of an outpatient prescription drug while the prior authorization is in process."

Renumber accordingly

Date: 1-23-01
Roll Call Vote #: 1

2001 HOUSE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. HB 1116

House Human Services Committee

☐ Subcommittee on _____
or
☐ Conference Committee

Legislative Council Amendment Number _____

Action Taken Do Not Pass as Amended

Motion Made By Rep. Galvin Seconded By Rep. Sandvig

Representatives	Yes	No	Representatives	Yes	No
Rep. Clara Sue Price, Chairman	✓		Rep. Audrey Cleary	✓	
Rep. William Devlin, V, Chairman	✓		Rep. Ralph Metcalf	✓	
Rep. Mark Dosch	✓		Rep. Carol Niemeier	✓	
Rep. Pat Galvin	✓		Rep. Sally Sandvig	✓	
Rep. Frank Klein					
Rep. Chet Pollert	✓				
Rep. Todd Porter	✓				
Rep. Wayne Tieman	✓				
Rep. Dave Weiler	✓				
Rep. Robin Weisz	✓				

Total (Yes) 13 No 0

Absent 1

Floor Assignment Rep. Devlin

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

REPORT OF STANDING COMMITTEE

HB 1116, as amended, Human Services Committee (Rep. Price, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO NOT PASS** (13 YEAS, 0 NAYS, 1 ABSENT AND NOT VOTING). placed on the Sixth order on the calendar.

Page 1, line 2, replace "medical assistance-covered services and" with "outpatient"

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Renumber accordingly

2001 TESTIMONY

HB 1116

TESTIMONY BEFORE THE HOUSE HUMAN SERVICES COMMITTEE
REGARDING HOUSE BILL 1116
JANUARY 23, 2001

Chairman Price, members of the committee, I am David Zentner, Director of Medical Services for the Department of Human Services. I appear before you today to provide information and support this bill.

The Medicaid Program has used the prior authorization process to ensure that recipients who receive services paid by the taxpayers of North Dakota use services appropriately and in the most cost effective manner possible without compromising quality medical services. Federal regulations also require states to have adequate utilization processes in place to ensure that services are delivered in an appropriate manner. For example, a Medicaid recipient cannot simply show up at the doors of a nursing facility and request to be admitted. All potential admissions must be first reviewed to determine if the individual has sufficient medical needs that require skilled nursing care.

Medicaid currently prior authorizes a number of other services such as certain expensive dental procedures, orthodontics for children, durable medical equipment and supplies costing more than $200, non-emergency out of state services, smoking cessation services and mental health partial hospitalization services. The purpose of the prior authorization process is not to prevent recipients from receiving needed services but to ensure that the services are appropriate based on medical need and not on the wants of recipients.

Prior authorization of services is a standard practice used by most insurance companies, managed care organizations and state Medicaid Programs as a tool to ensure proper utilization of services and to control costs.

Previously, the Department has used the Medicaid State Plan and its rule making authority to establish prior authorization policies within the Medicaid Program. The Department proposed rules last year that would permit Medicaid to prior authorize certain classes of drugs that have high utilization rates where less costly drugs are available and based on individual patient need could provide similar relief at a lower cost. During a meeting of the Administrative Rules Committee there was concern expressed that the use of prior authorization in the Medicaid Program was a public policy issue that should be debated and approved by the Legislature. The Department did agree to withdraw the proposed rule and submit a bill draft, which you see before you today. The Department has continued to use prior authorization as a utilization tool for those services that had previously required such authorization.

This bill specifically permits the Department to establish a prior authorization process for outpatient drugs determined by the Department's Drug Utilization Review (DUR) Board to be subject to clinical abuse or inappropriate use. The DUR Board is required by federal regulations to, in part, make recommendations as to what interventions would most effectively lead to improvement in the quality of drug therapy based on an in-depth review of utilization data.

In our previous attempt to introduce prior authorization of drugs, the Department did provide information to the DUR Board regarding the utilization of various classes of drugs. The DUR Board consists of independent physicians and pharmacists who have agreed to serve on the board. The DUR Board did review data concerning drug utilization and recommended that the Department institute prior authorization for three therapeutic classes of drugs including antiulcers, antiarthritics and non-sedating antihistamines. Based on this recommendation, the Department proposed the rules that were later withdrawn.

Due to federal regulations, the Medicaid program has few mechanisms available to control drug costs. The budget for drugs was estimated at about $50 million

for the current biennium. Our latest projections indicate that we will actually expend in excess of $65 million. We are projecting a budget in excess of $80 million for the next biennium. The federal regulations require states to pay for all drugs approved by the Federal Drug Administration for all approved therapeutic uses. In exchange, Medicaid Programs receive a drug rebate that represents the difference between our payment to providers for the cost of the drug and the drug manufacturer's best price. Medicaid Programs cannot use formularies and are either prevented from or can impose only minimal cost sharing to try to influence the use of less costly but effective drugs.

Prior authorization is one of the few options available to Medicaid Programs to control drug utilization. We are aware of at least 42 states that use this mechanism of which at least 26 prior authorize the same drug classes we are proposing to control. Both Minnesota and Montana prior authorize a greater number of categories than we are proposing without compromising the medical needs of Medicaid recipients.

Costs for certain highly advertised drugs are very expensive. For example, Prilosec, an antiulcer medication, cost the Department $1.1 million in fiscal year 1999, up 30% from the previous year. A one-month supply costs in excess of $200 per month. Other products that could also provide relief to Medicaid recipients have costs of less then $40 per month.

The cost of drugs is a national issue. Information available from the Barents Group analysis of Scott-Levin Source Prescription Audit Data for 1993 and 1998 notes that spending on oral antihistamines increased by 612% during this period at a cost of $1.9 billion. Spending on anti-ulcer drugs increased by 71% or $2.7 billion. Some of these same drugs are on the top ten list of drugs most heavily advertised directly to consumers. In 1998 drug manufacturers spent $1.3 billion promoting their products directly to consumers.

The Department does not have the authority to prevent recipients from accessing any approved drug that is necessary to relieve the symptoms of a particular medical condition. If the most expensive drug is necessary to do the job, it will be made available to the recipient. The Department is merely attempting to ensure that less expensive treatments are not therapeutically effective in controlling a recipient's condition. If the most expensive medication is the only appropriate drug, the Department will gladly pay for it.

The Department is confident that the prior authorization process will be acceptable to recipients, physicians and pharmacists. We intend to use a short one-page form that will include check-off boxes with only minimum information required. Also, in order to ensure that recipients and providers have adequate time to respond to the prior authorization process, the Department is proposing an amendment. It will permit an initial 30-day supply of any product to be available without prior authorization. This will provide adequate time for pharmacists to counsel patients regarding the prior authorization process. In addition, pharmacists would be permitted to provide an additional 7-day supply during the prior authorization process. In addition, the Department is required by federal requirements to respond to prior authorization requests within 24 hours.

The Department has estimated cost savings of at least $600,000 if prior authorization of these three classes of drug is permitted, of which about $180,000 is general funds. We plan to implement the process without adding staff, which will be difficult but we believe attainable. The Executive budget did not include the additional $600,000. It will be necessary to increase the Medicaid budget by that amount if this bill is defeated.

In conclusion, the Department needs to be able to continue to use the prior authorization process to ensure the proper utilization of services provided to Medicaid recipients. Without this process the cost of the program will escalate. We also request approval to institute prior authorization for certain drug services.

Recipients who need appropriate drugs should have access to them, but only if it is the least expensive drug available to accomplish the desired result.

I would be happy to answer any questions you may have.

Prepared by the North Dakota
Department of Human Services
1/22/01

PROPOSED AMENDMENTS TO HOUSE BILL NO. 1116

Page 1, line 13, replace "seven-day" with "thirty-day"

Page 1, line 14, after the period insert "The department shall provide medical assistance coverage of an additional seven-day supply of an outpatient prescription drug while the prior authorization is in process."

Renumber accordingly

TESTIMONY BY

CALVIN N. ROLFSON, LEGISLATIVE CONSULTANT

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PHRMA)

REGARDING

HOUSE BILL NO. 1116

My name is Cal Rolfson. I am an attorney practicing law in Bismarck. I am also the Legislative Consultant for the Pharmaceutical Research and Manufacturers of America (PhRMA). On behalf of PhRMA, I appear in opposition to HB 1116. I hope the information I provide to you today will help clarify why this is a Bill that should be defeated.

PHARMACEUTICAL INDUSTRY

PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies, approximately 100 of them, which are devoted to inventing medicines that allow patients to live longer, healthier, happier and more productive lives.

Please allow a very brief overview of the industry I represent. Most new medicines are discovered and developed by pharmaceutical company researchers. US research-based pharmaceutical companies have about 50,000 scientists looking into new treatments or cures for hundreds of diseases. In 2000, these companies invested $26 billion to discover and develop new medicines. Of every five dollars these companies make, one dollar (20%) is plowed back into research and development - a higher ratio than virtually any other industry.

Prescription medicines play in an increasingly important role in health care. Yet

they account for only about 7¢ of every health care dollar. As more and better medicines are developed, and as patients, doctors and insurers become more aware of the enormous value and cost effectiveness of prescription drugs – this share of the health care pie will get bigger. This is a healthy trend. Over time, more spending on prescription medicines will reduce both the human and financial costs of disease. In 1998, spending on outpatient prescription medicines grew by 15.7%. However, only 3.2% of this number represents drug price increases. The other 12.5% reflects the fact that more people are using more and better medicines.

Developing a new medicine is a long, costly and high-risk process. On average, it costs more than $500 million to bring just one new medicine from the laboratory to the pharmacy – more then the costs of 3 jumbo jets. It takes 12-15 years to develop a new medicine, from initial discovery in the lab through approval by the Food and Drug Administration. That means, if a new medicine was discovered when a child was starting kindergarten, it might not be ready for patients until that same child was almost finished with college.

Only 1 in every 5,000 compounds tested becomes a marketed drug, and only 3 out of 10 approved drugs make more money than the average drug development costs. Despite these huddles, pharmaceutical companies are committed to finding cures. Right now, PhRMA companies have more than 1,000 new medicines in development, including:

- 104 for heart disease and stroke
- 354 for cancer
- 191 for such debilitating diseases of aging as Alzheimers and Arthritis

- 113 for AIDS
- 107 to meet the special needs of children
- 85 for mental illnesses

I have distributed a series of brochures for your review that elaborates upon these innovations.

BACKGROUND

The foundation of House Bill 1116 has an interesting history. In late 1999 and early 2000, the Department of Human Services drafted administrative rules that called for prior authorization of drugs. Those rules, when they were adopted by the Department, were required to go before the Legislature's Administrative Rules Committee for approval. That Committee held hearings in May, 2000, and voided the Department's rules regarding prior authorization. The Department is now asking the Legislative Assembly to place into law what was voided by your Administrative Rules Committee.

RATIONALE FOR OPPOSITION

I hope to share with you today why any law permitting the Department to prior authorize drugs for our citizens is a wrong approach as a money-saving tool.

The Pharmaceutical Research and Manufacturers of America recognize the challenges encountered by state Medicaid agencies to provide quality health care services while also conserving expenditures. However, prior authorization of drugs is the wrong approach. We ask that the Legislature and this Committee consider the following:

1. **Pharmaceuticals are recognized as one of the most cost-effective**

least invasive health care resources available. Limiting access to life-sustaining pharmaceuticals through prior authorization concepts contradicts present standards of care in which the use of pharmaceuticals is encouraged as a means to conserve health care expenditures by preventing disease and modifying the progression of certain illnesses. For example:

- A study sponsored by the National Institutes of Health found that treating stroke patients promptly with a new clot-busting drug nets an average savings of $4,400 per patient by reducing the need for hospitalization, rehabilitation and nursing home care.
- A study by the Agency for Health Care Policy and Research concluded that increased use of blood thinning drugs would prevent 40,000 strokes a year, saving $600 million per year nationally.
- Deaths from heart disease decreased more than 30% from 1980 to 1990. Nearly 50% of the decrease was due to advances in medicines. Appropriate use of beta blockers following an initial heart attack has been shown to result in an annual cost savings of up to $3 billion nationally in preventing second heart attacks and up to $237 million nationally in treating angina.
- To help reduce the crippling effects of osteoporosis, estrogen replacement therapy costs approximately $3,000 for 15 years of treatment, while treating a hip fracture costs an estimated $41,000. Medicines available today - both hormonal and non-hormonal - can

help women remain active and independent, while saving significant health care dollars.

2. **State Medicaid Departments already receive considerable assistance from the pharmaceutical industry for drug expenditures.** Federal law requires pharmaceutical companies to sell drugs to state Medicaid departments at the "best-price" that is offered to other private-sector purchasers. At a minimum, for each prescription dispensed, states receive 15.1% rebates on brand name products and 11.0% rebates on generic drugs off the average manufacturer's price. Brand name manufacturers are also required to pay additional rebates for any price increase for a product that exceeds the increase in the Consumer Price Index (CPI). If a particular product is offered to another purchaser at a price lower than the average manufacturer's price minus the rebate and CPI penalty, the State is entitled to this lower price.

North Dakota Rebate Dollars

1998 -- $4,990,065 1999 -- $5,954,387

3. **Prior authorization programs interfere with the provision of appropriate and necessary medical care.** Targeting new and expensive drugs for inclusion in a prior authorization program essentially creates a formulary of preferred products and prevents the most optimal therapeutic agents from being prescribed. Often recently approved products offer patients substantial advantages with regard to disease prevention and a more tolerable side effect profile that may facilitate

patient compliance with the prescribed regimen; thereby improving the overall health of the patient and reducing future health care expenditures. Prior authorization programs interfere with the doctor-patient relationship by preventing physicians and other prescribers from being able to select the best drug for each patient's individual needs. An added concern is that an onerous prior authorization program may be a disincentive for physicians to care for Medicaid patients.

4. **Prior authorization programs often result in *Increased* expenditures, contrary to the savings projections anticipated during development.** For example, the Arkansas Medicaid Department actually experienced *additional* expenditures of $46 million dollars over 5 months due to increased physician visits and hospitalizations resulting from frequent treatment failures of less expensive drugs. Studies addressing Medicaid cost containment strategies have shown that restrictive formularies and prior authorization procedures actually elevate Medicaid expenditures by 4.1% overall. Additionally, as restrictive formularies have been found to result in greater utilization of other health care resources, successful managed care cost containment programs have progressed to a "systems approach", rather than a line-item approach, to reduce expenditures. In addition, development and administration of a Medicaid prior authorization program requires a substantial financial and personnel investment on behalf of the Department. I see nothing in the Bill that addresses that.

5. **Prescription and non-prescription medications vary considerably**

and should not be viewed as equally effective alternatives for the management of illnesses. Non-prescription medications are notably different with regard to potency, side effect profile and approved indications as compared to products requiring a prescription. Encouraging utilization of non-prescription products could prompt an increase in Medicaid expenditures due to treatment failures or disease progression after subtherapeutic dosing. Authorizing payment for non-prescription drugs would expand the overall number of medications reimbursed through the Medicaid system.

ALTERNATIVES

In order to continue to provide quality pharmaceutical services without restricting access to valuable medications, some Medicaid departments in other states are using innovative approaches to conserve expenditures. Specifically, states are implementing the following programs:

1. **Disease State Management** - Disease management is an integrated process of prevention, treatment, monitoring, and education to achieve the best clinical outcomes in a cost-effective manner while utilizing the most appropriate medical procedures, services, and products available. Coordination of care and communication between the patient, physician, and other members of the health care team are essential elements of disease management. Using disease state management techniques, a strong emphasis is placed on provider education to ensure that physicians are using national treatment guidelines to develop a patient specific plan

for assessment and care. Several state Medicaid agencies and managed care organizations have recognized the cost savings and improvement in quality of care associated with disease state management and are implementing programs for AIDS, diabetes, hypertension, and asthma.

A recent example of a successful Medicaid disease management pilot initiative is the Virginia Health Outcomes Project (VHOP) which demonstrated a 42% reduction in expensive, unnecessary emergency room visits when physicians were taught appropriate prescribing of asthma drugs and utilization was consistently monitored. The net savings for the pilot program was $285,000; the projected statewide savings in Virginia from this asthma disease management program was $2 million.

2. **Fraud and Abuse Detection and Prevention** - Many health care experts and the General Accounting Office estimate Medicaid and private health care fraud represents between 5% and 10% of total expenditures. As utilization of pharmaceuticals increases, pharmacy programs can no longer afford to take a passive role in addressing fraud and abuse. It is imperative that pharmacy programs consider enhancing efforts in auditing and recovery of overpayments for prescribed drugs as this component of the budget continues to grow. This will ensure that dollars are efficiently used to promote patient care and are not wasted. New detection strategies and sophisticated software programs have been developed to assist health plans in the identification of fraudulent and abusive practices.

In Florida, the State Auditor General put the price tag for Medicaid

fraud generally at approximately $230 million in 1997. Of that figure, roughly $100 million was attributed to fraud in the Medicaid pharmacy program. In response, Florida's Agency for Health Care Administration developed a number of innovative fraud and abuse control measures. Its arsenal of weapons in fighting fraud include enforcement of civil and criminal false claims laws, administrative sanctions and whistle-blower laws. It also includes a new generation of fraud detection software control devices and improved audit processes.

3. **Enhanced Drug Utilization Review (DUR) and Drug Utilization Education (DUE)** - DUR is a means of helping physicians improve their prescribing practices by ensuring that each patient receives the most appropriate drug therapy. DUR also helps physicians and pharmacists evaluate patient compliance with prescribed drug therapy. In turn, this can reduce spending and often improve the quality of care. DUR helps ensure that prescriptions are appropriate, medically necessary, being taken properly, and are not likely to interact adversely with the patient's other conditions and drug therapies. Each state has a DUR committee. The Department has a DUR committee in place, but I don't believe it has been used much during the past year.

Appropriate prospective and retrospective DUR/DUE interventions integrated with disease management can greatly enhance the appropriate utilization of drugs and promote cost effective clinical outcomes.

As the Department considers strategies to curtail Medicaid program spending, emphasis should be placed on preserving access to state-of-the-art pharmaceuticals that aggressively and optimally treat disease as a means to prevent future medical expenditures. PhRMA maintains the position that appropriate, safe prescription drug use results in savings in other health care services, including nursing home admissions, hospital stays, and emergency room visits.

For these reasons, I urge you to vote "Do Not Pass" on HB 1116. There are so many other ways to cut health care costs in the Department of Human Services rather than intrude between the patient and his or her physician under this Bill.

North Dakota Pharmaceutical Association

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Testimony on HB 1116
House Human Services Committee
January 23, 2001
Galen Jordre, R.Ph. – Executive Vice President

The North Dakota Pharmaceutical Association (NDPhA) represents the 670 pharmacists licensed to practice pharmacy in this state. These pharmacists provide services to patients through 175 community retail pharmacies and 56 institutional pharmacies located in 73 different communities of our state. Almost 100% of our pharmacies participate in the Medicaid program and provide needed services to both ambulatory patients and those within nursing care facilities.

The reason that House Bill No. 1116 is before you is because of the rapidly increasing expenditures for prescription drugs in the Medicaid program. These expenditures are driven by increased utilization and introduction of innovative prescription drug products that treat and prevent diseases in more effective ways than other forms of therapy. We are facing a dilemma of providing the most effective treatments to our Medicaid patients while under budget restraints. House Bill 1116 is an attempt to balance the provision of therapy while living within a budget but we feel that it lacks the detail necessary to insure that other approaches are attempted before instituting a prior authorization process.

The North Dakota Pharmaceutical Association is not supportive of prior authorization as a primary way of controlling utilization of prescription drug products. We would prefer to see more aggressive use of the Drug Utilization Review board to outline specific utilization problems and then direct educational programs outlining treatment protocols to both prescribers and pharmacists who work with Medicaid patients. Along with these educational programs we are proponents of implementing disease state programs that will insure appropriate drug use among the most difficult and high cost patients. The Drug Utilization Review board should use Department and national data to set outcomes goals so all programs can be evaluated for effectiveness. Such approaches will require strong support from the medical and pharmacy communities in the state along with resources from the pharmaceutical manufacturers in order to be effective.

While we prefer that the approaches outlined above, we also realize that these programs may fall short of the goals established by the Drug Utilization Review board. In that case we do feel that use of a prior authorization program may be necessary to promote appropriate utilization of prescription drugs. There are provisions for use of prior authorization in federal regulations and it is used extensively by other state Medicaid programs and privately administered prescription drug programs. The North Dakota Pharmaceutical Association would support authority for the Department to implement prior authorization as a final measure when other approaches have failed and when improper utilization of certain classes of prescription drugs threatens the overall integrity of the prescription drug program. We would be very happy to work with the other stakeholders to reach a satisfactory approach for the difficult drug utilization decisions that the Department is currently facing.

Testimony HB 1116
North Dakota Medical Association

David Leske

HB 1116 would give the Department of Human Services discretion to require prior authorization for (1) medical services, and (2) certain outpatient drugs under Medicaid. The North Dakota Medical Association opposes HB 1116, and opposed a similar proposal made last year by the Department before the Legislative Council's Administrative Rules Committee, relating specifically to outpatient drugs. Attached is a copy of NDMA's comments on the proposed rule.

Different from the administrative rule proposal, HB 1116 would also authorize prior authorization for "medical services," with no standard that would apply to determine when prior authorization would be appropriate or which medical services would be subject to prior authorization.

The thrust of NDMA's opposition reflects concern that the Department has not fully explored alternatives to a prior authorization program, that prior authorization would interfere unfairly in the patient-physician relationship and the ability of a patient's physician to assure that the patient is receiving appropriate medical care, and that a prior authorization program may be more costly to implement than the anticipated savings. In our earlier comments to the Department we stressed that administrative costs and extra patient visits may offset any potential savings realized under the program. Restricting access to physician-prescribed medications, particularly new and more effective treatments, may cause patients to suffer medically and require more costly treatment in the long-run. We understand that Minnesota has identified a cost of $13.88 to administer each prior authorization request, and nine out of ten requests are approved. In Iowa, 95% of the requests for one of the anti-ulcer drugs are approved.

In our earlier comments, we suggested that one alternative may be educational programs under the Drug Utilization Review (DUR) Program. Federal law is quite clear in requiring each state to institute a drug use review program to ensure that covered outpatient drugs are appropriate, are medically necessary, and are not likely to result in adverse medical results. The DUR program must include prospective drug review, retrospective drug use review, assessment of drug data against predetermined standards, and educational programs. The state has broad discretion in implementing educational programs through the DUR Board, accredited health care educational institutions, state medical societies or state pharmacists associations, or other organizations. The state must "provide for active and ongoing educational outreach programs to educate practitioners on

common drug therapy problems with the aim of improving prescribing or dispensing practices." The DUR Board is required by the federal law to provide ongoing interventions for physicians and pharmacists. *See* 42 USC 1396r-8(g).

While HB 1116 states that decisions relating to prior authorization for outpatient drugs would be made by the Department's DUR Board, it has been many months since the Department has brought the DUR Board together to meet on this or any other related issue. In our earlier comments, we encouraged the Department to identify educational programs that could be developed to address the problems the Department believes would be alleviated by the prior authorization program. Other states use their DUR programs to help physicians improve their prescribing practices to ensure that each patient receives the most appropriate drug therapy. Under the guidance of the DUR Board, the Department could develop materials identifying their concerns regarding certain categories of drugs, and provide the materials to physicians and pharmacists through direct mailings or educational forums in cooperation with those professional organizations.

Until the Department better utilizes the DUR Board and its intended scope, HB 1116 is premature in granting the Department the ability to impose prior authorization. For these reasons, the North Dakota Medical Association urges a DO NOT PASS on HB 1116.

NORTH DAKOTA
MEDICAL ASSOCIATION

December 3, 1999

David Zentner, Medical Services Director
North Dakota Department of Human Services
State Capitol - Judicial Wing
600 East Boulevard Avenue - Dept. 325
Bismarck, ND 58505-0250

Re: Additional Comments Regarding Proposed Amendments to NDAC 75-02-02-08

Dear Mr. Zentner,

At your suggestion, the North Dakota Medical Association submits this addendum to our previous comments regarding the proposed rules, specifically with respect to the proposed amendments to NDAC 75-02-02-08(2) with the addition of paragraph (p) which states:

> Coverage may not be extended and payment may not be made for therapeutic classes of medically necessary prescribed drugs, described in the state plan as requiring prior authorization, to the extent permitted under 42 USC 1396r-8(d)(5), unless the provider requests and receives prior authorization from the department.

We appreciate this opportunity to provide further comments.

The referenced federal law, 42 USC 1396, states in part:

> (5) Requirements of prior authorization programs
> A State plan under this subchapter may require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section, with respect to drugs dispensed on or after July 1, 1991, the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6) of this section) only if the system providing for such approval - (A) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and (B) except with respect to the drugs on the list referred to in paragraph (2), provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

The current state plan places limits on the amount, duration, and scope of services, including a provision stating that "Drugs identified by the Medical Services division as requiring prior approval and listed in the Pharmacy Provider Manual will not be allowed for payment except in accordance with SSA 1927(d) [Services, 12a(8)]."

The "Notice of Intent to Amend Administrative Rules" indicates that the purpose of the proposed amendments to NDAC Ch. 75-02-02, including the addition of the preauthorization program is to "remove ambiguous and duplicative language, simplify, and clarify requirements."

Since September 10, the date the comment period closed, the Department has moved forward in establishing the preauthorization program at the same time a rule is being proposed to give the Department authority to establish the program. This has caused confusion and a reconsideration of the issue by our Association's Commission on Socio Economics, resulting in our need to submit these additional comments.

Regulatory Analysis

The Notice states that the proposed rules are not expected to have an impact on the regulated community in excess of $50,000.

In testimony to the Legislative Council's Interim Budget Committee on Human Services, it was stated in the prepared testimony of the Department that savings from the preauthorization process "could reach about $500,000 annually [Minutes of the Legislative Council's Interim Budget Committee on Human Services, October 6-7, 1999]." Clearly, the expected impact on the regulated community of patients, physicians, and other professionals (due to the rule changes affecting preauthorization authority and the new definition of "medically necessary") is in excess of $50,000, and a regulatory analysis is required under NDCC Section 28-32-02.2(1)(b) and (5).

At the October 6-7 meeting, there was skepticism expressed by several members of the interim Budget Committee on Human Services regarding the underlying data and factual basis for the proposed preauthorization program, resulting in their action to request a future update from the Department on the proposed preauthorization program that includes "resulting savings and other impacts." The Committee was not made aware that the Department's preauthorization authority was being addressed or clarified in a proposed administrative rule.

A regulatory analysis would be beneficial. The analysis could provide some answers to the many questions asked by the interim committee, as well as substantiate or refute the basis for the apparent reluctance of physicians and other health professionals to participate in the proposed preauthorization program. By its very nature, the regulatory analysis would address probable costs in implementation of the rule and alternative methods, such as Drug Use Review educational programs, for achieving further cost savings and why those alternative methods were rejected [NDCC Section 28-32-02.2(2)].

We request that the regulatory analysis be performed to substantially comply with Chapter 28-32.

The Drug Use Review Program is a Possible Alternative to a Preauthorization Program

A regulatory analysis would include a review of alternatives and specific reasons why alternatives are rejected. One alternative may be further educational programs under the Drug Use Review (DUR) Program. Federal law is quite clear in requiring each state to institute a drug use review program to ensure that covered outpatient drugs are appropriate, are medically

necessary, and are not likely to result in adverse medical results. The DUR program must include prospective drug review, retrospective drug use review, assessment of drug data against predetermined standards, and educational programs. The state has broad discretion in implementing educational programs through the DUR Board, accredited health care educational institutions, state medical societies or state pharmacists associations, or other organizations. The state must "provide for active and ongoing educational outreach programs to educate practitioners on common drug therapy problems with the aim of improving prescribing or dispensing practices." The DUR Board is required by the federal law to provide ongoing interventions for physicians and pharmacists. *See* 42 USC 1396r-8(g).

The 1998 DUR Annual report you provided indicates substantial savings realized by the DUR program.

We suggest that the Department, as part of a regulatory analysis of the proposed rules, review the current DUR program. That review might identify additional educational programs that could be developed to address the problems the Department proposes would be addressed by the preauthorization program. The review could specify why the DUR program, if implemented or expanded to the extent allowed by law, would either (1) adequately address those problems and preclude the need for the preauthorization program, or (2) not address those problems and be rejected as an alternative to the preauthorization program.

The Proposed Rule Would Circumvent Public Input

Any process for developing or revising patient care should include patients and other affected parties. The proposed rule would authorize the Department to add classes of medically necessary prescribed drugs to the state plan as requiring prior authorization, without the benefit of public comment in each instance as provided in the Administrative Agencies Practice Act or through some other specified opportunity for public comment.

The Necessity and Anticipated Effectiveness of the Preauthorization Program Have Not Been Substantiated

We start from the premise that any policy predicated on therapeutic interchangeability of prescription drugs will inevitably interfere with the patient-physician relationship and the ability of a patient's physician to assure that the patient is receiving appropriate medical care.

The details of the proposed preauthorization program have not been formally submitted to the North Dakota Medical Association for comment. In our informal conversations with Department staff on the preauthorization issue, we have suggested that the program would interfere unfairly with the physician-patient relationship and may be more costly to implement than the anticipated savings. We have said that administrative costs and extra patient visits may offset any potential savings realized under the program. Restricting access to physician-prescribed medications, particularly new and more effective treatments which may cost more, may cause patients to suffer medically and require more costly treatment in the long-run.

Thank you for allowing the Association the opportunity to provide these additional comments and for providing the materials I requested. We look forward to working with the Department further and assisting in resolving the budgetary problem.

Sincerely,

Bruce Levi

Bruce Levi
Executive Director

cc Pierre Rioux, MD. Drug Use Review Board
Gregory Culver, MD, Drug Use Review Board
NDMA Commission on Socio Economics