MICROFILM DIVIDER

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

ROLL NUMBER

DESCRIPTION

1430

2003 HOUSE HUMAN SERVICES

HB 1430

2003 HOUSE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. HB 1430

House Human Services Committee

☐ Conference Committee

Hearing Date January 29, 2003

Tape Number	Side A	Side B	Meter #
1	x		41.0 - 61.7
		x	0.0 - 42.1
Committee Clerk Signature	Sharon Rathgeber		

Minutes:

Rep. Devlin appeared as prime sponsor with written testimony.

Cal Rolfson, Legal Counsel for PHRMA appeared in support with written testimony and will propose or work with amendments.

Rep. Amerman regarding the makeup of the board, will these members be voting on different things and are they from within ND or out of state? Answer: yes, they would be the experts in those areas and feels it would be someone within ND.

Rep. Sandvig: What extra paper work is this going to be for the providers, doctors, hospitals, clinics, etc. for prior authorization. Answer: Believes there would be little or no difference in the work involved.

Rep. Wieland: Who specifically serves on the board. Answer: 3 or 4 physicians, & 3 or 4 pharmacists and not sure who else., Mr. Zentner should be able to answer.

Rep. Porter: Section 8 & 9 that directly go to district court, is there any reason why we bypass the administrative hearing process first and go right to the court? Answer: It was just a selection that was made, I have no objection to modifying that process to go through the administrative agencies practice act and then to the district court.

David Zentner, Dept. of H.S. appeared in opposition with written testimony and hand out.

Rep. Sandvig asked to explain prior authorization. Answer: now the Dept. has no prior authorization for drugs.

Rep. Niemeier: how are these saving achieved through prior authorization? Answer: 3 tiered process, generic drugs, brand name drugs and non-formulated.

Rep. Weisz: why the new board couldn't essentially take the formularies that have already been established, through PERS or whatever.

Brandon Joyce, Pharmacist on the Board with Dept. of H.S. - explained the process

Rep. Sandvig: how many other states have a formulary list? Answer: we don't, but 46 states have prior authorization lists.

Rep. Potter: The bill suggests 2 bids, any problem with combining them? Answer: Could

Rep. Potter: This bill suggests 3 physicians, 3 pharmacists, 1 from the medical assistance and 1 representing the pharmaceutical company, would you have trouble with this? Answer: would like to have enough to be competent and cross-section of information.

Galen Jordre appeared in opposition, opposing the part on section 4 (approval of patient). This troubles me because if you would read this on the face, that would mean that the prescription could not be changed even if there were clear evidence of something unless the patient would approve in addition to the physician and pharmacists.

2003 HOUSE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. HB 1430

House Human Services Committee

❑ Conference Committee

Hearing Date February 5, 2003

Tape Number	Side A	Side B	Meter #
2	x		10.7 - 44.7
Committee Clerk Signature	Sharon Rayfrai		

Minutes: Committee Work

Cal Rolfson, Pharma appeared to explain the amendments and stated that SB 2088 failed in the Senate.

Rep. Niemeier questioned what the members would be paid. Answer: $50 per day plus mileage.

Rep. Devlin had concerns with Subsection 3

Rep. Weisz wanted a definition of priority review and what it means to have a drug under that. Answer by Cal Rolfson: it is a special classification. There are a special classifications of Drugs called Priority Review, they are special drugs with increased importance for health and life and may be aged drugs, they may be hepatitis drugs that have a priority for life threatening issues rather than something less important. Those are so important they should not be tweaked by the Dept.

Rep. Porter was wondering about the savings it brings to the state and if this should be declared an emergency to bring into effect before August 1st.

Answer: Dr. Joyce believes that it will take a half a year to get this committee organized. They are having problems with getting Dr.'s to show up at DUR Board meetings. We would not object to the emergency clause but isn't necessary.

Rep. Sandvig asked if there wasn't a DUR Board that already existed and couldn't we use that one.

Answer: There was a suggestion by Dr. Joyce that they use the BCBS Formulary as a guide.

Rep. Devlin made motion to move the amendments with adding emergency clause presented by Cal Rolfson and also delete lines 25 through 29 on Page 8, changes on Page 5 to change 11 to 8 and Section 8, add reasonable, second by Rep. Porter.

Rep Price stated it seemed like we were created a whole another board and how come 46 other states are using a preferred drug list, aren't they doing something right? Isn't there something we can learn from them?

Answer: Cal Rolfson responded by stated that there are 46 states that have prior drug lists, that is not correct, they have prior authorization. Only 5 states have preferred drug lists and all 5 of those have been sued because of it.

VOTE: 13 - 0 - 0 Amendments Passed

Rep. Devlin made a motion for DO PASS as AMENDED and refer to Appropriations if needed, second by Rep. Weisz. 12 - 1 - 0 Rep. Devlin to carry the bill.

FISCAL NOTE

Requested by Legislative Council
03/26/2003

Amendment to: HB 1430

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.*

	2001-2003 Biennium		2003-2005 Biennium		2005-2007 Biennium	
	General Fund	Other Funds	General Fund	Other Funds	General Fund	Other Funds
Revenues	$0	$0	$0	($2,222,991)	$0	($3,483,528)
Expenditures	$0	$0	($772,570)	($2,222,991)	($1,400,269)	($3,483,528)
Appropriations	$0	$0	$227,430	$710,904	$0	$0

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

2001-2003 Biennium			2003-2005 Biennium			2005-2007 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 establish a medical assistance drug review program and drug prior authorization program within the Department of Human Services. It would create a separate board to review and recommend what classes of drugs would require prior authorization.

The executive budget included funding for a prior authorization program beginning July 1, 2003 which would utilize an outside contractor. Creating a program within the Department instead would delay implementation of the program to approximately January 1, 2004, thereby reducing prescription drug savings in the 2003-2005 biennium. Because of this, an additional $938,334 appropriations would be required, of which $227,430 would be general funds.

If the amendments proposed to SB 2012 by the House Human Resources Appropriation Committee are adopted relating to HB 1430 an additional $1,000,000 in general funds, which "is not" reflected in the numbers above would need to be added to the Department's appropriation.

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.*

The reduction in other revenues relates to federal medicaid funds.

   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.*

For 2003-2005, grant expenditures for prescription drugs would be decreased by $4,037,921 of which $1,293,750 would be general funds. This savings would be offset by an increase in operating expenditures from creating and operating a utilization review board and from contracting for prior authorization services. Operating expenditures would increase by $1,042,360 of which $521,180 would be general funds.

   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 includes savings of $3,933,895 of which $1,000,000 is general funds for prior authorization. Passage of this bill would require an increase in appropriations for 2003-05 of $938,334 of which $227,430 would be general funds.

If the amendments proposed to SB 2012 by the House Human Resources Appropriation Committee are adopted relating to HB 1430 an additional $1,000,000 in general funds, which "is not" reflected in the numbers above would need to be added to the Department's appropriation.

Name:	Debra McDermott	**Agency:**	Human Services
Phone Number:	328-3695	**Date Prepared:**	03/28/2003

FISCAL NOTE

Requested by Legislative Council
02/11/2003

Amendment to: HB 1430

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.*

	2001-2003 Biennium		2003-2005 Biennium		2005-2007 Biennium	
	General Fund	Other Funds	General Fund	Other Funds	General Fund	Other Funds
Revenues	$0	$0	$0	$22,704	$0	$23,493
Expenditures	$0	$0	$22,704	$22,704	$23,493	$23,493
Appropriations	$0	$0	$1,022,704	$2,956,599	$0	$0

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

2001-2003 Biennium			2003-2005 Biennium			2005-2007 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 as amended would establish a drug utilization review program and drug prior authorization program within the Department of Human Services. It would create a separate board to review and recommend what classes of drugs would require prior authorization. It would also created potential legal consequences that would make providing prior authorization services prohibitive to outside vendors; therefore no savings would be realized for prescription drugs.

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.*

Other revenues relate to federal medicaid funds for board expenses at the administrative match rate of fifty percent.

   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.*

For 2003-2005, operating expenditures would consist of $45,408 in board costs at the administrative match rate of fifty percent.

   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 includes savings of $3,933,895 of which $1,000,000 is general funds for prior authorization. This bill as amended would make it impraticable for outside vendors to provide prior authorization services; therefore the Department's appropriation authority for the 2003-2005 biennium would need to be increased by $3,933,895, with $1,000,000 being general funds.

Also the operating authority would need to be increased by an additional $45,408, with $22,704 being general funds for the cost of the review board.

Name:	Debra McDermott	**Agency:**	Human Services
Phone Number:	328-3695	**Date Prepared:**	02/13/2003

FISCAL NOTE

Requested by Legislative Council
01/21/2003

Bill/Resolution No.: HB 1430

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.*

	2001-2003 Biennium		2003-2005 Biennium		2005-2007 Biennium	
	General Fund	Other Funds	General Fund	Other Funds	General Fund	Other Funds
Revenues	$0	$0	$0	($1,769,289)	$0	($3,487,316)
Expenditures	$0	$0	($560,605)	($1,769,289)	($1,404,056)	($3,487,316)
Appropriations	$0	$0	$439,395	$1,164,606	$0	$0

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

2001-2003 Biennium			2003-2005 Biennium			2005-2007 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 establish a drug utilization review program and drug prior authorization program within the Department of Human Services. It would create a separate board to review and recommend what classes of drugs would require prior authorization.

The Department has proposed to implement a prior authorization process through SB 2088. The savings from SB 2088 have been incorporated into the Department's appropriation bill. The delays caused by the requirements of this bill (HB 1430) would reduce the projected savings for prescription drugs by $2,018,961.

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.*

The reduction in other revenues relates to federal medicaid funds.

   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.*

For 2003-2005, grant expenditures would be decreased by $3,364,934 of which $1,078,125 would be general funds. This savings would be offset by an increase in operating expenditures from creating and operating a utilization review board and from contracting for prior authorization services. Operating expenditures would increase by $1,035,040 of which $517,520 would be general funds.

   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 includes the implementation of SB 2088, with a savings of $3,933,895 of which $1,000,000 would be general funds. **Passage of this bill in lieu of SB 2088 would require an increase in appropriations for 2003-2005 of $1,604,001 of which $439,395 would be general funds.**

Name:	Debra A. McDermott	**Agency:**	Human Services
Phone Number:	328-3695	**Date Prepared:**	01/24/2003

30674.0101
Title.0200

Adopted by the Human Services Committee
February 5, 2003

VR
2/7/03
1083

HOUSE AMENDMENTS TO HOUSE BILL NO. 1430 **HS 2-7-03**

Page 1, line 1, remove the second "to"

Page 1, line 2, after "services" insert "; and to declare an emergency"

Page 1, line 8, remove "peer-review medical literature,"

HOUSE AMENDMENTS TO HOUSE BILL NO. 1430 HS 2-7-03

Page 2, line 14, replace "eleven" with "eighteen"

Page 2, line 16, replace "Four" with "Six"

Page 2, line 17, after "medicine" insert ", four of whom are"

Page 2, line 19, replace "Five pharmacist" with "Six pharmacists"

Page 2, line 20, replace "and" with "four of whom are"

Page 2, line 22, replace "One person" with "Two individuals" and replace "is a resident" with "are residents"

Page 2, line 23, remove "and"

Page 2, line 24, replace "One person" with "Two individuals"

Page 2, line 26, replace the period with ";

e. The pharmacy administrator of the department; and

f. The medical consultant to the department."

Page 2, line 27, replace "One physician, one" with "Two physicians, two pharmacists"

Page 2, line 28, remove "pharmacist" and replace "the" with "one"

Page 2, line 29, replace "one physician" with "two physicians" and replace "the" with "one"

HOUSE AMENDMENTS TO HOUSE BILL NO. 1430 HS 2-7-03

Page 3, line 1, remove "nominee lists for"

Page 3, line 5, replace "monthly" with "once every two months"

Page 3, line 7, after "The" insert "duties of the board must be consistent with 42 U.S.C. 1396r-8(g)(3). In addition, the"

Page 3, line 16, replace "part" with "Act"

HOUSE AMENDMENTS TO HOUSE BILL NO. 1430 2-7-03

Page 5, line 17, after the period insert "Members appointed to the committee may be appointed from among the board and may also serve as members of the board."

2 of 3

Page 5, line 18, replace "eleven" with "eight"

Page 5, line 20, replace "Five" with "Three" and after "physicians" insert "of different medical specialties"

Page 5, line 21, after "medicine" insert "who may be" and after "from" insert "among physician members of the board or from"

Page 5, line 23, replace "Four" with "Three"

Page 5, line 24, after the comma insert "who may be" and after "from" insert "among the pharmacist members of the board or from"

Page 5, line 30, replace "Board" with "Committee" and replace "Two physicians" with "One physician"

HOUSE AMENDMENTS TO HOUSE BILL NO. 1430 HS 2-7-03

Page 6, line 21, replace "a semiannual" with "at least an annual"

Page 6, line 28, after "the" insert "completed"

HOUSE AMENDMENTS TO HOUSE BILL NO. 1430 HS 2-7-03

Page 7, line 6, replace the comma with "or"

Page 7, line 7, remove "or peer-review literature"

Page 7, line 8, after the period insert "The department may contract with third parties to collect and analyze the documentation required by this subsection."

HOUSE AMENDMENTS TO HOUSE BILL NO. 1430 HS 2-7-03

Page 8, remove lines 25 through 29

Page 8, line 30, replace "4." with "3."

HOUSE AMENDMENTS TO HOUSE BILL NO. 1430 HS 2-7-03

Page 9, line 3, after "department" insert "under chapter 28-32"

Page 9, line 4, replace "5." with "4." and replace "every six" with "not less than once each year"

Page 9, line 5, remove "months"

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

Page 9, after line 8, insert:

"**SECTION 8. Denial or delay of care.** Notwithstanding any other provision of law, any individual whose health care has been denied or delayed more than twenty-four hours as a result of an administrative procedure implemented by the department or any of its contractors may bring an action in district court. The administrative procedures include prior authorization, formularies, preferred drug lists, step therapy, or treatment protocols. The court may provide equitable relief and specific remedies. If a department contractor has acted with disregard for the prescribing physician's judgment regarding medically necessary care for the individual, the court may provide for exemplary damages. If the court finds against the department, the court shall award reasonable attorney's fees and court costs, regardless of whether the court awards specific relief or damages to the plaintiff.

3 of 3

SECTION 9. Preferred drug list procedures. A pharmaceutical manufacturer may appeal to the district court a decision of the department or its contractor to exclude a specific drug from a preferred drug list or formulary on the grounds that the decision is arbitrary, unfair, or a violation of state law, or in the case of a single source drug, on the grounds that the exclusion is not consistent with 42 U.S.C. 1396r-8(d)(4).

SECTION 10. Financial incentives prohibited. The department may not offer or pay directly or indirectly any material inducement, bonus, or other financial incentive to a participating provider based on the denial or delay of medically necessary and appropriate prescription drug therapy, or a reduction in the proportion of beneficiaries who receive prescription drug therapy under the medical assistance program."

Page 9, after line 10, insert:

"**SECTION 12. EMERGENCY.** This Act is declared to be an emergency measure."

Renumber accordingly

Date: Feb 5, 2003
Roll Call Vote #: 1

2003 HOUSE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. HB 1430

House HUMAN SERVICES Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken Do Pass as Amended

Motion Made By Rep Devlin Seconded By Rep Weisz

Representatives	Yes	No	Representatives	Yes	No
Rep. Clara Sue Price - Chair	✓		Rep. Sally Sandvig	✓	
Rep. Bill Devlin, Vice-Chair	✓		Rep. Bill Amerman		✓
Rep. Robin Weisz	✓		Rep. Carol Niemeier	✓	
Rep. Vonnie Pietsch	✓		Rep. Louise Potter	✓	
Rep. Gerald Uglem	✓				
Rep. Chet Pollert	✓				
Rep. Todd Porter	✓				
Rep. Gary Kreidt	✓				
Rep. Alon Wieland	✓				

Total (Yes) 12 No 1

Absent 0

Floor Assignment Rep. Devlin

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

REPORT OF STANDING COMMITTEE (410)
February 7, 2003 4:10 p.m.

Module No: HR-24-2056
Carrier: Devlin
Insert LC: 30674.0101 Title: .0200

REPORT OF STANDING COMMITTEE

HB 1430: Human Services Committee (Rep. Price, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** and **BE REREFERRED** to the **Appropriations Committee** (12 YEAS, 1 NAY, 0 ABSENT AND NOT VOTING). HB 1430 was placed on the Sixth order on the calendar.

Page 1, line 1, remove the second "to"

Page 1, line 2, after "services" insert "; and to declare an emergency"

Page 1, line 8, remove "peer-review medical literature,"

Page 2, line 14, replace "eleven" with "eighteen"

Page 2, line 16, replace "Four" with "Six"

Page 2, line 17, after "medicine" insert ", four of whom are"

Page 2, line 19, replace "Five pharmacist" with "Six pharmacists"

Page 2, line 20, replace "and" with "four of whom are"

Page 2, line 22, replace "One person" with "Two individuals" and replace "is a resident" with "are residents"

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Page 2, line 28, remove "pharmacist" and replace "the" with "one"

Page 2, line 29, replace "one physician" with "two physicians" and replace "the" with "one"

Page 3, line 1, remove "nominee lists for"

Page 3, line 5, replace "monthly" with "once every two months"

Page 3, line 7, after "The" insert "duties of the board must be consistent with 42 U.S.C. 1396r-8(g)(3). In addition, the"

Page 3, line 16, replace "part" with "Act"

Page 5, line 17, after the period insert "Members appointed to the committee may be appointed from among the board and may also serve as members of the board."

Page 5, line 18, replace "eleven" with "eight"

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Page 5, line 21, after "medicine" insert "who may be" and after "from" insert "among physician members of the board or from"

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Page 5, line 24, after the comma insert "who may be" and after "from" insert "among the pharmacist members of the board or from"

Page 5, line 30, replace "Board" with "Committee" and replace "Two physicians" with "One physician"

Page 6, line 21, replace "a semiannual" with "at least an annual"

Page 6, line 28, after "the" insert "completed"

Page 7, line 6, replace the comma with "or"

Page 7, line 7, remove "or peer-review literature"

Page 7, line 8, after the period insert "The department may contract with third parties to collect and analyze the documentation required by this subsection."

Page 8, remove lines 25 through 29

Page 8, line 30, replace "4." with "3."

Page 9, line 3, after "department" insert "under chapter 28-32"

Page 9, line 4, replace "5." with "4." and replace "every six" with "not less than once each year"

Page 9, line 5, remove "months"

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

Page 9, after line 8, insert:

"**SECTION 8. Denial or delay of care.** Notwithstanding any other provision of law, any individual whose health care has been denied or delayed more than twenty-four hours as a result of an administrative procedure implemented by the department or any of its contractors may bring an action in district court. The administrative procedures include prior authorization, formularies, preferred drug lists, step therapy, or treatment protocols. The court may provide equitable relief and specific remedies. If a department contractor has acted with disregard for the prescribing physician's judgment regarding medically necessary care for the individual, the court may provide for exemplary damages. If the court finds against the department, the court shall award reasonable attorney's fees and court costs, regardless of whether the court awards specific relief or damages to the plaintiff.

SECTION 9. Preferred drug list procedures. A pharmaceutical manufacturer may appeal to the district court a decision of the department or its contractor to exclude a specific drug from a preferred drug list or formulary on the grounds that the decision is arbitrary, unfair, or a violation of state law, or in the case of a single source drug, on the grounds that the exclusion is not consistent with 42 U.S.C. 1396r-8(d)(4).

SECTION 10. Financial incentives prohibited. The department may not offer or pay directly or indirectly any material inducement, bonus, or other financial

incentive to a participating provider based on the denial or delay of medically necessary and appropriate prescription drug therapy, or a reduction in the proportion of beneficiaries who receive prescription drug therapy under the medical assistance program."

Page 9, after line 10, insert:

"**SECTION 12. EMERGENCY.** This Act is declared to be an emergency measure."

Renumber accordingly

2003 HOUSE APPROPRIATIONS

HB 1430

2003 HOUSE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. HB 1430

House Appropriations Committee

☐ Conference Committee

Hearing Date 02-17-03

Tape Number	Side A	Side B	Meter #
2		X	8.0 - 11.0
Committee Clerk Signature			

Minutes:

Chairman Svedjan Opened HB 1430 for discussion. A quorum was present.

Rep. Devlin This will give substantial savings on the state's Medicaid.

Rep. Carlisle How is Human Services affected with this?

Rep. Devlin The department will be on board with this.

Rep. Timm If the Senate killed it, why will this work?

Rep. Devlin It's a different approach.

Dave Zentner The fiscal note, in its current form, won't save any money.

Chairman Svedjan What were your estimated savings?

Zentner Originally, we were looking at about 1 million dollars. Due to some of the provisions in HB 1430, we'd save ½ or 2/3rds of that amount. The previous fiscal note would indicate the original savings.

Rep. Gulleson Your litigation concerns is that we'd be treating this class of people than we'd be treating other people who weren't accessing Medicaid or drug access?

Zentner Sections 8 and 9 were added via amendment and they talk about any manufacturer who has an issue can go directly to the courts.

Chairman Svedjan It appears to me that the department wants this bill killed.

Rep. Devlin That may be the case, but if the state wants prior authorization they must have a vehicle for it.

Chairman Svedjan I don't think its wise to have fiscal notes generated that are contingent on receiving bids.

Rep. Devlin I don't have an answer. I agree with you. I think we will find someone to bid on it.

Chairman Svedjan I'm of the opinion that prior authorization will save us money.

Rep. Delzer I move a Do Pass. 2nd by Rep. Carlson. Motion Carries 19-4-0. Rep. Devlin will carry this bill.

REPORT OF STANDING COMMITTEE (410)
February 17, 2003 3:14 p.m.

Module No: HR-30-2961
Carrier: Devlin
Insert LC: . Title: .

REPORT OF STANDING COMMITTEE

HB 1430, as engrossed: Appropriations Committee (Rep. Svedjan, Chairman) recommends **DO PASS** (19 YEAS, 4 NAYS, 0 ABSENT AND NOT VOTING). Engrossed HB 1430 was placed on the Eleventh order on the calendar.

2003 SENATE HUMAN SERVICES

HB 1430

2003 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. **HB 1430**

Senate Human Services Committee

☐ Conference Committee

Hearing Date 03/17/03

Tape Number	Side A	Side B	Meter #
Tape 1	x		1000 to end
1		x	0 to end
2	x		0 to end
Committee Clerk Signature	Donna Kramer, Clerk		

Minutes:

Senator Judy Lee opens HB 1430. All senators present.

Representative Bill Devlin, sponsor of the bill, goes through bill (Testimony and amendment attached)

Cal Rolfson, Pharmaceutical Research and Manufacturers of America (Testimony and amendment attached)

Senator Lee: On page 8 of your testimony you said it requires authorization before the drug be granted unless there is a generic equivalence, what about other prescription drugs that might be a different prescription but might be more cost effective.

Rolfson: That is what prior authorization is about. cost is certainly a relevant issue..

Christopher Ward, Pharmaceutical Research and Manufacturers of America (Testimony attached)

Opposition

Al Stenehjem, Executive Director, Mental Health Association (Testimony attached)

Amendments from SB 2088 would be the same.

Senator Lee: Question why we should exempt anything? I so think it is okay to examine everything. I not saying that just one drug will treat every situation, but I feel that we shouldn't exempt the medications for mental health and not for other serious positions.

Stenehjem: On section 7 of the bill it gives us some comfort that the sponsor of the bill do recognize implications that just because you limit the prescription drug that there are going to try to give them the best prescription available.

Senator Lee: I think there should be a psychiatrist on the board.

Stenehjem: One of the amendments help on this issue and we would support the psychiatrist but we would rather be excluded.

Bruce Murry, *Neutral*, Protection and Advocacy Program

The 72 hour emergency is a saving feature. The Department understands that that is a hearing through the office of administrative hearings not an internal hearing and that it is to be given a recommended decision to the director who can either follow it or reverse it.

Senator Lee: It isn't the administrative hearing that concerns you but just being assured that we have in statue that it would be through the office of administrative hearing and not internal.

Murry: Or just an independent.

Opposition

David Zentner, Director of Medical Services for the Department of Human Services,

(Testimony attached) I fail to see why we can't use a process that is already in place. It bothers him that everyone is looking at the bottom dollar.

Senator Fischer: I would call my doctor to see the difference between 2 prescriptions before I decided on a generic or the real thing.

Zentner: The pharmacist or patient would be smart to call the physician and most likely the physician would say yes.

Dr. Brendan Joyce, Administrator of Pharmacy Services for the Department of Human Services (Testimony attached) We were not is 100% agreement with PhRMA. Max and use of edits of Rep. Devlin's amendment. (5.10 to 4.60) We wanted to do a maximum allowable cost list. If working with a pharmacy association we didn't necessarily agree. We gave them a $.50 dispensing fee increase as an incentive. Come January we saw we needed to save money. The net cost of the dispensing fee cost, the generic fee there was no dispensing fee. Monthly was $30,000 fee the savings was $200,000. taking this away would take away our negotiating fee. Against Section 13 dispensing fee we also went above and beyond the Section 11.

Section 12, generic rebates, we are going to be paying to much rebates so we re opposed to this.

Section 14, copayments for drugs. Back in '88 we were giving out equal #'s of generics than brand names. and the branches shot up and then we put a copy of brands and the generic and brand name snapped back together as abort the same. We feel getting the brand names is not necessary a lot of the time.

Senator Lee: Federal law says it is $1.00 for $25.00

Joyce: Yes

Senator Lee: $25 is the ceiling?

Joyce: Yes. We are hearing that doctor's are using a lot of samples. The problem is pharmaceutical reps sometimes switch to different samples. Page 8 and 9, I contacted other states

regarding this. Only 18 states responded, 17 had no allowance. One has but they have lots of pending appeals.

Senator Brown: Does prior authorization mean drug formula also?

Joyce: It does not mean formulary Formulary is a term that should be best used in private sectors in hospitals. There is an allowance for formulary's in SFR's for Medicaid. If they participate in the drug rebate agreement you have to allow coverage for any product. Every patient in Medicaid will have access, you may have to go through prior authorization but you would still have access.

Senator Brown: On the formulary you have access to anything is just depends on how much you pay for it.

Joyce: That is correct, we don't have ability to charge more.

Krista Andrews, Attorney for Department of Human Services (Testimony attached)

Galen Jorde, Executive Vice President, North Dakota Pharmaceutical Association (Testimony attached) We are not in full compliance with the MAC list. The MAC list does cost the pharmacies a lot. How do you know what is right for me if I have never tried the drug before.

Bruce Levi, ND Medical Association, I am not sure whether we are in support, neutral, or in opposition anymore. I think we are in support of the concept. We do need to look at the cost issue. The fiscal note shows the Department is not in favor of the bill. WE are willing to work with anyone to make bill work.

Closed HB 1430

Tape 3 (Meter 530 to end on Side A and 0-end on Side B)

Committee gets together with Dr. Joyce, Mr. Rolfson, Mr. Jorde, and other interested entities and just have a casual discussion on how they would all like to see this bill go. The entities decide

they are going to get together and come back to the committee with some compromises. the entities come back with what they agreed on and the committee will discuss at a further time.

2003 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. HB 1430

Senate Human Services Committee

❑ Conference Committee

Hearing Date March 19, 2003

Tape Number	Side A	Side B	Meter #
1		X	2415-end
2	X		1-4230

Committee Clerk Signature

Minutes:

Senator J. Lee opened the discussion on HB1430. All committee members are present. The amendments for 1430 have arrived.

Galen Jordre, Executive VP, ND Pharmaceutical Association (mtr #2620) - Presented a copy of e-mail he sent to stakeholders this morning. This should accurately show what the committee did yesterday. Requested help from Intern to convert diskette to Word.

Talisa (mtr #2800) - Commented that the amendment could be drafted at Legislative Council.

Senator J. Lee (mtr #2855) - Requested that copies be made for committee. At this time have not accepted anyone's amendments. How can we provide incentives for pharmacists to focus on generics

Mr. Jordre (mtr #3245) - Program with maximums works as a two-edged sword. Because Pharmacy's were making more margin on generics, which the SMACK program has taken a

considerable amount of that away. Do you make more money letting the brand name go through? Or do you promote the generic where you make less money with the SMACK? When the department expanded the MAC list, we did not have a lot of input. Found that dispensing fee would be increased, may have been better handled if at that time they would have moved all of that onto the generic side. One thing that has happened since going with the copayment, have seen a lot of shift, our generic rate has gone up about 4%. Pharmacists have done a lot of work with the recipients to let them know that there is a generic available for this, if not direct, may be in the same therapeutic class. We are at about 49% generics. If we can move that 1% that saves the department about $500,000.00 per year. Are maxed out within the program. Down to about 2-3% where prescription designates generic. Might see a few physicians that tend to do it all the time. Have talked about, if there is a generic equivalent available, then the prescription must be filled with the generic. Department will need prior authorization approved in order to do.

Mr. Jordre (mtr #3884) - Continued with an explanation of the amendments proposed yesterday. Went through each section and clarified the language and the intent.

Senator J. Lee (mtr #4146) - In discussion we talked about who the representative would be. Was changed at my request after the discussion. Should it be a pharmacist rather than a person from ND. If it is going to be in, feel it would be better.

Mr. Jordre (mtr #4220) - Continued with clarifying the language of the amendment.

Senator J. Lee (mtr #4282) - That would be because we want whoever the Pharmacy Administrator is to be able to be advisors and part of the committee. Feel it is appropriate that they accept the advice and counsel of the committee.

Mr. Jordre (mtr #4341) - Continued with clarifying language in section three of the amendment. Talked about a question on number 7, from the blue engrossed copy, feels that hits at the heart of what the DUR board should be. Clarified section four and the new wording. Also clarified each additional section of the amendment.

Senator Fischer (mtr #5845) - Adoption of rules at the end so it can be for the entire act not just a section. Addresses what parts of the bill can be, it empowers them. Is there something in here you don't like?

Mr. Jordre (mtr #5944) - Given the political realities, I think this provides a better streamlined thing/committee than we had before. Likes the idea of panels of specialists. If we can get this started with the department. Another thing the department will have to do.

Tape 2, Side A

Mr. Jordre (mtr #1) - Will go back to office and see if anything received to confirm 8 & 9 and the sunset language. Clean up and bring back clean copies.

Senator J. Lee (mtr #165) - Will recess meeting until after the sesseion.

Tape 2, Side A

Senator J. Lee - reopened discussion on HB1430.

Mr. Jordre (mtr #180) - Distributed copies of the **modified draft - proposed amendments to HB1420 (2nd draft).** Reviewed each section of the amendment for the committee and explained the intent.

Senator Polovitz (mtr #429) - Question, you are not going to have a problem getting people with that experience?

Mr. Jordre (mtr #448) - Virtually every pharmacist in the State works has familiarity with prior authorization drug programs. Definition would include pharmacists in hospitals who are used to working with formula's. Continued on with explanation of amendment at section two.

Senator Fischer (mtr #689) - You are currently happy with this? There is nothing in here you wouldn't like? Asked of Mr. Jordre and Mr. Rolfson.

Senator J. Lee (mtr #744) - The Medical Association is generally satisfied?

General members of the group answered in the affirmative that they are satisfied with the amendment.

Senator Fairfield (mtr #788) - Questions regarding section five, #3, isn't really a grandfather clause, but says benefits can not be denied until it on the preauthorized? Please clarify.

Mr. Jordre (mtr #851) - Clarified his understanding of the section, dealing with preauthorization's. Allows patient to continue on with therapy. Gave explanation of what happens when prescription expires and patient gets a renewal.

General discussion by several people at one time, regarding the clause, the grandfathering and the effect on the patient.

Senator J. Lee (mtr #1115) - The appeals process right now, is limited only to patients, but section 8 & 9 would also allow drug manufacturers to appeal. Part of the question is whether we

feel it is appropriate to allow drug manufacturers should be a part of the appeals process. If they are section 8 and 9 as amended would end up being what we have now in this draft.

Senator Fairfield (mtr #1157) - Could you direct me to where the patients grievance process is outlined in this?

Mr. Jordre (mtr #1168) - When we say "any party" in section six.

Several Senators talked about the different sections of the amendments and what the sections contained. Discussion about the availability of drugs to patients.

Dr. Brenden Joyce, Department of Human Services (mtr #1330) - Concerned about cuts in the appeals budget and opening up to more appeals by expanding who can appeal. If choice of bill as it stands or the **modified draft 2:00pm**, would chose the modified 2:00 PM draft. Talked about the appeals process and the effect that other states have felt.

Senator J. Lee (mtr #1442) - Other options, one would be to sunset that, or leave it out and see if we have a critical issue, which means it could be brought up two years from now and could be put back in there. Are doing something kind of new here, don't think it would hurt if we didn't put something in that we don't have now.

Dr. Joyce (mtr #1496) - Mr. Rolfson and myself discussed sun setting, and agreed with that in the previous bill. Agreed to sunset section 8 & 9 to allow for that, to make sure it is addressed in the next legislative session.

Cal Rolfson (mtr #1530) - Would rather have it in and sunset it, so you can see what it is like and test it, rather than not have it here and jeopardize the lack of ability to appeal.

Senator J. Lee (mtr #1550) - Trying to make this work, there is a budget issue.

Mr. Rolfson (mtr #1580) - We agreed to a sunset. That is fine with us. We also have a study section in there that can test whether or not there is a problem. We believe there is a need for it.

Senator J. Lee (mtr #1612) - I don't think there is a shortage in due process, but the appeal process, it is important for patients to appeal, but now we have opened it up to more than patients.

Senator Fischer (mtr #1631) - In other states that have prior authorization such as this, what are we looking at for appeals, what is the history?

Dr. Joyce (mtr #1672) - Surveyed state last week, received comments from 22-23 states that responded. Only one has appeals process beyond patients, specifically allowing pharmaceutical manufacturers to appeal the placement of a product. That was added to their language in 2001.

Mr. Rolfson (mtr #1770) - Understand that the appeals that have taken place involve the preferred drug list issues. Those are because there are federal law violations in those circumstances. Not aware of significant appeals where there has been, because of prior authorization. If appeal is inappropriate or frivolous, then sanctions should be applied.

Senator J. Lee (mtr #1845) - If majority of appeals have to do with preferred drug list, and we don't have a preferred drug list and we don't have accept appeals, it won't matter if that section isn't in there.

Senator Polovitz (mtr #1878) - Likes the idea of the sunset clause.

Senator Brown (mtr #1913) - Comment, feels this program is for the patients not necessarily for the Pharma or the Department. Why does Pharma feel the need to have an appeals process?

Senator J. Lee (mtr #1951) - Feels it is harder to get rid of something you've had than it is to put something in you didn't have. Thinks we have something really good to work with, whatever happens will end up in conference committee to make sure this is good.

Dr. Joyce (mtr #2017) - Remind to toss in the request for a fiscal note. Went over the amount that would be needed to make this work.

Senator Fischer (mtr #2143) - The issue of the appeal and the board member, feels there needs to be some sort of due process for the appeals procedure, is in favor of the sunset clause. How would it work to have the representative to be "ex-offico", be there but not have a vote.

Mr. Rolfson (mtr #2225) - Haven't spoken about that because had an "agreement" that it would be supported as submitted. Can talk to them about that, personal view is that they will be satisfied with that. Understand that "ex-offico" does not automatically mean no vote. Feels "ex-offico" means by virtue of the office. If going to be without vote, should clarify that.

Senator Fischer (mtr #2322) - As far as appeals procedure, we are not necessarily in full agreement, concerned with ability to work out differences. Feels all parties, including the patient, should have some sort of remedial process in place. I would be comfortable with a sunset. Feels parties should have mediator or arbitrator, something where they can state their case.

Mr. Jordre (mtr #2473) - When looking at that, do say that the Department shall develop rules for a grievance mechanism for interested parties. Would see that the Department could develop the rules, to take to board and have it covered in the board process. If recipients are aggrieved, recipients could then go on through the 2832 process. Proposed some changes to the amendment.

Senator J. Lee (mtr #2641) - Clarified, would have a grievance mechanism for other parties such as manufacturers, physician etc., but recipients would be able to have the full administrative (?).

Senator Fischer (mtr #2665) - That may be a partial solution. Need to understand that when rules are developed, all players will have an opportunity to participate. In the rulemaking process, Mr. Rolfson, you would have input into that. At the administrative rules meeting we are provided with all the objections to the rulemaking in writing, everybody has to agree. Feels there is a place in there for that mechanism, would that satisfy you in the rulemaking?

Mr. Rolfson (mtr #2786) - Input into rulemaking.

General discussion between Mr. Rolfson and Senator's regarding the amendment and the rulemaking.

Dr. Joyce (mtr #2883) - We just want a bill that allows us to do prior authorization. We would welcome any resolution. Are concerned about opening it up to more parties.

Senator J. Lee (mtr #3005) - Comment on the difficulties of the bill. Questioned if the language needs to changed at all.

Senator Fischer (mtr #3073) - Likes the idea of splitting the process. As long as rulemaking process will be fair.

Dr. Joyce (mtr #3093) - Commented on the bill the structure and the procedures that will be followed.

General discussion between several Senators to clarify their understanding of the bill and amendments.

Senator J. Lee (mtr #3294) - Commented, proposed some changes to the bill.

Senator Fischer moves to accept the amendment to section 6. Second by Senator Erbele.

Roll call vote 6 yea, 0 nay, 0 absent.

Senator Brown moves to accept the amendment on section 2. Second by Senator Polovitz.

Roll call vote 6 yea, 0 nay, 0 absent.

General discussion on a compromise.

Senator Brown moves to accept full amendment as proposed. Second by Senator Polovitz.

Roll call vote 6 yea, 0 nay, 0 absent.

Senator Brown moved a Do Pass as Amended and rerefer to Appropriations. Second by Senator Polovitz. Roll call vote 6 yea, 0 nay, 0 absent. Carrier is Senator J. Lee.

2003 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. HB 1430

Senate Human Services Committee

❑ Conference Committee

Hearing Date March 24, 2003

Tape Number	Side A	Side B	Meter #
1	X		4574 - 5880
Committee Clerk Signature	Donna Kramer, Clerk		

Minutes:

SENATOR JUDY LEE reopened the committee discussion on HB 1430 regarding prescription drugs. She passed out a revised amendment correcting two small errors. This amendment should have everything that we discussed last week, she said. Senator Lee stated that the committee had gone through the amendments last Friday afternoon and she then briefly went over the changes.

SENATOR FAIRFIELD: Housekeeping?

SENATOR LEE: Right.

SENATOR FAIRFIELD: Did we act on this last week?

SENATOR LEE: We did, but it needs to get to the floor. No action needs to be taken.

SENATOR BROWN: Said he had just been at a meeting and he did not feel we were going far enough with this. ... A preferred drug list is the way to go. ... We will see this bill again. ...

SENATOR LEE: I feel good about this although I would like to see the preferred drug list as well. But, at least we got a good start. We got everybody involved, hearing what the concerns were and coming up with some language we could all live with. ... At least we have got a start on trying to contain costs of prescription drugs under Medicaid but still being very sensitive to the needs of the patient. ... compromise bill ... (Meter # 5880)

30674.0201
Title.

Prepared by the Legislative Council staff for
Representative Svedjan and Senator J. Lee
March 12, 2003

PROPOSED AMENDMENTS TO ENGROSSED HOUSE BILL NO. 1430

Page 1, line 1, after "A BILL" replace the remainder of the bill with "for an Act to establish a drug use review program, preferred drug list, and drug prior authorization program within the department of human services; to provide for a legislative council study of use of pharmacy benefit management programs; and to declare an emergency.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. Definitions. As used in sections 1 through 7 of this Act, unless the context otherwise requires:

1. "Board" means the drug use review board.

2. "Department" means the department of human services.

3. "Drug use review" means a program as described in 42 U.S.C. 1396r-8(g)(2).

4. "Preferred drug list" means a listing of prescription products approved by the board as efficacious, safe, and cost-effective choices when prescribed for eligible medical assistance program recipients.

5. "Prior authorization" means a process requiring the prescriber or the dispenser to verify with the department or the department's contractor that proposed medical use of a particular drug for a medical assistance program recipient meets predetermined criteria for coverage by the medical assistance program.

SECTION 2. Drug use review board.

1. The board is established within the department for the implementation of a drug use review program.

2. The board consists of twelve members appointed by the executive director of the department. A majority of the members of the board must be physicians and pharmacists participating in the medical assistance program. Four or more members must have experience in developing or practicing under a preferred drug list. The membership of the board is:

   a. Six physicians licensed in this state and actively engaged in the practice of medicine, one of whom is a psychiatrist, and four of whom are chosen from a list of nominees provided by the North Dakota medical association; and

   b. Six pharmacists licensed in this state, actively engaged in the practice of pharmacy, four of whom are chosen from a list of nominees provided by the North Dakota pharmaceutical association.

3. Board members shall serve staggered three-year terms. Two physicians and two pharmacists must be initially appointed for two-year terms, and two physicians and two pharmacists must be initially appointed for one-year terms. A member may be reappointed for a period not to exceed three 3-year terms. A vacancy on the board must be filled for the balance of the

unexpired term from the appropriate board category as provided under subsection 2. The executive director of the department may replace a member of the board who fails to attend three consecutive meetings of the board without advance excuse or fails to perform the duties expected of a board member.

4. Board members shall select a chairman and a vice chairman on an annual basis from the board membership.

5. The board shall meet in person at least once every three months and may meet at other times by teleconference or electronically at the discretion of the chairman.

6. The department shall provide administrative services for the committee.

SECTION 3. Duties of the board. The board shall:

1. Comply with 42 U.S.C. 1396r-8(g)(3);

2. Advise and make recommendations regarding any rule proposed for adoption by the state health officer to implement the provisions of state and federal law related to drug use review;

3. Receive and consider information regarding the drug use review process which is provided by the department and by interested parties, including prescribers who treat significant numbers of patients under the department's medical assistance program;

opposed — 4. Review and recommend to the department any drugs to be included on a preferred drug list;

5. Review and recommend to the department any drugs to be included on prior authorization status;

opposed 6. Review at least once each year the status of a preferred drug list adopted by the department;

7. Review at least once each year the status of the list of drugs that have been placed on prior authorization; and

8. Review and approve the prior authorization process used by the department, including the process to accommodate the provision of a drug benefit in an emergency situation.

SECTION 4. Preferred drug list.

1. The department shall establish a pharmacy best practices and cost control program designed to reduce the cost to the medical assistance program of providing prescription drug benefits to medical assistance recipients while maintaining high quality in prescription drug therapies. The program must include a preferred list of covered prescription drugs which identifies preferred choices within therapeutic classes for particular diseases and conditions, including generic drug alternatives. The program may also include educational activities designed to reduce the cost of providing prescription drugs while maintaining high quality in prescription drug therapies.

Omit

2. The department may negotiate or accept additional rebates from drug manufacturers to supplement the rebates required by federal law governing the medical assistance program.

3. The department may implement all or a portion of the best practices and cost control program through a contract with a third party that has expertise in the management of a prescription drug benefit program. If the preferred drug list is developed through a contract with a third party, in developing the list the third party shall use the services of an appointed pharmacy and therapeutics committee composed of physicians and pharmacists practicing in this state. The drug use review board may modify the preferred drug list developed by the third party as the drug use review board deems appropriate.

SECTION 5. Prior authorization program.

1. The department shall use a prior authorization process to determine coverage of drug products when a medical assistance recipient's health care provider prescribes a drug that is not on the preferred drug list or that is not identified on the list as a preferred choice. The coverage of drug products under this process must be under the same terms as coverage for preferred choice drugs if:

   a. The preferred choice has not been effective, or with reasonable certainty is not expected to be effective, in treating the recipient's condition; or

   b. The preferred choice causes or is reasonably expected to cause adverse or harmful reactions to the health of the recipient.

2. For any drug placed on the prior authorization process in addition to the preferred drug list, the department shall provide medical and clinical criteria, cost information, and utilization data to the drug use review board for review and consideration. The board may consider department data and information from other sources to make a decision about placement of the drug on prior authorization.

3. The prior authorization process used by the department must be consistent with 42 U.S.C. 1396r-8(d).

4. To support a prior authorization request, the department shall consult with the board to develop a process that allows the prescriber to furnish any documentation required to obtain approval for a drug without interfering with patient care activities.

SECTION 6. Public notice - Applicability.

1. The department shall provide thirty days' public notice of all meetings of the board. Any interested party may attend a meeting of the board and provide information or recommendations related to the placement of a drug on the preferred drug list or inclusion of a drug in a prior authorization process.

2. The department shall post on the department's web site the most current and applicable list of preferred drugs and any drugs requiring prior authorization, together with any limits on coverage of these drugs.

3. The department may not discontinue the provision of prescription drug benefits being provided to medical assistance recipients before the effective date of this Act based solely on the subsequent placement or exclusion of the drugs on the department's preferred drug list or under the prior authorization program.

SECTION 7. Adoption of rules. The health officer may adopt rules to implement sections 1 through 6 of this Act.

SECTION 8. PHARMACY BENEFIT MANAGEMENT PROGRAM - LEGISLATIVE COUNCIL STUDY. The legislative council shall consider studying, during the 2003-04 interim, use of pharmacy benefit management programs. If the study is conducted by the legislative council, the legislative council shall report its findings and recommendations, together with any legislation required to implement the recommendations, to the fifty-ninth legislative assembly.

SECTION 9. EMERGENCY. This Act is declared to be an emergency measure."

Renumber accordingly

Date: 9-19-03
Roll Call Vote #: (1)

2003 SENATE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 1430

Senate Human Services Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken Move Amendment on Section 6

Motion Made By Sen. Fischer Seconded By Sen. Erbele

Senators	Yes	No	Senators	Yes	No
Senator Judy Lee - Chairman	✓				
Senator Richard Brown - V. Chair.	✓				
Senator Robert S. Erbele	✓				
Senator Tom Fischer	✓				
Senator April Fairfield	✓				
Senator Michael Polovitz	✓				

Total (Yes) 6 No 0

Absent _____

Floor Assignment _____

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

30674.0202
Title.

Prepared by the Legislative Council staff for
Senate Human Services
March 21, 2003

PROPOSED AMENDMENTS TO ENGROSSED HOUSE BILL NO. 1430

Page 1, line 1, after "A BILL" replace the remainder of the bill with "for an Act to establish a medical assistance drug use review program and drug prior authorization program within the department of human services; to provide for a legislative council study of medical assistance pharmacy benefit management; to provide an expiration date; and to declare an emergency.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. Definitions. As used in this Act, unless the context otherwise requires:

1. "Board" means the drug use review board.

2. "Compendium" means the American hospital formulary service drug information, United States pharmacopeia-drug information, the DRUGDEX information system, American medical association drug evaluations, or nonproprietary peer-reviewed medical literature.

3. "Department" means the department of human services.

4. "Drug use review" means a program as described in 42 U.S.C. 1396r-8(g)(2).

5. "Drug use review criteria" means standards approved by the board for use in determining whether use of a drug is likely to be medically appropriate, to be medically necessary, and not result in adverse medical outcomes.

6. "Prior authorization" means a process requiring the prescriber or the dispenser to verify with the department or the department's contractor that proposed medical use of a particular drug for a medical assistance program recipient meets predetermined criteria for coverage by the medical assistance program.

SECTION 2. Drug use review board.

1. The board is established within the department for the implementation of a drug use review program.

2. The board consists of fifteen members. The pharmacy administrator of the department and the medical consultant to the department are ex officio nonvoting board members who shall provide administrative services to the board. The executive director of the department shall appoint the remaining thirteen board members. A majority of the appointed members must be physicians and pharmacists participating in the medical assistance program. Four or more of the appointed members must have experience in developing or practicing under a preferred drug list. The appointed members of the board must be:

   a. Six physicians licensed in this state and actively engaged in the practice of medicine, one of whom is a psychiatrist, and four of whom are chosen from a list of nominees provided by the North Dakota medical association;

b. Six pharmacists licensed in this state and actively engaged in the practice of pharmacy, four of whom are chosen from a list of nominees provided by the North Dakota pharmaceutical association; and

c. One pharmacist or physician representing the pharmaceutical industry who is chosen from a list of nominees provided by the pharmaceutical research manufacturers of America.

3. Appointed board members shall serve staggered three-year terms. Two physicians and two pharmacists must be initially appointed for two-year terms, and two physicians and two pharmacists must be initially appointed for one-year terms. An appointed member may be reappointed for a period not to exceed three 3-year terms. A vacancy on the board must be filled for the balance of the unexpired term from the appropriate board category as provided under subsection 2. The executive director of the department may replace an appointed member of the board who fails to attend three consecutive meetings of the board without advance excuse or who fails to perform the duties expected of a board member. The pharmaceutical industry representative is a nonvoting board member.

4. Voting board members shall select a chairman and a vice chairman on an annual basis from the board's voting membership.

5. The board shall meet in person at least once every three months and may meet at other times by teleconference or electronically at the discretion of the chairman. A board member is entitled to receive from the department per diem compensation and reimbursement of expenses as determined by the department, except that no compensation under this section may be paid to any board member who receives compensation or salary as a state employee or official.

SECTION 3. Duties of the board. The board shall:

1. Cooperate with the department to create and implement a prospective and retrospective drug use review program for outpatient prescription drugs under the medical assistance program. This drug use review program must be based on a compendium and drug use review criteria and must comply with 42 U.S.C. 1396r-8(g)(3).

2. Advise and make recommendations regarding any rule proposed for adoption by the department to implement the provisions of state and federal law related to drug use review.

3. Receive and consider information regarding the drug use review process which is provided by the department and by interested parties, including prescribers who treat significant numbers of patients under the department's medical assistance program.

4. Review and recommend to the department any drugs to be included on prior authorization status.

5. Review no less than once each year the status of the list of drugs that have been placed on prior authorization.

6. Review and approve the prior authorization program process used by the department, including the process to accommodate the provision of a drug benefit in an emergency situation.

7. Propose remedial strategies to improve the quality of care and to promote effective use of medical assistance program funds or recipient expenditures.

SECTION 4. Prior authorization program.

1. The department shall develop and implement a prior authorization program that meets the requirements of 42 U.S.C. 1396r-8(d) to determine coverage of drug products when a medical assistance recipient's health care provider prescribes a drug that is identified as requiring prior authorization. Authorization must be granted for provision of the drug if:

   a. The drug not requiring prior authorization has not been effective, or with reasonable certainty is not expected to be effective, in treating the recipient's condition;

   b. The drug not requiring prior authorization causes or is reasonably expected to cause adverse or harmful reactions to the health of the recipient; or

   c. The drug is prescribed for a medically accepted use supported by a compendium or by approved product labeling unless there is a therapeutically equivalent drug that is available without prior authorization.

2. For any drug placed on the prior authorization program, the department shall provide medical and clinical criteria, cost information, and utilization data to the drug use review board for review and consideration. The board may consider department data and information from other sources to make a decision about placement of the drug on prior authorization.

3. The department may use contractors to collect and analyze the documentation required under this section and to facilitate the prior authorization program.

4. The department shall consult with the board in the course of adopting rules to implement the prior authorization program. The rules must:

   a. Establish policies and procedures necessary to implement the prior authorization program.

   b. Develop a process that allows prescribers to furnish documentation required to obtain approval for a drug without interfering with patient care activities.

   c. Allow the board to establish panels of physicians and pharmacists which provide expert guidance and recommendations to the board in considering specific drugs or therapeutic classes of drugs to be included in the prior authorization program.

SECTION 5. Public notice - Applicability.

1. The department shall provide thirty days' notice of all meetings of the board. The notice requirement is met if the department provides notice of the meeting on the department's web site and provides, by written or electronic means, individual notice to each person that has requested such notice. If the meeting agenda includes board consideration of a change to the prior authorization program, the department shall include in the notice a list of the affected drugs, and upon request the board shall provide background information. Any interested party may attend a meeting of the

board and provide information or recommendations related to the inclusion of a drug in a prior authorization program.

2. The department shall post on the department's web site:

   a. The most current and applicable list of drugs requiring prior authorization, together with any limits on coverage of these drugs.

   b. In downloadable format, forms necessary to complete prior authorization requests.

   c. Decisions regarding changes to the prior authorization program list. The department shall allow a period of no less than thirty days for public comment following posting on the web site.

   d. Meeting notice.

3. The department may not discontinue the provision of prescription drug benefits being provided to medical assistance recipients before the effective date of this Act based solely on the subsequent placement of the drug on the prior authorization program.

SECTION 6. Grievances. The department shall adopt rules for a grievance procedure by which an interested person may appeal a department decision to place a drug on prior authorization.

SECTION 7. Appeals. An individual who is aggrieved by the placement of a drug on prior authorization may appeal as authorized under chapter 28-32.

SECTION 8. Financial incentives prohibited. The department may not offer or pay, directly or indirectly, any material inducement, bonus, or other financial incentive to a participating provider based on the denial or delay of medically necessary and appropriate prescription drug therapy or based on a reduction in the proportion of recipients who receive prescription drug therapy under the medical assistance program.

SECTION 9. Maximum allowable costs and use of edits. To promote efficiency and savings in the department's service to eligible medical assistance program recipients, the department shall create and implement the broadest possible list of drugs that can be paid at the maximum allowable costs. To further promote efficiency and savings, the department shall maximize use of edit programs that pertain to payment of medical assistance program pharmaceutical claims. Upon request of a member of the legislative assembly, the department shall provide to that member a summary of edit programs available to the medical assistance program and a description of the department's progress in implementing the edit programs.

SECTION 10. Adoption of rules. The department shall adopt rules to implement sections 1 through 9 of this Act.

SECTION 11. MEDICAL ASSISTANCE PHARMACY BENEFIT MANAGEMENT - LEGISLATIVE COUNCIL STUDY. The legislative council shall consider studying, during the 2003-04 interim, the value of medical assistance program use of benefit purchasing pools, preferred drug lists, and other pharmacy benefit management concepts, including the fiscal impact of the appeals and grievance process on existing programs. If the study is conducted by the legislative council, the legislative council shall report its findings and recommendations, together with any legislation required to implement the recommendations, to the fifty-ninth legislative assembly.

SECTION 12. EXPIRATION DATE. Section 6 of this Act is effective through June 30, 2005, and after that date is ineffective.

SECTION 13. EMERGENCY. This Act is declared to be an emergency measure."

Renumber accordingly

Date: 03-19-03
Roll Call Vote #: 2

2003 SENATE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 1430

Senate Human Services Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number

Action Taken Move amendments on Section 2

Motion Made By Sen. Brown Seconded By Sen. Polovitz

Senators	Yes	No	Senators	Yes	No
Senator Judy Lee - Chairman	✓				
Senator Richard Brown - V. Chair.	✓				
Senator Robert S. Erbele	✓				
Senator Tom Fischer	✓				
Senator April Fairfield	✓				
Senator Michael Polovitz	✓				

Total (Yes) 6 No 0

Absent

Floor Assignment

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

30674.0203
Title.0300

Prepared by the Legislative Council staff for
Senate Human Services
March 21, 2003

3-25-03
1 of 5

PROPOSED AMENDMENTS TO ENGROSSED HOUSE BILL NO. 1430

Page 1, line 1, after "A BILL" replace the remainder of the bill with "for an Act to establish a medical assistance drug use review program and drug prior authorization program within the department of human services; to provide for a legislative council study of medical assistance pharmacy benefit management; to provide an expiration date; and to declare an emergency.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. Definitions. As used in this Act, unless the context otherwise requires:

1. "Board" means the drug use review board.
2. "Compendium" means the American hospital formulary service drug information, United States pharmacopeia-drug information, the DRUGDEX information system, American medical association drug evaluations, or nonproprietary peer-reviewed medical literature.
3. "Department" means the department of human services.
4. "Drug use review" means a program as described in 42 U.S.C. 1396r-8(g)(2).
5. "Drug use review criteria" means standards approved by the board for use in determining whether use of a drug is likely to be medically appropriate, to be medically necessary, and not result in adverse medical outcomes.
6. "Prior authorization" means a process requiring the prescriber or the dispenser to verify with the department or the department's contractor that proposed medical use of a particular drug for a medical assistance program recipient meets predetermined criteria for coverage by the medical assistance program.

SECTION 2. Drug use review board.

1. The board is established within the department for the implementation of a drug use review program.
2. The board consists of fifteen members. The pharmacy administrator of the department and the medical consultant to the department are ex officio nonvoting board members who shall provide administrative services to the board. The executive director of the department shall appoint the remaining thirteen board members. A majority of the appointed members must be physicians and pharmacists participating in the medical assistance program. Four or more of the appointed members must have experience with a drug use review process or have participated in programs in which prior authorization is used. The appointed members of the board must be:
   a. Six physicians licensed in this state and actively engaged in the practice of medicine, one of whom is a psychiatrist, and four of whom are chosen from a list of nominees provided by the North Dakota medical association;

b. Six pharmacists licensed in this state and actively engaged in the practice of pharmacy, four of whom are chosen from a list of nominees provided by the North Dakota pharmaceutical association; and

c. One pharmacist or physician representing the pharmaceutical industry who is chosen from a list of nominees provided by the pharmaceutical research manufacturers of America.

3. Appointed board members shall serve staggered three-year terms. Two physicians and two pharmacists must be initially appointed for two-year terms, and two physicians and two pharmacists must be initially appointed for one-year terms. An appointed member may be reappointed for a period not to exceed three 3-year terms. A vacancy on the board must be filled for the balance of the unexpired term from the appropriate board category as provided under subsection 2. The executive director of the department may replace an appointed member of the board who fails to attend three consecutive meetings of the board without advance excuse or who fails to perform the duties expected of a board member. The pharmaceutical industry representative is a nonvoting board member.

4. Voting board members shall select a chairman and a vice chairman on an annual basis from the board's voting membership.

5. The board shall meet in person at least once every three months and may meet at other times by teleconference or electronically at the discretion of the chairman. A board member is entitled to receive from the department per diem compensation and reimbursement of expenses as determined by the department, except that no compensation under this section may be paid to any board member who receives compensation or salary as a state employee or official.

SECTION 3. Duties of the board. The board shall:

1. Cooperate with the department to create and implement a prospective and retrospective drug use review program for outpatient prescription drugs under the medical assistance program. This drug use review program must be based on a compendium and drug use review criteria and must comply with 42 U.S.C. 1396r-8(g)(3).

2. Advise and make recommendations regarding any rule proposed for adoption by the department to implement the provisions of state and federal law related to drug use review.

3. Receive and consider information regarding the drug use review process which is provided by the department and by interested parties, including prescribers who treat significant numbers of patients under the department's medical assistance program.

4. Review and recommend to the department any drugs to be included on prior authorization status.

5. Review no less than once each year the status of the list of drugs that have been placed on prior authorization.

6. Review and approve the prior authorization program process used by the department, including the process to accommodate the provision of a drug benefit in an emergency situation.

3045

7. Propose remedial strategies to improve the quality of care and to promote effective use of medical assistance program funds or recipient expenditures.

SECTION 4. Prior authorization program.

1. The department shall develop and implement a prior authorization program that meets the requirements of 42 U.S.C. 1396r-8(d) to determine coverage of drug products when a medical assistance recipient's health care provider prescribes a drug that is identified as requiring prior authorization. Authorization must be granted for provision of the drug if:

   a. The drug not requiring prior authorization has not been effective, or with reasonable certainty is not expected to be effective, in treating the recipient's condition;

   b. The drug not requiring prior authorization causes or is reasonably expected to cause adverse or harmful reactions to the health of the recipient; or

   c. The drug is prescribed for a medically accepted use supported by a compendium or by approved product labeling unless there is a therapeutically equivalent drug that is available without prior authorization.

2. For any drug placed on the prior authorization program, the department shall provide medical and clinical criteria, cost information, and utilization data to the drug use review board for review and consideration. The board may consider department data and information from other sources to make a decision about placement of the drug on prior authorization.

3. The department may use contractors to collect and analyze the documentation required under this section and to facilitate the prior authorization program.

4. The department shall consult with the board in the course of adopting rules to implement the prior authorization program. The rules must:

   a. Establish policies and procedures necessary to implement the prior authorization program.

   b. Develop a process that allows prescribers to furnish documentation required to obtain approval for a drug without interfering with patient care activities.

   c. Allow the board to establish panels of physicians and pharmacists which provide expert guidance and recommendations to the board in considering specific drugs or therapeutic classes of drugs to be included in the prior authorization program.

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1. The department shall provide thirty days' notice of all meetings of the board. The notice requirement is met if the department provides notice of the meeting on the department's web site and provides, by written or electronic means, individual notice to each person that has requested such notice. If the meeting agenda includes board consideration of a change to the prior authorization program, the department shall include in the notice a list of the affected drugs, and upon request the board shall provide background information. Any interested party may attend a meeting of the

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SECTION 7. Appeals. A medical assistance recipient who is aggrieved by the placement of a drug on prior authorization may appeal as authorized under chapter 28-32.

SECTION 8. Financial incentives prohibited. The department may not offer or pay, directly or indirectly, any material inducement, bonus, or other financial incentive to a participating provider based on the denial or delay of medically necessary and appropriate prescription drug therapy or based on a reduction in the proportion of recipients who receive prescription drug therapy under the medical assistance program.

SECTION 9. Maximum allowable costs and use of edits. To promote efficiency and savings in the department's service to eligible medical assistance program recipients, the department shall create and implement the broadest possible list of drugs that can be paid at the maximum allowable costs. To further promote efficiency and savings, the department shall maximize use of edit programs that pertain to payment of medical assistance program pharmaceutical claims. Upon request of a member of the legislative assembly, the department shall provide to that member a summary of edit programs available to the medical assistance program and a description of the department's progress in implementing the edit programs.

SECTION 10. Adoption of rules. The department shall adopt rules to implement sections 1 through 9 of this Act.

SECTION 11. MEDICAL ASSISTANCE PHARMACY BENEFIT MANAGEMENT - LEGISLATIVE COUNCIL STUDY. The legislative council shall consider studying, during the 2003-04 interim, the value of medical assistance program use of benefit purchasing pools, preferred drug lists, and other pharmacy benefit management concepts, including the fiscal impact of the appeals and grievance process on existing programs. If the study is conducted by the legislative council, the legislative council shall report its findings and recommendations, together with any legislation required to implement the recommendations, to the fifty-ninth legislative assembly.

SECTION 12. EXPIRATION DATE. Section 6 of this Act is effective through June 30, 2005, and after that date is ineffective.

SECTION 13. EMERGENCY. This Act is declared to be an emergency measure."

Renumber accordingly

Date: 03-19-03
Roll Call Vote #: (3)

2003 SENATE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 1430

Senate Human Services Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken Move full amendment as amended

Motion Made By Sen. Brown Seconded By Sen. Polovitz

Senators	Yes	No	Senators	Yes	No
Senator Judy Lee - Chairman	✓				
Senator Richard Brown - V. Chair.	✓				
Senator Robert S. Erbele	✓				
Senator Tom Fischer	✓				
Senator April Fairfield	✓				
Senator Michael Polovitz	✓				

Total (Yes) 6 No 0

Absent _____

Floor Assignment _____

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

Date: 03-19-03
Roll Call Vote #: 4

2003 SENATE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 1430

Senate Human Services Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number

Action Taken Do Pass as Amended and rerefer.

Motion Made By Sen. Brown Seconded By Sen. Polovitz

Senators	Yes	No	Senators	Yes	No
Senator Judy Lee - Chairman	✓				
Senator Richard Brown - V. Chair.	✓				
Senator Robert S. Erbele	✓				
Senator Tom Fischer	✓				
Senator April Fairfield	✓				
Senator Michael Polovitz	✓				

Total (Yes) 6 No 0

Absent

Floor Assignment Sen. Lee

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

REPORT OF STANDING COMMITTEE

HB 1430, as engrossed: Human Services Committee (Sen. J. Lee, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (6 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). Engrossed HB 1430 was placed on the Sixth order on the calendar.

Page 1, line 1, after "A BILL" replace the remainder of the bill with "for an Act to establish a medical assistance drug use review program and drug prior authorization program within the department of human services; to provide for a legislative council study of medical assistance pharmacy benefit management; to provide an expiration date; and to declare an emergency.

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SECTION 13. EMERGENCY. This Act is declared to be an emergency measure."

Renumber accordingly

2003 SENATE APPROPRIATIONS

HB 1430

2003 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. HB 1430 & Vote

Senate Appropriations Committee

❑ Conference Committee

Hearing Date 3-31-03

Tape Number	Side A	Side B	Meter #
1		X	0-1800
Committee Clerk Signature Sandra Dawson			

Minutes: CHAIRMAN HOLMBERG opened the hearing to HB 1430. A bill for an Act to establish a drug utilization review program and drug prior to authorization program within the department of human services.

(Meter 14) SENATOR JUDY LEE testified on HB 1430. She introduced the changes in this bill. It is intended to provide some avenues for some cost containment on prescription drugs in Medicaid but also barring in mind that the patients best interest need to served as well. Note of point that she was very pleased with the collaborated work that was done by all of the parties that had an interest in this with very different views. She stated they would set up a Drug Review Board with 6 physicians and 6 pharmacists. One physician would be a psychiatrist because 40% of the cost of Medicaid prescriptions has to do with areas of mental illness. She talked about the web site and feels this has a good structure but also feels they need to get a good handle on the cost of prescriptions.

(Meter 274) SENATOR KRAUTER asked about the 15 members of 6 pharmacists, 6 physicians and...JUDY LEE added the pharmacy director, medical consultant and the drug manufacture representative are three non voting members of the Board in addition to the 6 physicians and 6 pharmacist.

(Meter 328) SENATOR THANE asked about the fiscal note dated 3/26/03. There is a notation about amendments proposed by the House human resources appropriation committee that an additional one million dollars in general funds that does not show up in this fiscal note would have to be added. Could you enlighten the committee on this amendment could be?

(Meter 379) SENATOR JUDY LEE stated that is the first she heard of that. CELESTE KUBASTA, OMB stated from last week when the House was proposing amendments for 2012, they moved the million dollars that was there out of the operating line and used it for optional services in Medicaid so the million dollars that was going to be used to implement this is no longer available. That is why the fiscal note was amended.

(Meter 450) SENATOR THANE wanted to know if that was going to survive? CELESTE stated the amendments from the House have not been adopted as of yet. They are just trying to keep people aware of the issues that might be coming up. SENATOR JUDY LEE stated that was the first she had heard that the House Appropriation committee did that. She is disappointed they do not see the value in this bill.

(Meter 493) SENATOR KILZER asked if this would just pertain to just outpatient prescriptions not inpatients, or nursing homes? SENATOR LEE answered it would pertain to all medications but there will be a process in place. Every single drug isn't going to have to be prior authorized. It would just be certain drugs that would have to be prior authorization list. It does not contain a

preferred drug list, that is something that was discussed but not acceptable. There were discussions with certain entities who wanted to have exclusions from drugs related to mental health. They wanted exclusions for oncology treatments, HIV and others and pretty soon we would have been exempting the majority of the drugs of high expenses are involved. It was the thought of the committee and the consensus of the parties working on it that there would be some work in getting this up to speed but there will be a benefit of having every prescription drug reviewed and standing on its own. The idea of making sure that the people getting the drugs that best serve them and there is also an evaluation of where or not that is the only appropriate prescription seemed right where a person is in a nursing home or an outpatient.

(Meter 624) SENATOR KILZER asked would it cover all then? SENATOR LEE stated that it would cover all medications covered under Medicaid.

(Meter 705) DAVE ZENTNER, Director of Medical Services for the Department of Human Services testified on HB 1430. See written testimony Exhibit 1.

(Meter 999) SENATOR MATHERN stated that this bill does not meet all of the expectations. One of them, as you stated, was the use of an already established list verses creating a committee to come up with a list. Are there other expectations that this bill does not meet ? And what are they? DAVE ZENTNER answered they had original wanted a preferred drug list with the possibility with looking at the issue of supplemental rebates but that is not contained in this bill. It would have been nice to have but they can still implement a prior authorization process without having a preferred drugs list and potential of supplemental rebates. There is some concern about the grievance process but it does give the department the opportunity to establish what that grievance process will be.

(Meter 1109) CHAIRMAN HOLMBERG stated for the committee to note that when the Senate had SB 2088, which is referred, the Senate had decided on a vote of 0-45 that they did not like the concept of SB 2088. They failed to pass that early on the session.

(Meter 1185) BRUCE MURRY, member of the ND Protection and Advocacy Project testified on HB 1430. See written testimony Exhibit 2. He spoke on the process of needing prescription on a short time basis.

(Meter 1300) HOWARD ANDERSON, Executive Director of the Board of Pharmacy testified on HB 1430. See written testimony Exhibit 3 from Galen Jorde. He agreed with SENATOR LEE'S description and summary of the bill and comes together with an opportunity to give the department some tools to get some handle on the drug costs in the budgets. He feels it is a step in the right directions.

(Meter 1434) SENATOR MATHERN asked his view of the 72 hour process that was removed? HOWARD ANDERSON answered that he was not the negotiator on that part, Galen Jorde was. He believed all parties are interested in the best care of the patient.

There was a motion of a DO PASS by SENATOR BOWMAN and seconded by SENATOR KRINGSTAD.

Discussion with SENATOR MATHERN was concerned about putting the money in this bill? He is concerned they might create a program but would have the inability to carry it out- without the general fund money in it.

(Meter 1666) CHAIRMAN HOLMBERG stated the conferees and the appropriate place for the funding is in the Human services department budget.

SENATOR MATHERN stated that they already have taken it out so he felt this was the vehicle to put it back in. CHAIRMAN HOLMBERG reminded him that it has not been voted on yet. To have this bill floating around with money in it, it has potential of causing problems later in the session. It is best to keep all the money in the budgets in case there would have to be any changes in the end with the approval of the Senate.

A voice roll call vote of 12 yeas, 1 nay and 1 absent with SENATOR JUDY LEE from Human Services to carry the bill on the floor.

(Meter 1876) CHAIRMAN HOLMBERG closed the hearing on HB 1430

Date:
Roll Call Vote #:

2003 SENATE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 1430

Senate Appropriations Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken do Pass

Motion Made By Bowman Seconded By Kringstad

Senators	Yes	No	Senators	Yes	No
Senator Holmberg, Chairman	✓				
Senator Bowman, Vice Chair	✓				
Senator Grindberg, Vice Chair					
Senator Andrist	✓				
Senator Christmann	✓				
Senator Kilzer	✓				
Senator Krauter	✓				
Senator Kringstad	✓				
Senator Lindaas	✓				
Senator Mathern		✓			
Senator Robinson	✓				
Senator Schobinger	✓				
Senator Tallackson	✓				
Senator Thane	✓				

Total (Yes) 12 No 1

Absent 1

Floor Assignment Human Services Judy Lee.

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

REPORT OF STANDING COMMITTEE (410)
March 31, 2003 11:21 a.m.

Module No: SR-57-6181
Carrier: J. Lee
Insert LC: . Title: .

REPORT OF STANDING COMMITTEE

HB 1430, as engrossed and amended: Appropriations Committee (Sen. Holmberg, Chairman) recommends **DO PASS** (12 YEAS, 1 NAY, 1 ABSENT AND NOT VOTING). Engrossed HB 1430, as amended, was placed on the Fourteenth order on the calendar.

2003 TESTIMONY

HB 1430

Good morning Chairman Price and members of the House Human Services Committee. For the record I am Rep. Bill Devlin, District 23 of Finley.

I appear before you today to ask your consideration of HB 1430 which will establish a drug utilization review board and drug prior authorization program within the department of Human Services.

Those of you that were in the House last session will probably find this bill to be a bit of a surprise as I have opposed Prior Authorization in the past. In fact the House rejected prior authorization 98-0 last session.

However there were a number of reasons for that vote including the fact that the Drug Utilization Review Board had not met as required by federal laws. We were also very concerned about establishing a prior authorization process, For the freshman the term means prior authorization means have the department or other agency decided whether a drug to can be provided to a medicaid patient in the state.

The process is supposed to find the lower cost drugs that provide the same benefits. Many of us have been frustrated by statements on how much prescription drug costs have went up in our medicaid program but we never heard the benefits explained. Less hospitalization, less surgery, less absence from work and many other benefits of the correct drug therapy should also be included in any cost/benefit analysis for prior authorization.

I want to make sure the doctor-patient relationship is protected. At no time should we ever allow a bean counter to determine which is the best drug for a person on public assistance or anywhere else.

If we are to ever have a full prior authorization program in the state, I think it is vital that we protect the clients, we fully evaluate all of the data, we respect the doctor-patient relationship and we work to insure that we provide the medicine needed to treat the condition of the patient and not the pharmaceutical product that is provided at the lowest costs.

The bill before you is model legislation that has been used as a basis for responding to these needs in other states. I expect there will be people here on both sides of this issue. I would hope we can take their ideas and input as we craft this legislation.

As the committee works through this issue I am confident that we can bring forth a piece of legislation that most if not all of us can support.

Thank you Chairman Price and members of the committee. There are expert witnesses in this room to answer the questions the committee might have but I am willing to try answer any questions you might have at this time.

TESTIMONY

BY
CALVIN N. ROLFSON
ON BEHALF OF
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
(PhRMA)
IN SUPPORT OF
HOUSE BILL NO. 1430

My name is Cal Rolfson, I am an attorney in Bismarck and am the legislative consultant for the Pharmaceutical Research and Manufacturers of America (PhRMA). I appear on PhRMA's behalf in support of House Bill No. 1430.

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading research-based pharmaceutical and biotechnology companies that are devoted to inventing medicines that allow patients to live longer, healthier and more productive lives. The industry invested more than 30 billion dollars in 2001 in discovering and developing new medicines. PhRMA companies are leading the way in the search for new cures for young and old alike.

PhRMA supports House Bill 1430. At the conclusion of my testimony I will offer several amendments that will speak to some of the objections that I am aware the Department of Human Services has to this Bill. We pledge to work with

the Department and this Committee in any recommended amendments that will help mutually approve this legislation and may respond to some of the issues or objections the Department of Human Services may have.

The purpose of my testimony will be to generally review the specifics of the Bill. Following my testimony, representatives of PhRMA will speak to the philosophical need for such legislation and why it will be beneficial to the State of North Dakota, the recipients of pharmaceuticals through the State's Medicaid program and to promote due process and fairness for all parties.

Currently there already exists a Drug Utilization Review (DUR) Board. The federal Medicaid laws under the Social Security Act require that state Medicaid agencies establish such boards. The general purpose of such boards is to review Medicaid drug utilization to determine drugs that are medically appropriate, medically necessary and have appropriate medical results for the population served by the state's Medicaid program.

However, the current DUR Board exists only because the Department of Human Services has followed through internally within that Department for the creation of such a board. It is PhRMA's belief that, as in other states, the Board should be established in state law and the legislative policy makers of this state should have a stake in determining the composition of the Board, its functions, and

its goals, as long as that determination complies with the federal Medicaid laws. It is our belief that House Bill 1430 does that and raises the responsibilities associated with this Board to the state policy level, rather than leaving it in the control of a particular department.

Section 1 of the Bill contains the definitions. I will be submitting amendments that will amend the definition of "Compendia" found beginning on Line 7 of Page 1 of the Bill, in which I will be recommending that the words "peer review medical literature" be deleted from that definition. According to representatives of the Department, that term was eliminated from the federal law under OBRA-93, and while we could still require that to be included in this Bill, PhRMA agrees with the Department to eliminate that definitional portion.

Drug Utilization review involves both retrospective and prospective review processes. As the definition states (pg. 1, line 13,, such reviews are designed to insure that drug utilization is medically appropriate, medically necessary, and not likely to have adverse medical results. The "drug utilization review criteria" that is used in the Bill means standards that are approved by the Board for use in determining whether a drug is likely to be appropriate, etc. It would be up to the appointed professionals on the board to determine and approve what those standards are.

"Prior authorization" as set out on Page 1, line 19, is defined as a process that requires a prescriber (physician or nurse practitioner, for example) to verify with the Department that a proposed drug meets predetermined criteria for coverage under the program. Historically, PhRMA has always opposed prior authorization as a concept. Prior authorization is effectively an intrusion by the government (in this case the Department) into the relationship between a patient and a provider. It is PhRMA's belief that physicians should be free to prescribe what they believe in their medical judgment is in the best interests of their patients, and that the government regulators should not interfere with that relationship. Those providers are on the front lines and are in the best positions to know exactly what is in the best interest of their patients. PhRMA recognizes, however, that because Medicaid is federal and state funded, and tax dollars are involved, it is appropriate that prior authorization be permitted, but that if it is permitted, prior authorization should carry with it appropriate due process for the benefit of the providers and patients that allows for a review of decisions by a board that is broad based and competent, rather than by individual decisions of department heads. That is not to say by any means that individuals in the Department are not conscientious and competent to make those decisions interfering with doctor/patient relationships. However, because those

relationships are so important, PhRMA believes that the involvement of broad based, statutorily established DUR board and pharmacy therapeutics committees is the least that the policy makers of this state should do to insure fairness to both taxpayers and recipients of Medicaid funding.

"Prospective drug utilization review" and "retrospective drug utilization review" are defined at the bottom of Page 1 and top of Page 2 of the Bill and essentially defines reviewing a drug and its program both before and historically reviewing drug utilization afterwards, to determine whether the drug has been over utilized, underutilized, whether appropriate use of generic drugs have been considered, whether duplication exists, and the like.

Section 2 of the Bill establishes the DUR board in state law. Originally the Bill, as you can see, calls for four physicians and five pharmacists. My amendment, after discussions with Department officials, suggests that we reduce the board for the sake of economy to three physicians and three pharmacists, and my amendment will suggest that change. In addition, there will be one person on the board that represents program beneficiaries, which could be a representative of the Mental Health Association, Long Term Care Association, or the like. In addition, one person representing the pharmaceutical industry would be included on the board. Currently there is no pharmaceutical representative on the board at

the department level and it seems appropriate that the industry that scientifically discovers, develops, sells and must stand behind their products, ought to be represented. Board members would serve staggering terms as noted at the bottom of Page 2 and there is a process for filling unexpired terms. A chairman and vice chairman are elected from among the board membership. This is a departure from the current voluntary board that exists within the Department, which is essentially chaired by the pharmaceutical director of the Department. The Bill states on Line 5, page 3, that it should meet at least monthly. In my discussions with Department officials, it was their sense that monthly was too often and it should be at least bimonthly. I agree with that and I have prepared an amendment accordingly.

The duties of the Drug Utilization Review Board are set out in Section 3. They are to advise and make recommendations regarding rules adopted by the Department. They are to oversee the implementation of drug utilization within the medical assistance program. They are to develop and apply drug utilization review criteria, both retrospectively and prospectively. They are to establish a process to periodically review and modify the drug utilization program of the Department and they are to provide the period of time for public comments during each board meeting. That documented public policy contact with the public is important in our view.

Section 4 of the Bill discusses the criteria regarding prospective and retrospective drug utilization review. The purpose is, again, to insure that drug utilization is medically appropriate, necessary and not adverse. The Department may contract with outside entities to review drug claims and profiles. The board is required to establish criteria whereby before a prescription is delivered, a review is conducted by a pharmacist at the point of sale to screen for potential drug therapy problems. The drug therapy prescribed by the provider, under this section, cannot be altered without either a new prescription or approval by the patient. In other words, the physician should be involved in making determinations that are appropriate, rather than the Department as an intervening third party.

Subsection 3 of Section 4 sets out the various criteria for screening, including duplication, contra-indications, drug allergies and the like. Subsection 4 of Section 4 sets out the retrospective drug utilization review and seeks to identify patterns of fraud, abuse, gross overuse or under use, and inappropriate or unnecessary care.

Section 5 of the Bill establishes a new Pharmacy and Therapeutics Committee (PAT committee). The PAT committee is created to implement prior authorization for outpatient prescription drugs under the Department's medical assistance program. The Bill currently has this committee at eleven members as

well. However, again, in consultation with the Department, their suggestion is that it should be reduced in size for the sake of economy, and we agree. The amendments I will propose establishes a PAT committee of three physicians, three pharmacists, one person representing medical assistance beneficiaries, and one person representing the pharmaceutical industry. Again, this committee would serve staggered terms, select a chair and vice-chair and meet at least bimonthly.

Section 6 sets out the duties of the PAT committee. As noted, they are to make recommendations regarding rules to be adopted by the Department regarding outpatient prescription drug prior authorization, they are to oversee and implement the drug prior authorization program, they are to establish a drug prior authorization review process, review their program at least annually, and modify the prior authorization process as necessary.

Under Section 7, the PAT committee would provide telephone or other electronic means by which to approve or deny within 24 hours a prior authorization request. It provides for emergency situations and a 72 hour supply of drugs in case the PAT committee or its staff is unavailable. It sets out the requirement that the authorization for the prescribed drug must be granted if the drug is medically accepted for the condition under which it is labeled unless there is a generic equivalent that is available without prior authorization. This, then,

supports the use of generic drugs where they are available.

This committee is intentionally separated from the DUR board because this committee specifically deals with prior authorization of particular drugs and is the working committee to recommend whether or not a drug should be prior authorized. While the Department believes that the function of this committee and the DUR board can be combined, they are separated intentionally because of the different functions of the two and to specifically separate the prior authorization function from the overview function. However, we are willing to work with the Department if there are ways to recommend to you that these committees be combined, as long as the separate functions and integrities of the two committees can be identified and not eroded.

The bottom half of Page 7 sets out guidelines to the PAT committee as to what drugs may or may not be recommended for replacement on prior authorization. For a drug to be placed on prior authorization, the committee must analyze the retrospective drug utilization review data, must consider the potential impact on patient care, as well as the fiscal impact, and the like. The criterial also includes the requirement that the committee must take into consideration total cost of treating the condition for which the drug is prescribed, including non-pharmaceutical costs. Examples might be that a newly developed drug might be

the preferred treatment for a condition that would otherwise require hospitalization at a significantly higher cost to the patient and the state. On Page 8 of the Bill, the PAT committee must provide at least thirty days advance notice of any public hearing before meetings are held to develop recommendations for drugs placed on prior authorization. This then allows the general public, including the patient and the patient's physician, to provide input into this process. The committee then makes formal recommendations to the Department which drugs should be placed on prior authorization. The Department either accepts or rejects the recommendation and determines whether a drug should be placed on prior authorization. The Department is given flexibility to consider any additional or clarifying information. Following the Department's decision to place a drug on prior authorization, its decision is published for public comment for at least thirty days.

Subsection 3 on Page 8, as I understand it, is strenuously objected to by the Department. That subsection states that a drug may not be recommended to require prior authorization by the committee or the Department if it has been approved or had any particular uses approved by the Federal Drug Administration under a priority review classification. We believe that if a drug has been approved for a particular use and a physician prescribes it, unless there are adverse

consequences to that, that decision between the patient and the physician are to be respected. In addition, there is a grievance mechanism established where interested parties may appeal in the administrative process any decision regarding prior authorization.

On Page 9, subsection 5, the Bill as printed requires the PAT committee to review the PA status of a drug every six months. The Department believes that is too frequent and that it should be annually. I have proposed amendments that will concur with the Department's recommendation that would require review no less than once each year.

Section 8 of the printed bill allows the Department to adopt rules to implement this act.

Additionally, the amendments that I have proposed add three due process protections for patients, their physicians, and the public.

A new Section 8 is proposed to give patients the authority to access the district court of North Dakota in cases where their healthcare provider prescribed medication and the Department has delayed that medication for more than 24 hours. It permits equitable relief if there is disregard of the prescribing physician's judgment that has no basis for such disregard and provider for damages and attorneys fees. The purpose of this proposed amendment is to give

rights to patients who are arbitrarily denied access to drug therapies that they medically need and that their physicians have prescribed. I am aware of no such new process language that currently exists in the Department.

The proposed Section 9 of the Bill allows the pharmaceutical manufacturer to appeal to the district court any decision of the Department to exclude a specific drug from a preferred drug list or a formulary if that decision is arbitrary, unfair, in violation of state law, or in violation of the federal law under the Federal Assistance Program and the Social Security Act that allows the state to establish a drug formulary if it meets certain federal statutory requirements.

Under Section 10 of the proposed amendments, the language suggested prohibits the Department from any conflicts of interest, bonus, or other financial incentives to a participating provider that is based upon denial or delay of a medically necessary drug to a patient. We are unaware of any situation where this has occurred, but to have that in the law seems like good public policy for the future.

With that perhaps overly verbose explanation of the Bill, I will certainly stand for questions but would suggest that the witnesses that will follow are more technically capable of discussing the philosophical importance of this legislation and can further support the details of the bill.

I thank you for the privilege of being able to appear before you. May I respond to questions?

Calvin N. Rolfson
Legislative Counsel
PhRMA
(Lobbyist No. 144)

PROPOSED AMENDMENTS TO HOUSE BILL NO. 1430

Page 1, line 1, remove the second "to"

Page 1, line 8, remove "peer review medical literature"

Page 2, line 14, replace "eleven" with "eight"

Page 2, line 15, replace "Four" with "Three"

Page 2, line 19, replace "Five" with "Three"

Page 2, line 29, replace "two" with "one"

Page 3, line 5, replace "monthly" with "bimonthly"

Page 5, line 18, replace "eleven" with "eight"

Page 5, line 20, replace "Five" with "Three"

Page 5, line 23, replace "Four" with "Three"

Page 5, line 30, replace "Two" with "One"

Page 6, line 21, replace "a semiannual" with "at least an annual"

Page 7, line 6, remove the comma and insert "or"

Page 7, line 7, remove "or peer review literature"

Page 9, line 3, after "department" insert "under Chapter 28-32"

Page 9, line 4, replace "every six" with "no less than once each year"

Page 9, line 5, remove "months"

Page 9, after line 8, insert:

"**SECTION 8. Denial or delay of care.** Notwithstanding any other provision of law, the district court shall be available to any individual whose health care has been denied or delayed more than 24 hours as a result of an administrative procedure implemented by the department or any of its contractors. Such administrative procedures include but are not limited to prior authorization,

formularies, preferred drug lists, step therapy or treatment protocols. The district court may provide equitable relief, as well as specific remedies, and may, where a department contractor has acted with disregard for the prescribing physicians' judgment regarding medically necessary care for the individual, provide for exemplary damages. Where the district court finds against the department, the district court shall award attorney fees and court costs, whether or not it awards specific relief or damages to the plaintiff."

"**SECTION 9. Preferred drug list procedures.** Any pharmaceutical manufacturer may appeal to the district court of this state a decision of the department or its contractor to exclude a specific drug from a preferred drug list or formulary on the grounds that the decision is arbitrary, unfair, a violation of state law, or in the case of a single source drug, on the grounds that the exclusion is not consistent with the provisions of 42 U.S.C. 1396r-8(d)(4)."

"**SECTION 10. Financial incentives prohibited.** The department may not offer or pay directly or indirectly any material inducement, bonus, or other financial incentive to a participating provider based on the denial or delay of medically necessary and appropriate prescription drug therapy, or a reduction in the proportion of beneficiaries who receive prescription drug therapy under the Medicaid program."

Page 9, line 9, Replace "**SECTION 8**" with "**SECTION 11**"

Renumber accordingly.

TESTIMONY BEFORE THE HOUSE HUMAN SERVICES COMMITTEE
REGARDING HOUSE BILL 1430
JANUARY 29, 2003

Chairman Price, members of the committee, I am David Zentner, Director of Medical Services for the Department of Human Services. I appear to provide information regarding the fiscal note on this bill.

This bill would significantly decrease the cost savings that have been budgeted for the coming biennium that was anticipated in SB 2088 as introduced by the Department. The Department had planned on saving $1 million in general funds through prior authorization. With HB 1430, the administration of the prior authorization process would change significantly from what was planned. First, I will outline what the Department had planned, and then I will explain the impact of HB 1430.

The Department, with SB 2088, intends to utilize the existing DUR Board (which is mandated by SSA section 1903(l)(10)(B)) to review an existing private industry drug formulary (e.g. the North Dakota Public Employees Retirement System – PERS drug formulary through Blue Cross Blue Shield of North Dakota) and utilize that formulary to initiate a prior authorization system for North Dakota Medicaid. This partnership with private industry would build on private industry solutions for rising healthcare costs. Also, the existing familiarity within North Dakota's healthcare system will increase compliance and minimize inconvenience for the patients and the healthcare professionals. Since the private industry drug formularies are developed first with safety and efficacy, and lastly with cost, they can effectively be used for the Medicaid population and would correlate very closely with a list generated by the committee outlined in this bill.

The impact of HB 1430 would be significant. The requirement to independently develop a list of products for prior authorization will completely alter the process

on which the cost savings were estimated. There are three steps for a prior authorization program implemented with this bill. First, the list would have to be developed. Second, the education of the providers and recipients would have to be done. Third, implementation and the subsequent savings would occur. With SB 2088, the first two steps are essentially completed.

Given the large task of developing this list from scratch, the review process would likely be limited to one drug class at a time. This delay in implementation would delay our savings. Though difficult to estimate, conservatively we would say that the delay for implementation of any portion of prior authorization would take nine months and the quantity of products would be limited by the progress of the committees. The Department estimates that the delay would require an increase in the 2003-05 Medical appropriations of $1.6 million, of which about $439,000 are general funds.

The burden of becoming familiar with yet another process within the healthcare system in North Dakota would impact our provider network. Discussions have made it evident that there is a desire for North Dakota Medicaid to utilize private industry. This bill would unfortunately provide yet another level of processes and potentially impact the providers' satisfaction with Medicaid more than a prior authorization program that is tied with existing industry practice.

Regarding the formation of an additional committee, our past experience predicts that it will be difficult to recruit and retain professionals for the committees. Past searches for members has been frustrating for both the Department and the respective association (Medical and Pharmacy). The difficulty can be attributed mainly to the time and travel commitments that must be made. It is very doubtful that two committees could reach full membership, retain the membership, and have appropriate attendance.

Absent from this bill is an allowance for the Department to negotiate supplemental rebates. Recently, Minnesota, Washington, and West Virginia have joined California, Michigan, and Florida in signing supplemental rebate agreements. It appears that this may become a more common practice for state Medicaid programs and it is specifically allowed by Centers for Medicare & Medicaid Services (see attachment). Currently, the Department has no plans on collecting supplemental rebates, but given the increases in healthcare costs, it may be necessary before the close of the next biennium.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations

SMDL #02-014

September 18, 2002

Dear State Medicaid Director:

This letter is to clarify issues related to supplemental drug rebate agreements and prior authorization of Medicaid covered outpatient drugs. A number of States have sought CMS approval of supplemental drug rebate agreements between a State and drug manufacturers with respect to Medicaid covered outpatient prescription drugs. Some of these States subject covered outpatient drugs to prior authorization as a means of encouraging drug manufacturers to enter into separate or supplemental rebate agreements for covered drugs purchased by Medicaid recipients.

Medicaid Supplemental Drug Rebate Agreements

States may enter separate or supplemental drug rebate agreements as long as such agreements achieve drug rebates equal to or greater than the drug rebates set forth in the Secretary's national rebate agreement with drug manufacturers, which is published at 56 F.R. 7049 (1991). The drug rebate statute, at section 1927(a)(1) of the Social Security Act (Act), provides that "the Secretary may authorize a State to enter directly into agreements with a manufacturer." Also, section 1927(a)(4) of the Act provides that any drug rebate agreement between a State and drug manufacturers and in effect on November 5, 1990, may constitute a rebate agreement in compliance with the statute if CMS determines that any such agreement "provides for rebates that are at least as large as the rebates otherwise required under this section." CMS accordingly believes that Congress intended that States that seek CMS approval under section 1927(a)(1) to enter directly into agreements with manufacturers must ensure that any such agreement will achieve drug rebates that are at least equal to the rebates set forth in the Secretary's rebate agreements with manufacturers.

We remind States that supplemental drug rebates must be "considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance" as required by section 1927(b)(1)(B) of the Act.

Prior Authorization Requirements Related to Supplemental Rebate Agreements

States may subject covered outpatient prescription drugs to prior authorization as a means of encouraging drug manufacturers to enter into separate or supplemental rebate agreements for covered drugs purchased by Medicaid recipients. Section 1927(d)(1)(A) of the Act permits States to subject any covered outpatient drug to a requirement of prior authorization as long as the State complies with the requirements set forth in section 1927(d)(5). A prior authorization program used to negotiate drug discounts for the Medicaid program is consistent with those provisions as well as the paramount purpose of the drug rebate provisions which is to reduce the costs to the Medicaid program for prescription drugs.

A prior authorization program does not need to comply with the requirements for restrictive formularies. The formulary provisions of section 1927(d)(4) were added to the drug rebate provisions in 1993 to give States additional authority to implement restrictive formularies. Congress passed paragraph (d)(4) expressly stating that "[a] prior authorization program established by a State under [section 1927(d)(5)] is not a formulary subject to the requirements of this paragraph."* Furthermore, since concerns related to drug use, monitoring, waste, fraud or abuse are separately and independently addressed by the procedures authorized by sections 1927(d)(6) and 1927(g), a prior authorization program need not be limited to those concerns. The Act affords States broad authority and flexibility to implement a prior authorization program in order to secure cost savings for the Medicaid program.

The operation of a prior authorization program used to negotiate drug discounts for the Medicaid population is a significant component of a State plan. We would therefore expect that a State that does not currently have an approved prior authorization State plan amendment, and that seeks to undertake such a program, would submit to CMS for review a State plan amendment incorporating the program's prior authorization requirements, while simultaneously seeking CMS's authorization for its proposed separate or supplemental rebate agreement. A State that has an approved State plan amendment governing prior authorization requirements, but which seeks for the first time to use its prior authorization authority to negotiate drug discounts for the Medicaid program, must amend its State plan to refer to the separate or supplemental rebate agreement and submit its proposed rebate agreement for CMS authorization.

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* Of course, the formulary provisions of section 1927(d)(4) continue to apply if a State chooses to make judgments about the therapeutic advantages of a drug excluded from a formulary, and the State plan must permit coverage of any such drug pursuant to a prior authorization program that complies with section 1927(d)(5).

Non-Medicaid Supplemental Rebates and Medicaid Prior Authorization

A number of States secure prescription drug benefits, rebates, or discounts for non-Medicaid populations by linking such benefits to a Medicaid prior authorization program. The Act does not preclude States from negotiating prices, including manufacturer discounts and rebates for non-Medicaid drug purchases. However, the establishment of a prior authorization program for Medicaid covered drugs to secure drug benefits, rebates, or discounts for non-Medicaid populations is a significant component of a State plan and we would therefore expect that a State would submit such a program for CMS review under the State plan process. Similarly, the use of any pre-existing prior authorization program to secure drug benefits, rebates, or discounts for non-Medicaid populations would constitute a "[m]aterial change[] in State law, . . . policy, or in the State's operation of the Medicaid program" and we would therefore expect that a State would submit a plan amendment to CMS for review. (See section 430.12(c)(1)(ii) of the regulations.) In submitting such a State plan amendment, the State should be prepared to demonstrate through appropriate evidence that the prior authorization program will further the goals and objectives of the Medicaid program. A State could make such a demonstration by submitting appropriate evidence that its prior authorization requirement is designed to increase the efficiency and economy of the Medicaid program. A State could demonstrate that its prior authorization requirement furthers Medicaid goals and objectives by submitting appropriate evidence that the requirement sufficiently benefits the Medicaid population as a whole by making available to financially needy individuals medically necessary prescription drugs, thereby improving their health status and making it less likely that they will become Medicaid eligible.

If you have any questions regarding CMS policy relating to supplemental drug rebate agreements or prior authorization programs, please direct them to Larry Reed at (410) 786-3325 or Deirdre Duzor at (410) 786-4626.

Sincerely,

/s/

Dennis G. Smith
Director

cc:

CMS Regional Administrators

CMS Associate Regional Administrators
for Medicaid and State Operations

Lee Partridge
Director, Health Policy Unit
American Public Human Services Association

Joy Wilson
Director, Health Committee
National Conference of State Legislatures

Matt Salo
Director of Health Legislation
National Governors Association

Brent Ewig
Senior Director, Access Policy
Association of State and Territorial Health Officials

Trudi Matthews
Senior Health Policy Analyst
Council of State Governments

Jim Frogue
Acting Director, Health and Human Services Task Force
American Legislative Exchange Council

North Dakota Medicaid Program:

Prior Authorization of Prescription Drugs

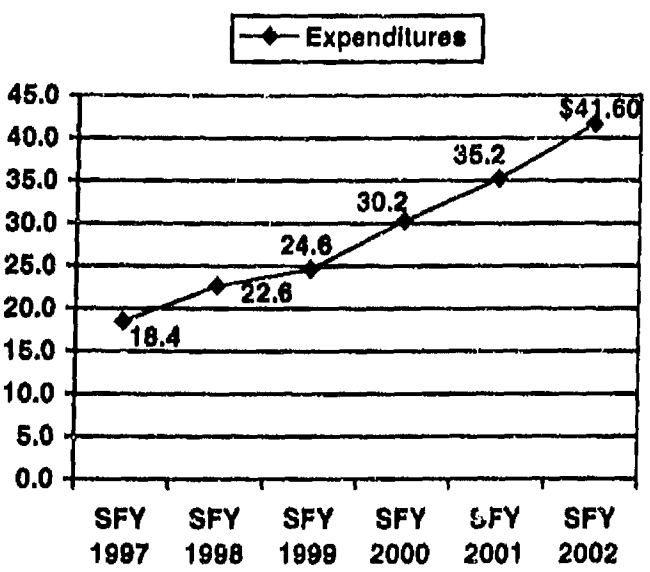
Background:

Under federal law, drug companies must provide states with a Medicaid rebate. Even with the rebates, the North Dakota Medicaid Program's expenditures for prescription drugs have risen 126 percent since 1997.

Faced with rising drug prices and revenue shortfalls, many states are exploring ways to curb increases in their Medicaid prescription drug budgets. Their goal is to preserve vital health benefits for low-income and older residents without raising taxes.

During the first year of the 2001-2003 biennium, the North Dakota Department of Human Services spent $41.6 million on prescriptions through Medicaid. Increases in this budget area, if left unchecked, may force reductions in other health services provided to low-income, vulnerable state residents. A prior authorization process similar to the private sector, could address this.

N.D. Medicaid Program Prescription Drug Expenditures In Millions of Dollars



What is the state's Medicaid Program doing to curb rising drug costs?

The North Dakota Department of Human Services is working to contain Medicaid prescription drug costs. The department has already implemented Maximum Allowable Cost (MAC) for generically available drugs. This means that Medicaid has started using a payment schedule that is comparable to what private insurance companies use in the state. Pharmacies will be paid more appropriately than under the old payment system, which often resulted in the taxpayer-funded Medicaid program paying more for identical prescriptions than health insurers in North Dakota. The department is also continuing its physician education efforts.

In addition to these initiatives, Governor Hoeven's Administration is proposing to expand the Medicaid Program's prior authorization requirements to include some prescription drugs (Senate Bill 2088). The federal Department of Health and Human Services must approve this change in the state Medicaid Program.

What is prior authorization?

Prior authorization is used by public and private health insurance to ensure that covered individuals use services appropriately and in the most cost effective manner. Prior authorization means that people must seek approval from their insurer (or Medicaid) for certain services before obtaining those services. Over 45 states use prior authorization in their Medicaid pharmacy programs.

The North Dakota Medicaid Program already requires prior authorization for some medical services. For example, people covered by Medicaid who seek nursing home care are screened first to assure that their medical needs warrant skilled nursing care. The state also requires Medicaid recipients to obtain prior authorization before receiving orthodontics for

OVER →

children, durable medical equipment and supplies costing over $200, non-emergency out-of-state services, and a few other services. The proposal to require prior authorization for prescriptions would apply to some prescription drugs. Prior authorization may be required for prescription drugs when there is evidence that other products may produce the same desired effect for less cost.

How would prior authorization affect people?

To be approved by the federal government, state Medicaid programs must safeguard consumers and ensure that people can obtain medically necessary drugs. In the 46 states that have prior authorization for prescriptions, people continue to have access to appropriate medications.

The state is proposing to adopt portions of the prior authorization policies and processes now used by Blue Cross Blue Shield of North Dakota (BCBS), which are based on drug safety, drug effectiveness, and lastly on cost. Any prior authorization requirements would be implemented over time. There is a possibility that people already receiving certain medications would be "grandfathered in," if their medication later required prior authorization. The prior authorization would apply to new Medicaid prescriptions.

What does prior authorization mean for providers?

If a physician and patient believe that a prescription included under a prior authorization requirement would be the most appropriate treatment, they would simply seek prior authorization so that Medicaid would cover the cost.

Because the department is proposing to adopt portions of the existing prior authorization process used by BCBS, the largest health insurer in North Dakota, physicians and other providers would be dealing with familiar standards and processes.

Prepared January 2003

How would North Dakota benefit by adopting prior authorization?

The fiscal environment and the current shortfall in the state's Medicaid budget have created renewed interest in strategies to curb Medicaid costs, while sustaining this healthcare safety net for low-income children, as well as low-income adults who are mainly elderly or disabled. By adopting this private sector practice, the state Medicaid Program could assure appropriate services to Medicaid clients while saving taxpayers $3.9 million per biennium ($1 million in state general funds).

State residents would benefit because the cost savings to this part of the Medicaid budget could reduce the need to trim or limit other vital health services provided by Medicaid.

Prior authorization seems to promote generic drugs. Are they as effective as brand-name drugs?

Physicians and pharmacists are in the best position to identify the unique health care needs of patients and to recommend appropriate and effective treatment. Direct-to-consumer marketing of brand-name drugs may be coloring public perception of generics, as well as certain brand-name products. Generic drugs are safe, effective, and Food and Drug Administration (FDA) approved. Generic drugs go through a rigorous, multi-step approval process required by the FDA. From quality and performance to manufacturing and labeling, everything must meet FDA standards. Adverse side effects sometimes cause new drugs to be pulled from the market. However generic drugs have a record of effectiveness that dates back to when the drugs were patent-protected.

Prior authorization may encourage the use of generic drugs, but it does not prevent people from receiving brand-name medications prescribed by their physicians. They simply follow the pre-approval process modeled after private insurers in North Dakota.

N.D. Department of Human Services
Medical Services Division
600 E Boulevard Avenue, Dept 325
Bismarck ND 58505-0250, (701) 328-2321
David Zentner, Director

Healthy SeniorsR_X

Providing affordable prescription drug coverage for North Dakota seniors

What is *Healthy SeniorsRx?*

Healthy SeniorsRx is a new program proposed by Governor John Hoeven in the 2003 Executive Budget to provide prescription drug assistance to North Dakota citizens age 65 and older who meet income criteria.

Modeled after a plan Blue Cross Blue Shield of North Dakota offers to its insured, *Healthy SeniorsRx* is a prescription drug plan for seniors that will save eligible individuals up to 66 percent of the cost of generic drugs and from 35 percent to 50 percent of the cost of brand name prescription drugs.

Who qualifies for *Healthy SeniorsRx*?

North Dakotans who are 65 years of age or older AND

- Have gross incomes up to 210 percent of the federal poverty level or less,
  Individuals: up to $18,620/year
  Couples: up to $25,000/year
  AND,
- Do not qualify for the North Dakota Medicaid Program, AND
- Do not have other pharmaceutical benefits.
  NOTE: Eligibility will be delayed for one year if a person elects to close his or her current benefit.

How many people will qualify?

At least 20,000 seniors could be eligible to save, on average, between one-third and two-thirds of the cost of prescription drugs.

Of the eligible individuals, officials expect approximately 15,000 seniors to enroll in the *Healthy SeniorsRx* prescription drug coverage program.

How do seniors apply?

- Applicants will be screened first for possible Medicaid eligibility.
- Other program details are still being worked out.

How much will the program cost?

Projected costs for the 2003-2005 Biennium:

General Fund:	$3,373,735
Federal Match:	$6,911,734
Total:	$10,285,469

When will *Healthy SeniorsRx* coverage be available?

While Governor Hoeven hopes seniors can begin applying for the prescription drug coverage program in 2003, several things have to happen before the program is launched.

- The Department of Human Services must apply for a Medicaid Section 1115 Waiver, which must be approved by the federal Centers for Medicare and Medicaid Services (CMS).
- The necessary funds must be appropriated.
- Once approval is obtained from CMS and funds are appropriated, the Department of Human Services must develop a computer system to determine eligibility.
- Other program details will have to be worked out with agencies and organizations involved in providing the service.

OVER →

How will the program work?

- Eligible seniors will receive a *Healthy SeniorsRx* ID card to present to pharmacists, who would provide discounts. The state would reimburse pharmacies for the discounts.
- Co-payments and co-insurance would be imposed for prescription drugs in order to increase the available funds for the program. Co-payments and co-insurance would mirror other private sector prescription benefit plans.

Prescription Type	Co-payment /Co-insurance
Generic drug	$6 + 20%
Brand name drug on preferred drug list	$15 + 50%
Brand name drugs, not on preferred drug list	$30 + 70%

- The program will utilize a preferred drug list to promote the use of cost-effective products in order to meet the needs of a larger number of enrollees.
- Drug manufacturers set the eligibility policies for their prescription assistance programs, which benefit the uninsured or underinsured. An individual participating in a manufacturer's program who becomes eligible for *Healthy SeniorsRx* may want to contact the manufacturer to determine what impact, if any, this will have on his or her participation in the manufacturer's program.

How will payments be handled?

A Pharmacy Benefits Manager (PBM) under contract with the state may handle the payment process.

- The use of a PBM would mirror more closely what private third-party payers such as Blue Cross/Blue Shield use to process and pay their pharmacy claims.
- Transfer of eligibility data to the PBM would occur weekly or monthly.

What could Medicaid prescription drug rebates mean to N.D.?

If North Dakota obtains federal approval of the Medicaid waiver and is able to implement to program, *Healthy SeniorsRx* would generate about $6.9 million in rebates on prescription drugs during the 2003-2005 Biennium.

How will pharmacy providers be paid?

- The payment process will be modeled after current private industry payment structures.
- Payment to pharmacies will be based on current PBM Networks (BCBS of North Dakota Network for in-state pharmacies and Prime National Network for out-of-state pharmacies).

Summary of Projected Biennial Costs Associated With *Healthy SeniorsRx* Program:

	Gross	State Share
Expenditures		
Eligibility file programming	$232,348	$116,174
Eligibility determination by counties ($20/elig)	$317,000	$158,500
ID Card Production ($2/pkt)	$31,700	$7,925
Claims Processing ($0.50/claim)	$360,000	$90,000
Outreach (brochures, media, etc.)	$40,000	$20,000
Prescription Drugs (pre-rebate)	$16,252,265	$5,205,666
Revenue		
Drug Rebates	+$6,947,844	+$2,224,530
TOTAL	**$10,285,469**	**$3,373,735**

Contacts:

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Prepared January 2003
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Cal Koltson

PROPOSED AMENDMENTS TO HOUSE BILL NO. 1430

Page 1, line 1, remove the second "to"

Page 1, line 8, remove "peer review medical literature"

Page 2, line 14, replace "eleven" with "eighteen"

Page 2, line 16, replace "Four" with "Six"

Page 2, line 17, after "medicine" insert ", four of whom are"

Page 2, line 19, replace "Five pharmacist" with "Six pharmacists"

Page 2, line 20, replace "and" with "four of whom are"

Page 2, line 22, replace "One person" with "Two persons" and replace "is a resident" with "are residents"

Page 2, line 23, remove "and"

Page 2, line 24, replace "One person" with "Two persons"

Page 2, line 26, replace the period with a semicolon

Page 2, after line 26, insert:

"e. The pharmacy administrator of the department; and
f. The medical consultant to the department."

Page 2, line 27, replace "One physician, one" with "Two physicians, two"

Page 2, line 28, replace "pharmacist" with "pharmacists" and replace "the" with "one"

Page 2, line 29, replace "one physician" with "two physicians" and replace "the" with "one"

Page 3, line 1, remove "nominee lists"

Page 3, line 5, replace "monthly" with "bimonthly"

Page 3, line 7, replace "The" with "The duties of the board shall be consistent with the provisions of 42 U.S.C. §1396(r)(8)(g)(3). In addition, the"

Page 3, line 16, replace "part" with "act"

Page 5, after "program." insert "Members appointed to the committee may be appointed from among the board and may also serve as members of the board."

Page 5, line 20, replace "Five" with "Three" and after "physicians" insert "of different medical specialties."

Page 5, line 21, after "medicine" insert "who may be" and after "from" insert "among physician members of the board or from"

Page 5, line 23, replace "Four" with "Three"

Page 5, line 24, after the comma insert "who may be" and after "from" insert "among the pharmacist members of the board or from"

Page 5, line 30, replace "Board" with "Committee" and replace "Two physicians" with "One physician"

Page 6, line 21, replace "a semiannual" with "at least an annual"

Page 6, line 28, after "the" insert "completed"

Page 7, line 6, remove the comma and insert "or"

Page 7, line 7, remove "or peer review literature"

Page 7, after the period, insert "the department may contract with third parties to collect and analyze the documentation required by this subdivision."

Page 9, line 3, after "department" insert "under chapter 28-32"

Page 9, line 4, replace "every six" with "no less than once each year"

Page 9, line 5, remove "months"

Page 9, after line 8, insert:

"**SECTION 8. Denial or delay of care.** Notwithstanding any other provision of law, the district court shall be available to any individual whose health care has been denied or delayed more than 24 hours as a result of an administrative procedure implemented by the department or any of its contractors. Such administrative procedures include but are not limited to prior authorization,

formularies, preferred drug lists, step therapy or treatment protocols. The district court may provide equitable relief, as well as specific remedies, and may, where a department contractor has acted with disregard for the prescribing physicians' judgment regarding medically necessary care for the individual, provide for exemplary damages. Where the district court finds against the department, the district court shall award reasonable attorney fees and court costs, whether or not it awards specific relief or damages to the plaintiff."

"**SECTION 9. Preferred drug list procedures.** Any pharmaceutical manufacturer may appeal to the district court of this state a decision of the department or its contractor to exclude a specific drug from a preferred drug list or formulary on the grounds that the decision is arbitrary, unfair, a violation of state law, or in the case of a single source drug, on the grounds that the exclusion is not consistent with the provisions of 42 U.S.C. 1396r-8(d)(4)."

"**SECTION 10. Financial incentives prohibited.** The department may not offer or pay directly or indirectly any material inducement, bonus, or other financial incentive to a participating provider based on the denial or delay of medically necessary and appropriate prescription drug therapy, or a reduction in the proportion of beneficiaries who receive prescription drug therapy under the Medicaid program."

Page 9, line 9, Replace "**SECTION 8**" with "**SECTION 11**"

Renumber accordingly.

30674.0100

Fifty-eighth
Legislative Assembly
of North Dakota

HOUSE BILL NO. 1430

Introduced by

Representatives Devlin, Price, Weisz

Senators Fischer, J. Lee

A BILL for an Act to establish a drug utilization review program and drug prior ~~to~~ authorization program within the department of human services.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. Definitions.

1. "Board" means the drug utilization review board.
2. "Committee" means the pharmacy and therapeutics committee.
3. "Compendia" means the "American hospital formulary services drug information", "United States pharmacopeia - drug information", ~~peer-review medical literature~~, and clinical information submitted to the department by the pharmaceutical research company that developed the product and is registered with the federal food and drug administration as the product distributor.
4. "Department" means the department of human services.
5. "Drug utilization review" means both retrospective and prospective drug utilization review. The reviews are designed to ensure that drug utilization is medically appropriate, medically necessary, and not likely to have adverse medical results.
6. "Drug utilization review criteria" means standards approved by the board for use in determining whether use of a drug is likely to be medically appropriate, medically necessary, and not result in adverse medical outcomes.
7. "Prior authorization" means a process requiring the prescriber or the dispenser to verify with the department or its contractor that proposed medical use of a particular medicine for a patient meets predetermined criteria for coverage by the program.
8. "Prospective drug utilization review" means that part of the drug utilization review program that occurs before a drug is dispensed and that uses the drug utilization

review criteria to screen for potential drug therapy problems related to therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse or misuse.

9. "Retrospective drug utilization review" means that part of the drug utilization review program that is an historical review of drug utilization data using drug utilization review criteria examine pharmacy claims data and other information to identify overutilization, underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, and clinical abuse or misuse.

SECTION 2. Establishment of drug utilization review board.

1. The drug utilization review board is established within the department for the implementation of a retrospective and prospective drug utilization review program.
2. The board consists of ~~eleven~~ eighteen members appointed by the executive director of the department as follows:
   a. ~~Four~~ six physicians licensed in this state and actively engaged in the practice of medicine, four of whom are chosen from a list of nominees provided by the North Dakota medical association;
   b. ~~Five pharmacist~~ six pharmacists licensed in this state, actively engaged in the practice of pharmacy, ~~and~~ four of whom are chosen from a list of nominees provided by the North Dakota pharmacy association;
   c. ~~One person~~ Two persons are residents who ~~is a resident~~ of this state chosen to represent program beneficiaries in this state; ~~and~~
   d. ~~One person~~ Two persons representing the pharmaceutical industry chosen from a list of nominees provided by the pharmaceutical research and manufacturers of America;
   e. The pharmacy administrator of the department; and
   f. The medical consultant to the department.
3. Board members shall serve staggered three-year terms. ~~One physician, one pharmacist~~ Two physicians, two pharmacists, and ~~the~~ one beneficiary representative must be initially appointed for two-year terms; and ~~one physician~~ two physicians, two pharmacists, and ~~the~~ one industry representative must be initially appointed for one-year terms. A member may be reappointed for a period not to exceed three 3-year terms. Vacancies on the board

The duties of the board shall be consistant with the provisions of 42 U.S.C. 1396r-8(g)(3). In addition, the

must be filled for the balance of the unexpired term from ~~nominee lists for~~ the appropriate board category as provided under subsection 2.

4. Board members shall select a chairman and a vice chairman on an annual basis from the board membership.

5. The board shall meet at least ~~monthly~~ bimonthly and may meet at other times at the discretion of the chairman.

SECTION 3. Duties of the drug utilization review board. ~~The~~ board shall:

1. Advise and make recommendations regarding rules adopted by the department implementing the provisions of state and federal law related to drug utilization review;

2. Oversee the implementation of a retrospective and prospective drug utilization review program for the medical assistance program, including responsibility for recommending criteria for selection of contractors and reviewing contracts between the medical assistance program and any other entity that will process and review drug claims and profiles for the drug utilization review program in accordance with this ~~part~~ Act;

3. Develop and apply the drug utilization review criteria for the retrospective and prospective drug utilization review programs, provided that the drug utilization review criteria are consistent with the indications supported and rejected by the compendia and federal food and drug administration-approved labeling for the drug. The board also shall consider outside information provided by interested parties, including prescribers who treat significant numbers of patients under the department's medical assistance program;

4. Establish a process to reassess on a periodic basis the drug utilization review criteria and, as necessary, modify the prospective and retrospective drug utilization review programs; and

5. Provide a period for public comment during each board meeting. Notice of proposed changes to the drug utilization review criteria and modification of the prospective and retrospective drug utilization review programs must be furnished to the public thirty days before the consideration or recommendation of any proposed changes to the drug utilization review programs.

SECTION 4. Prospective and retrospective drug utilization review programs.

1. The board, in cooperation with the department, shall create and implement a prospective and retrospective drug utilization review program for outpatient prescription drugs under the medical assistance program using drug utilization review criteria to ensure that drug utilization is medically appropriate, medically necessary, and not likely to result in adverse medical outcomes.
2. The department may contract with an entity to process and review drug claims and profiles for the drug utilization review program provided that the department uses a competitive bidding process.
3. The prospective drug utilization review program must be based on drug utilization review criteria established by the board and must provide that, before a prescription is filled or delivered, a review must be conducted by a pharmacist at the point of sale to screen for potential drug therapy problems. In conducting the prospective drug utilization review, the prescribed outpatient drug therapy may not be altered without a new prescription order by the prescribing physician and approval by the patient. The prospective drug utilization review must screen for:
   a. Therapeutic duplication;
   b. Drug-disease contraindications;
   c. Drug-drug interactions;
   d. Incorrect drug dosage or duration of drug treatment;
   e. Drug-allergy interactions; and
   f. Clinical abuse or misuse.
4. The retrospective drug utilization review program must be based on drug utilization review criteria by the board using the department's mechanized drug claims processing and information retrieval system to analyze assistance claims to:
   a. Identify patterns of fraud, abuse, gross overuse or underuse, and inappropriate or medically unnecessary care;
   b. Assess data on drug use by applying and reviewing criteria developed from the compendia or federal drug administration-approved labeling for the purpose of evaluating:
      (1) Therapeutic appropriateness;

(2) Overutilization or underutilization;

(3) Appropriate use of generic products;

(4) Therapeutic duplication;

(5) Drug-disease contraindications;

(6) Drug-drug interactions;

(7) Incorrect drug dosage or duration of drug treatment; and

(8) Clinical abuse or misuse; and

c. Propose remedial strategies to improve the quality of care and to promote effective use of medical assistance program funds or beneficiary expenditures.

SECTION 5. Establishment of the pharmacy and therapeutics committee.

1. Notwithstanding any other law, the department may implement a prior authorization program for outpatient prescription drugs under the medical assistance program only as provided in this section.

2. The pharmacy and therapeutics committee is established within the department for the purposes of implementing prior authorization for outpatient prescription drugs under the medical assistance program. → Members appointed to the committee may be appointed from among and may also serve as members of the board. the board.

3. The committee consists of ~~eleven~~ eight members appointed by the executive director of the department as follows:

a. ~~Five~~ Three physicians licensed in this state and actively engaged in the practice of medicine chosen from a list of nominees provided by the North Dakota medical association; of different medical specialties who may be among physician members of the board or from

b. ~~Four~~ Three pharmacists licensed in this state and actively engaged in the practice of pharmacy, chosen from a list of nominees provided by North Dakota pharmacy association; who may be among the pharmacist members of the board or from

c. One person who represents medical assistance beneficiaries in this state; and

d. One person representing the pharmaceutical industry who is a resident of this state, chosen from a list of nominees provided by the pharmaceutical research and manufacturers of America.

4. ~~Board~~ Committee members shall serve staggered three-year terms. ~~Two physicians~~ One physician, one pharmacist, and the consumer representative must be initially appointed for

two-year terms; and one physician, one pharmacist, and the industry representative must be initially appointed for one-year terms. A member may be reappointed for a period not to exceed three 3-year terms. Vacancies on the board must be filled for the balance of the unexpired term from nominee lists for the appropriate board category as provided under subsection 3.

5. Committee members shall select a chairman and vice chairman on an annual basis from the committee membership.

6. The committee shall meet at least bimonthly and may meet at other times at the discretion of the chairman.

SECTION 6. Duties of the pharmacy and therapeutics committee. The committee shall:

1. Advise and make recommendations regarding rules to be adopted by the department regarding outpatient prescription drug prior authorization.

2. Oversee the implementation of a drug prior authorization program for the department's medical assistance program;

3. Establish the drug prior authorization review process in compliance with section 7 of this Act;

4. Make formal recommendations to the department regarding the outpatient prescription drug covered by the medical assistance program that is to be prior authorized;

5. Review on ~~a semiannual~~ at least an annual basis whether drugs placed on prior authorization should remain on prior authorization; and

6. Modify the prior authorization review process, as necessary, to achieve the objectives of this Act.

SECTION 7. Drug prior authorization review process.

1. Any drug prior authorization program must meet the following conditions:

   a. The program must provide telephone, facsimile, or other electronically transmitted approval or denial within twenty-four hours after receipt of the completed prior authorization request.

   b. In an emergency situation, including a situation in which a response to a prior authorization request is unavailable, a seventy-two hour supply of the

prescribed drug must be dispensed and paid for by the medical assistance program, or, at the discretion of the committee, a supply greater than seventy-two hours which will assure a minimum effective duration of therapy for an acute intervention.

c. Authorization must be granted if the drug is prescribed for a medically accepted use supported by either the compendia or approved product labeling ~~or peer review literature~~ unless there is a therapeutically equivalent generic drug that is available without prior authorization.

d. To support the prior authorization request, the program must consult with prescribers to develop a streamlined process for the prescriber to furnish any documentation required, including the name, title, address, and telephone number of the prescriber making the request; the date of the request; the product name of the requested drug; a description of the circumstances and basis for the request; and whether the request is an emergency. The process must flow directly from the patient care interaction and not a separate set of tasks required of the prescriber by the department.

2. A drug may not be recommended for prior authorization by the committee and placed on prior authorization by the department unless the following conditions are met:

a. The committee analyzes the retrospective drug utilization review data using the drug utilization review criteria to identify a drug whose use is likely not to be medically appropriate or medically necessary, or likely to result in adverse medical outcome;

b. The committee considers the potential impact on patient care and the potential fiscal impact that may result from placement of such a drug on prior authorization;

c. Any consideration of the cost of the drug by the committee must reflect the total cost of treating the conditions for which the drug is prescribed, including nonpharmaceutical costs and costs incurred by other sectors of the state health care program that may be affected by the drug's availability for use in treating program beneficiaries;

d. The committee provides at least thirty days' advance public notice before any meeting developing recommendations concerning whether such a drug should be placed on prior authorization. Any interested person may request an opportunity to make an oral presentation to the committee related to the prior authorization of the drug. The committee shall also consider any information provided by any interested person, including physicians, pharmacists, beneficiaries, and manufacturers or distributors of the drug;

e. The committee makes a formal written recommendation to the department that the drug be placed on prior authorization which must be supported by an analysis of prospective and retrospective drug utilization review data demonstrating:

(1) The expected impact of the decision on the clinical care likely to be received by beneficiaries for whom the drug is medically necessary;

(2) The expected impact on physicians whose patients require the drug; and

(3) The expected fiscal impact on the medical assistance program;

f. The department accepts or rejects the recommendation of the committee and, in a written decision, determines whether the drug should be placed on prior authorization. The department may consider any additional and clarifying information provided by any interested party rendering its decision;

g. The department's decision must be published for public comment for a period of no less than thirty days. The effective date of the decision may not be before the close of the comment period and effective notice of the decision's finality is available to prescribers.

3. Notwithstanding any other provision of this section, a drug may not be recommended to require prior authorization by the committee and placed on prior authorization by the department, which has been approved or had any of its particular uses approved by the federal food and drug administration under a priority review classification. *

4. The committee shall develop a grievance mechanism for interested parties to appeal the department's decision to place a drug on prior authorization. After *

participating in the grievance mechanism developed by the committee, any interested party aggrieved by the placement of a drug on prior authorization is entitled to an administrative hearing before the department under chapter 28-32

5. The committee shall review the prior authorization status of a drug ~~every six months~~ no less than once each year.

6. The committee shall provide at least thirty days advance public notice prior to any meeting determining whether changes should be made to the drug prior authorization review process.

SECTION 8. Adoption of rules. The department may adopt rules to implement this Act.

[add new SECTIONS 8, 9 & 10 as noted on amendments]

Distributed to committee on 3.19.03

Bruce Murry
<bmurry@mac.com>
03/17/2003 02:06 PM

To: jlee@state.nd.us, rlbrown@state.nd.us, rerbele@state.nd.us, afairfie@state.nd.us, tfischer@state.nd.us, mpolovit@state.nd.us, intern1@state.nd.us
cc: tlarsen@state.nd.us, dboeck@state.nd.us, bmurry@state.nd.us
Subject: HB 1430

Dear Chairman Lee and Members of the Senate Human Services Committee:

I am Bruce Murry, an employee of the North Dakota Protection and Advocacy Project. I offered brief impromptu testimony today on HB 1430 and various amendments of which was not previously aware. I wanted to provide that testimony to you in writing at your request.

I testified that a key component of current engrossed HB 1430 is that a consumer has access to a 72-hour emergency prescription and a hearing should the department disagree with the doctor as to the appropriate drug. The hearing would take place independently and be conducted by the Office of Administrative Hearings, who would make the record of the proceeding. I consider this due process step to be critical to the consumer's rights, the doctor-patient relationship, and proper health care management. I believe the risk of three days' higher expense for a prescription is outweighed by a doctor's belief that the prescribed drug was best.

I have now scanned the proposed amendments prepared by the Legislative Council staff for Representative Svedjan and Senator J. Lee on March 12, 2003. To the extent the proposed amendments resemble SB 2088, I would refer the Committee to the testimony and proposed amendments of Attorney David Boeck of P&A.

I did not see the 72-hour prescription and hearing terms in the March 12 proposed amendments. I believe the 72-hour emergency prescription and hearing requirements should be inserted into HB 1430.

I also recommend that a current or former Medicaid consumer or family member be included in the membership of the drug use review program board. Although I appreciate the hard work by the department, pharmacists, and the pharmaceutical industry, it does not appear that consumers have had a direct role in the drafting process. I believe a consumer role might avoid problems and increase consumer support for this reform.

Sincerely,

Bruce D. Murry
Attorney at Law

MODIFIED DRAFT – 2:00 PM 3/19/2003

PROPOSED AMENDMENTS TO HOUSE BILL NO. 1430 (2ND DRAFT)

Page 1, line 1, after "A BILL" replace the remainder of the bill with "for an Act to establish a drug use review program and drug prior authorization program within the department of human services; to provide for a legislative council study of **the value of** medical assistance program use of purchasing pools, preferred drug lists, and other pharmacy benefit management concepts **along with the fiscal impact of the appeals process on existing programs**; and to declare an emergency.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. Definitions. As used in sections 1 through 10 of this Act, unless the context otherwise requires:

1. "Board" means the drug use review board.
2. "Compendia" means the American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information, the DRUGDEX Information System, American Medical Association Drug Evaluations, and non-proprietary peer-reviewed medical literature.
3. "Department" means the department of human services.
4. "Drug use review" means a program as described in 42 U.S.C 1396r-8(g)(2).
5. "Drug use review criteria" means standards approved by the board for use in determining whether use of a drug is likely to be medically appropriate, medically necessary, and not result in adverse medical outcomes.
6. "Prior authorization" means a process requiring the prescriber or the dispenser to verify with the department or the department's contractor that proposed medical use of a particular drug for a medical assistance program recipient meets predetermined criteria for coverage by the medical assistance program.

SECTION 2. Drug use review board.

1. The board is established within the department for the implementation of a drug use review program.
2. The board consists of thirteen members appointed by the executive director of the department. A majority of the members of the board must be physicians and pharmacists participating in the medical assistance program. Four or more members ~~**must have experience in developing or practicing under a preferred drug list**~~ **shall have experience with a drug use review process or have participated in programs where prior authorization is used**. The membership of the board is:

MODIFIED DRAFT – 2:00 PM 3/19/2003

a. Six physicians licensed in this state and actively engaged in the practice of medicine, one of whom is a psychiatrist, and four of whom are chosen from a list of nominees provided by the North Dakota medical association;

b. Six pharmacists licensed in this state, actively engaged in the practice of pharmacy, four of whom are chosen from a list of nominees provided by the North Dakota pharmaceutical association; and

c. One pharmacist representing the pharmaceutical industry chosen from a list of nominees provided by the pharmaceutical research and manufacturers of America.

3. Board members shall serve staggered three-year terms. Two physicians and two pharmacists must be initially appointed for two-year terms, and two physicians and two pharmacists must be initially appointed for one-year terms. A member may be reappointed for a period not to exceed three 3-year terms. A vacancy on the board must be filled for the balance of the unexpired term from the appropriate board category as provided under subsection 2. The executive director of the department may replace a member of the board who fails to attend three consecutive meetings of the board without advance excuse or fails to perform the duties expected of a board member.

4. Board members shall select a chairman and a vice chairman on an annual basis from the board membership.

5. The board shall meet in person at least once every three months and may meet at other times by teleconference or electronically at the discretion of the chairman. **Each member of the board is entitled to receive a per diem and expense reimbursement as may be fixed by the department.**

6. The pharmacy administrator of the department and medical consultant to the department shall serve as ex officio members of the board and provide administrative services **to the board**.

SECTION 3. Duties of the board. The board shall:

1. Cooperate with the department to create and implement a prospective and retrospective drug use review program for outpatient prescription drugs under the medical assistance program based upon the compendia and drug use review criteria to comply with 42 U.S.C. 1396r-8(g)(3);

2. Advise and make recommendations regarding any rule proposed for adoption by the ~~**executive director of the**~~ department to implement the provisions of state and federal law related to drug use review;

3. Receive and consider information regarding the drug use review process that is provided by the department and by interested parties, including prescribers who

MODIFIED DRAFT – 2:00 PM 3/19/2003

treat significant numbers of patients under the department's medical assistance program;

4. Review and recommend to the department any drugs to be included on prior authorization status;

5. Review at least once each year the status of the list of drugs that have been placed on prior authorization;

6. Review and approve the prior authorization process used by the department, including the process to accommodate the provision of a drug benefit in an emergency situation; and

7. Propose remedial strategies to improve the quality of care and to promote effective use of medical assistance program funds or recipient expenditures.

SECTION 4. Prior authorization program.

1. The department shall develop a prior authorization program that meets the requirements of 42 U.S.C. 1396r-8(d) to determine coverage of drug products when a medical assistance recipient's health care provider prescribes a drug that is identified as requiring prior authorization. Authorization must be granted for provision of ~~a~~ **the** drug if:

   a. The drug not requiring prior authorization has not been effective, or with reasonable certainty is not expected to be effective, in treating the recipient's condition;

   b. The drug not requiring prior authorization causes or is reasonably expected to cause adverse or harmful reactions to the health of the recipient; or

   c. The drug is prescribed for a medically accepted use supported by either the compendia or approved product labeling unless there is a therapeutically equivalent drug that is available without prior authorization.

2. For any drug placed on the prior authorization program, the department shall provide medical and clinical criteria, cost information, and utilization data to the drug use review board for review and consideration. The board may consider department data and information from other sources to make a decision about placement of the drug on prior authorization.

3. The department may use contractors to collect and analyze the documentation required by this subsection and to facilitate the prior authorization program.

4. The department shall consult with the board to promulgate rules implementing the prior authorization program that:

   a. Establish policies and procedures required to implement the program;

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b. Develop a process that allows prescribers to furnish any documentation required to obtain approval for a drug without interfering with patient care activities; and

c. Allow the board to establish panels of physicians and pharmacists to provide expert guidance and recommendations when considering specific drugs or therapeutic classes of drugs to be included in the prior authorization program.

SECTION 5. Public notice – Applicability.

1. The department shall provide thirty days' notice of all meetings of the board by written or electronic means. **Notice is provided when the department responds to parties that have requested notice of meetings and by placement of the notice on the department's web site.** If the board is to consider a change to the prior authorization program, the department will list the affected drugs and provide background information upon request. Any interested party may attend a meeting of the board and provide information or recommendations related to inclusion of a drug in the prior authorization program. Any decisions about changes in the prior authorization list must be posted on the department's web site to allow for public comment for a period of no less than thirty days **from the date of posting**.

2. The department shall post on the department's web site the most current and applicable list of drugs requiring prior authorization, together with any limits on coverage of these drugs. The website shall also include in downloadable format, forms necessary to complete prior authorization requests.

3. The department may not discontinue the provision of prescription drug benefits provided to medical assistance recipients before the effective date of this Act based solely on the subsequent placement of the drug on the prior authorization program.

SECTION 6. Appeal procedures. The department shall develop rules for a grievance mechanism that interested parties can use to appeal the department's decision to place a drug on prior authorization. After participating in the grievance mechanism, any interested party aggrieved by the placement of a drug on prior authorization is entitled to an administrative hearing before the department under chapter 28-32.

SECTION 7. Financial incentives prohibited. The department may not offer or pay directly or indirectly any material inducement, bonus, or other financial incentive to a participating provider based on the denial or delay of medically necessary and appropriate prescription drug therapy, or a reduction in the proportion of recipients who receive prescription drug therapy under the medical assistance program.

SECTION 8. Maximum allowable costs and use of edits. In order to promote efficiency and savings in the department's service to eligible medical assistance program recipients, the department ~~**must**~~ **shall** create and implement the broadest possible list of drugs that can be paid at the maximum allowable cost. In order to further promote efficiency and savings, the department ~~**must**~~ **shall** maximize use of edit programs that pertain to payment of

medical assistance program pharmaceutical claims. Upon request, the department ~~must~~ **shall** disclose to the legislative assembly and any committee of the legislative assembly requesting it, a summary of edit programs available to the department's medical assistance program. Upon disclosure of the edit programs, the department ~~must~~ **shall** also provide to the legislative assembly and any committee of the legislative assembly requesting it, the department's progress in implementing ~~such~~ **the** edit programs.

SECTION 9. Adoption of rules. The department shall adopt rules to implement sections 1 through 6 of this Act.

SECTION 10. LEGISLATIVE COUNCIL STUDY. The legislative council shall consider studying during the 2003-2004 interim, **the value of** medical assistance program use of purchasing pools, preferred drug lists, and other pharmacy benefit management concepts **along with the fiscal impact of the appeals process on existing programs**. If the legislative council conducts the study, the legislative council shall report its findings and recommendations, together with any legislation required to implement the recommendations, to the fifty-ninth legislative assembly.

SECTION 11. EMERGENCY. This Act is declared to be an emergency measure."

Renumber accordingly

MODIFIED DRAFT – 2:00 PM 3/19/2003

Good morning Chairman Lee and members of the Senate Human Services Committee. For the record I am Rep. Bill Devlin, District 23 of Finley.

I appear before you today to ask your consideration of HB 1430 which will establish a drug utilization review board and drug prior authorization program within the department of Human Services.

Those of you that are familiar with my legislative track-record will probably find this bill to be a bit of a surprise as I have opposed Prior Authorization in the past. In fact the House rejected prior authorization 98-0 last session. The Senate also rejected a bill earlier this year. Senator Fisher and I have been involved in attempts by the Department of Human Services to establish a prior authorization plan without legislative authority. To put it nicely, we persuaded them the errors of their ways.

However there were a number of reasons for that vote including the fact that the Drug Utilization Review Board had not met as required by federal laws. We were also very concerned about establishing a prior authorization process, For the freshman the term means prior authorization means have the department or other agency decided whether a drug to can be provided to a medicaid patient in the state.

Many of us have deep concerns about any program where the savings need to be accomplished by getting the person on medicaid a lower cost drug. That puts the department between the person and their doctor. Many of us feel strongly that the doctor-patient relationship is nearly sacred. Therefore we want to make sure it is fully protected and any costs savings found through prior authorization are in the best interests of the patient and not the budget.

The process is supposed to find the lower cost drugs that provide the same benefits. Many of us have been frustrated by statements on how much prescription drug costs have went up in our medicaid program but we never heard the benefits explained. Less hospitalization, less surgery, less absence from work and many other benefits of the correct drug therapy should also be included in any cost/benefit analysis for prior authorization. We know proper drug therapy can keep people out of nursing homes and away from extended hospital stays but never see those savings projected in the budgets.

I want to make sure the doctor-patient relationship is protected. At no time should we ever allow a bean counter to determine which is the best drug for a person on public assistance or anywhere else.

If we are to ever have a full prior authorization program in the state, I think it is vital that we protect the clients, we fully evaluate all of the data, we respect the doctor-patient relationship and we work to insure that we provide the medicine needed to treat the condition of the patient and not the pharmaceutical product that is provided at the lowest costs.

One of the key components to any prior authorization program is to make sure that all the players are at the table when decisions are made. That means not only the providers, department and patient advocates but the representatives of the pharmaceutical industry as well. The companies who are spending billings of dollars to develop treatments and cures are often the best ones to provide the doctors and other providers with the information needed as well as cost/benefit facts about new as well as existing drugs.

The bill before you is model legislation that has been used as a basis for responding to these needs in other states. I expect there will be people here on both sides of this issue. I would hope we can take their ideas and input as we craft this legislation.

As the committee works through this issue I am confident that we can bring forth a piece of legislation that most if not all of us can support.

I hear there have been some amendments prepared for this committee that I feel will defeat the fairness of prior authorization and will ultimately lead to this bill's defeat on either the senate or house floor later in the session.

On the other hand we have started a process trying to work out some of the objections of the department over the original language. I believe Cal Ralston will present amendments that all the parties have agreed to at this time.

I have attached some other amendments for your consideration. They have not been to Legislative Council for a final check of style and content but I will deliver a set to them this morning and bring them back later, if you desire.

Briefly I will explain them.

The new section eleven was inadvertently left out of the bill when we patterned it after other states. The department has a number of edit programs that help sort through what is happening with the medical assistance programs and provide red flags in the case of any possible fraud or abuse. This amendment makes sure they use all of the programs and provides for legislative oversight.

Section 12 expands the rebates for generic drugs to 15% which is similar to what other states have went to and one seem to make sense or at least it should be part of the discussions.

Section 13. Sets the pharmacy dispensing fee at $4.60 which is lower than the $5.10 that was set by the department late last year. The current dispensing fee is the third highest in the nation and the $4.60 rate would still be one of the highest but I believe better reflects their costs. The other thing this does is clearly spells out it law that the authority for the feel change is in the hands of the legislature. That is where it is in many other states and I believe where it should be here.

Another place where the department could save money or drug costs is to change the Average Wholesale Price discount from -10% to -14% like Minnesota recently did. I did not propose that amendment and offer it for discussion purposes only, if the committee wishes.,

Section 14 of the proposed amendment would set a co-pay of $2.00 for prescription drugs for generic drugs and $4.00 for brand names. The departments reports show a drop in drug costs with a co-pay of $3.00 they instituted. This amendment will give them full legislative authority for that type of plan and perhaps encourage the use of more generic drugs by the smaller co-pay.

Thank you Chairman Lee and members of the committee. There are expert witnesses in this room to answer the questions the committee might have but I am willing to try answer any questions you might have at this time.

TESTIMONY

BY
CALVIN N. ROLFSON
ON BEHALF OF
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
(PhRMA)
IN SUPPORT OF
ENGROSSED HOUSE BILL NO. 1430

My name is Cal Rolfson, I am an attorney in Bismarck and am the legislative consultant for the Pharmaceutical Research and Manufacturers of America (PhRMA).

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading research-based pharmaceutical and biotechnology companies that are devoted to inventing medicines that allow patients to live longer, healthier and more productive lives. The industry invested more than 30 billion dollars in 2001 in discovering and developing new medicines. PhRMA companies are leading the way in the search for new cures for young and old alike.

PhRMA supports Engrossed House Bill 1430. At the conclusion of my testimony I will offer several amendments that will address some additional concerns that the Department of Human Services has to this Engrossed Bill. I had previously met with representatives of the department, and the Engrossed Bill

reflects many of the changes we negotiated. The amendments I will offer to the Engrossed Bill reflect yet more changes to the Bill based upon further discussions I have had with the Department.

The purpose of my testimony will be to generally review the specifics of the Bill and give you come history of how the Bill got here in this form. I understand there will be a "hoghouse" amendment presented by the opponents that will essentially reinstate SB 2088 - a Bill this Committee said "NO" to by a vote of 0-6, and that the Senate rejected 0-45. In that regard, following my testimony, Chris Ward, who is a former Ontario legislator and national drug policy speaker, will talk to you about some of the pitfalls we will face if the hoghouse version is put into place.

Currently there already exists a Drug Utilization Review (DUR) Board. The federal Medicaid laws under the Social Security Act require that state Medicaid agencies establish such boards. The general purpose of such boards is to review Medicaid drug utilization to determine drugs that are medically appropriate, medically necessary and have appropriate medical results for the low income population served by the state's Medicaid program.

The current DUR Board exists only because federal law broadly and generally requires the Department to create such a board. It is PhRMA's belief, as

it is in other states, that such a board should be established in state law and the legislative policy makers of this state should have a stake in determining the composition of the Board, its functions, its goals and its outcomes, as long as that determination complies with the federal Medicaid laws. It is our belief that Engrossed House Bill 1430 does that and raises the responsibilities associated with this Board to the state policy level, rather than leaving it in the control of the department with only federal policy direction.

Section 1 of the Bill contains the definitions. The Engrossed Bill has some changes that were urged by the Department and with which we agreed in our first round of negotiations.

The term "Drug utilization review" involves both retrospective and prospective review processes. As the definition states (pg. 1, lines 13-15), such reviews are designed to insure that drug utilization is medically appropriate, medically necessary, and not likely to have adverse medical results. The "drug utilization review criteria" (pg. 1 lines 16-18) that is used in the Bill means standards that are approved by the Board for use in determining whether a drug is likely to be appropriate, etc. It would be up to the appointed professionals on the board to determine and approve what those standards are to be.

"Prior authorization" (pg. 1, lines 19-22), is defined as a process that

requires a prescriber (physician or nurse practitioner, for example) to verify with the Department that a proposed drug meets predetermined criteria for coverage under the program.

Historically, PhRMA has always opposed prior authorization as a concept. Prior authorization is effectively an intrusion by the government (in this case the Department) into the relationship between a patient and a provider. It is PhRMA's belief that physicians should be free to prescribe what they believe in their medical judgment is in the best interests of their patients, and that government regulators should not interfere with that relationship. Those medical providers are on the front lines and are in the best positions to know exactly what is in the best interest of their patients.

PhRMA recognizes, however, that because Medicaid is federal and state funded, and tax dollars are involved, it may be appropriate that prior authorization be permitted, but that if it is permitted, prior authorization should carry with it appropriate due process protections for the benefit of providers and patients alike that allows for a review of decisions by a board that is broad based (as with this Bill), rather than by individual decisions of governmental department heads. That is not to say that individuals in the Department are not conscientious and competent to make those decisions that may interfere with the doctor/patient relationship.

However, because those relationships are so important, PhRMA believes that the involvement of a broad based, statutorily established DUR board and a pharmacy and therapeutics committee (P&T) is the least that the policy makers of this state should do to insure fairness to both taxpayers and recipients of Medicaid funding.

"Prospective drug utilization review" (pg. 1, line 24 - pg. 2, line 4) and "retrospective drug utilization review" (pg. 2, lines 5-10) essentially defines the process of reviewing a drug and its program before it is prescribed and historically reviewing post drug utilization, to determine whether the drug has been over-utilized, underutilized, whether appropriate use of generic drugs have been considered, whether duplication exists, and the like.

Section 2 of the Bill establishes the DUR board in state law and its make-up. In addition to 6 physicians and 6 pharmacists, there are two persons on the board that represents program beneficiaries, which could be a representative of the Mental Health Association, Long Term Care Association, or the like. In addition, two persons would be appointed to represent the pharmaceutical industry. Currently there is no pharmaceutical representative on the board at the department level and it seems appropriate that the industry that scientifically discovers, develops, sells and must stand behind their products, ought to be represented. The pharmacy administrator for the Department (currently Dr. Joyce) and the Department's

medical consultant (currently Dr. Wilson) would also be ex-officio board members.

Board members would serve staggering terms as noted at the bottom of page 2 and there is a process for filling unexpired terms. A chairman and vice chairman are elected from among the board membership. This is a departure from the current voluntary board that exists within the Department, which is only advisory to the Department and is chaired by the pharmaceutical director of the Department.

The Bill states that the board should meet at least bi-monthly.

Section 3 sets out the duties of the DUR Board. They are to advise and make recommendations regarding rules adopted by the Department. They are to oversee the implementation of drug utilization within the medical assistance program. They are to develop and apply drug utilization review criteria, both retrospectively and prospectively. They are to establish a process to periodically review and modify the drug utilization program of the Department and they are to provide the period of time for public comments during each board meeting, which we view as important.

Section 4 of the Bill discusses the criteria regarding prospective and retrospective drug utilization review. The purpose is, again, to insure that drug utilization is medically appropriate, necessary and not adverse. The Department

may contract with outside entities to review drug claims and profiles, which I understand they intend to do. The board is required to establish criteria by which before a prescription is delivered, a review is conducted by a pharmacist at the point of sale to screen for potential drug therapy problems. The drug therapy prescribed by the provider, under this section, cannot be altered without either a new prescription or approval by the ~~patient~~ physician. In other words, the physician should be involved in making determinations that are appropriate, rather than the Department as an intervening third party.

Subsection 3 of Section 4 (pg. 4, lines 13-25) sets out the various criteria for screening, including duplication, contra-indications, drug allergies and the like. Subsection 4 of Section 4 (pg. 4, line 30 - pg. 5, line 14) sets out the retrospective drug utilization review and seeks to identify patterns of fraud, abuse, gross overuse or under use, and inappropriate or unnecessary care.

Section 5 of the Bill establishes a Pharmacy and Therapeutics (P&T) Committee. The P&T committee is created to implement prior authorization for outpatient prescription drugs under the Department's medical assistance program (Medicaid). The Engrossed Bill currently establishes a P&T committee of three physicians, three pharmacists, one person representing medical assistance beneficiaries, and one person representing the pharmaceutical industry. It is

important to note that members of the P&T Committee may come from among the members of the DUR Board to create flexibility. Again, this committee would serve staggered terms, select a chair and vice-chair and meet at least bimonthly.

Section 6 sets out the duties of the P&T Committee. As noted, they are to make recommendations regarding rules to be adopted by the Department for outpatient prescription drug prior authorization, they are to oversee and implement the drug prior authorization program, they are to establish a drug prior authorization review process, review their program at least annually, and modify the prior authorization process as necessary.

Under Section 7, the P&T committee would provide telephone or other electronic means by which to approve or deny drugs within 24 hours of a prior authorization request. It provides for emergency situations and a 72 hour supply of drugs in case the P&T committee or its staff is unavailable. It requires that the authorization for the prescribed drug must be granted if the drug is medically accepted for the condition under which it is labeled, unless there is a generic equivalent that is available without prior authorization. This, then, supports the use of generic drugs where they are available.

This P&T Committee is intentionally separated from the DUR Board because this committee specifically deals with prior authorization of particular

drugs and is essentially the working committee to recommend whether or not a drug should be prior authorized. While the Department believes that the function of P&T committee and the DUR board should be combined, they are separated intentionally in this Bill because of their different functions and to specifically separate the prior authorization function (P&T) from the overview function (DUR). However, if you wish to have these two groups combined into one, we can support that, as long as the separate functions and integrity of the two groups can be identified and not eroded.

Subsection 2 of Section 7 (pg. 7, line 27 - pg. 9, line 4) sets out guidelines to the P&T Committee as to what drugs may or may not be recommended for placement on prior authorization. For a drug to be placed on prior authorization, the committee must analyze the retrospective drug utilization review data, must consider the potential impact on patient care, as well as the fiscal impact, and the like. The criteria also includes the requirement that the committee must take into consideration total cost of treating the condition for which the drug is prescribed, including non-pharmaceutical costs. Examples might be that a newly developed drug might be the preferred treatment for a condition that would otherwise require hospitalization at a significantly higher cost to the patient and the State.

The P&T committee must provide at least thirty days advance notice of any

public hearing before meetings are held to develop recommendations for drugs placed on prior authorization. This then allows the general public, including patients and their physicians, to offer input into this process. The committee then makes formal recommendations to the Department as to which drugs should be placed on prior authorization. The Department either accepts or rejects the recommendation and determines whether a drug should be placed on prior authorization. The Department is given flexibility to consider any additional or clarifying information. Following the Department's decision to place a drug on prior authorization, its decision is published for public comment for at least thirty days.

Subsection 3 of Section 7 (pg. 9, lines 5-9) creates a grievance procedure under NDCC Chapter 28-32 if a particular drug has not been prior authorized.

On Page 9, subsection 4, the Engrossed Bill requires the P&T Committee to review the PA status of a drug every year.

Section 8 of the Engrossed Bill allows that any recipient of drugs whose health care has been arbitrarily or unlawfully delayed or denied, may bring an action in district. The operative words are "arbitrarily" or "unlawfully". "Arbitrarily" means based upon a whim. Flipping a coin. The term "unlawfully" is obvious. So if this Department doesn't act arbitrarily or unlawfully, which is expected of

them anyway, there should be no problem. If they do act arbitrarily or unlawfully, this protection ought to be available to the public. The Department must also adopt rules to implement this Act.

Section 8 also permits equitable relief and attorneys fees. The purpose of this section is to give rights to patients who are arbitrarily denied access to drug therapies that they medically need and that their physicians have prescribed.

The proposed Section 9 of the Engrossed Bill (pg. 9, lines 25-29) allows the pharmaceutical manufacturer to appeal to the department any decision of the Department to exclude a specific drug from a preferred or approved drug list if that decision is arbitrary, or in violation of state law, or in violation of the federal law under the Federal Assistance Program and the Social Security Act which allows the State to establish drug lists if they meets certain federal statutory requirements.

Under Section 10 of the Engrossed Bill (pg. 9, line 30 - pg. 10, line 3), the language suggested prohibits the Department from any conflicts of interest, bonuses, or other financial incentives to a participating provider that is based upon denial or delay of a medically necessary drug to a patient. We are not aware of any situation where this has occurred, but to have that in the law seems like good public policy for the future. I understand some states have not been so fortunate.

With that perhaps overly verbose explanation of the Bill, I will certainly stand

for questions but I would suggest that Chris Ward that will follow me is more capable of discussing the technical details of this legislation and the anticipated hoghouse amendment.

Calvin N. Rolfson
Legislative Counsel
PhRMA
(Lobbyist No. 144)

by Cal Rolfson

PROPOSED AMENDMENTS TO ENGROSSED HOUSE BILL NO. 1430

Page 7, line 16, after "unless" insert "the committee determines"

Page 9, line 16, after "been" insert "arbitrarily or unlawfully"

Page 9, line 17, remove "or any of its contractors"

Page 9, line 19, remove "formularies, preferred drug lists,"

Page 9, line 20, remove "If a department contractor has acted with disregard for"

Page 9, remove line 21

Page 9, line 22, remove "court may provide for exemplary damages."

Page 9, line 23, replace "shall" with "may" and remove ", regardless of whether the court awards"

Page 9, line 24, remove "specific relief or damages"

Page 9, line 25, replace "**Preferred drug list**" with "**Appeal**" and replace "A" with "In addition to any other available legal remedy, a"

Page 9, line 26, replace "to the district court" with "under chapter 28-32" and remove "or its contractor"

Page 9, line 27, after "from" insert "inclusion on", replace "preferred" with "prior authorized or approved", remove "or formulary" and remove "unfair,"

Page 9, line 28, remove the first "or"

Renumber accordingly.

TESTIMONY

BY
Christopher Ward
ON BEHALF OF
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA)
REGARDING ENGROSSED HOUSE BILL 1430

My name is Christopher Ward. I am a health policy consultant specializing in issues relating to patient access to health services. I am based in Bethesda, Maryland, and Hamilton, Ontario, Canada and I am appearing today on behalf of PhRMA to generally support the current form of HB 1430, but to oppose what I understand will be a hoghouse amendment to H B 1430 that will restrict patient access to medicines that have been approved for use by the FDA and are included in the national formulary. Those restrictions include preferred drug lists and perhaps the inclusion of unlawful formularies. I will review each of these concerns with you today.

The Pharmaceutical Research and Manufacturers of America represent America's research-based, innovative pharmaceutical and biotechnology companies. These companies are responsible for the discovery, research and development of over 90% of the medicines in use today. Pharmaceutical innovation – both of breakthrough discoveries and of incremental

advancements – has a profound impact on the lives of patients. At any given time, there are hundreds of products in development – products that will diagnose, treat, cure and possibly prevent chronic and often fatal diseases.

PhRMA can reluctantly support Engrossed HB 1430, but opposes what will likely be the hoghouse version of the Bill because it restricts access to new medicines by creating a preferred drug list, a prior authorization program and a supplemental rebate program. These programs when implemented for drug cost containment purposes interfere with the patient-physician relationship, jeopardize the health of patients and ignore sound fiscal public policy when initiated in isolation of considering the cost-effectiveness of new medicines in the integrated context of overall health spending.

Why ensuring access to new medicines is important in the context of overall Medicaid spending.

Pharmaceutical innovation is changing the way in which health care is delivered. New medicines play an important role in maximizing health care resources because they decrease our reliance on other modalities such as hospitals and long term care facilities. Not only does this save health resources, it also allows patients to remain active, productive members of their communities much longer than in the past.

Because Medicaid covers some of the most vulnerable citizens within our community, Medicaid accounts for a disproportionate share of hospitalization and other institutional care. Although only about 12 percent of America's population is in Medicaid, nationally Medicaid is billed for about 50% of all hospitalizations for schizophrenia, nearly 28% of all hospitalizations for depression and a third of all hospital stays for asthma. All of these conditions can be significantly impacted by pharmaceutical care.

In North Dakota, the financial impacts of the preponderance of Medicaid spending on institutional care are overwhelming. According to CMS statistics, in 2001 over 60 percent of North Dakota's Medicaid spending was on institutional care (hospitals and nursing homes). In fact, during the last decade, institutional care accounted for more than 50% of North Dakota's Medicaid spending growth while drugs and other non durables accounted for less than 10 percent of spending growth during this period. Limiting access to new medicines available under North Dakota's Medicaid program will make it more difficult to contain the costs of institutional care.

The benefits of prescription drugs in reducing hospitalizations within Medicaid programs and allowing seniors to live independently in their own homes has been examined, documented and confirmed by numerous studies. Similarly the impacts of drug access restrictions on increasing hospital and nursing home expenditures are also well documented.

When New Hampshire Medicaid instituted a limit on the number of prescriptions for beneficiaries, Medicaid drug costs were indeed lowered. However, increased spending as a result of increased institutionalization contributed to cost increases that were 17 times greater than the savings achieved in the drug component of the Medicaid program.

The rates of hospitalization in this country have declined by over 30 percent over the last 20 years. Certainly not all of this improvement is due solely to new drugs. In fact, a variety of medical innovations contribute to the national improvement of health outcomes– innovative diagnostics, medical procedures, and better health promotion as a result of improved knowledge about illness and disease. But new drugs have had perhaps the greatest impact on cost-effectiveness. The best example is in the treatment of ulcers and reflux disease where the number of hospital bed days used annually for these conditions dropped by more than two thirds —from 3 million to less than 1 million in 10 short years. Virtually all of this improvement is attributable to new drug therapy.

What makes this example particularly relevant is that this remarkable improvement in outcomes which at the same time produced savings of billions of dollars of avoided health costs was achieved as the result of a variety of drug therapies rather than with a single block buster drug. Utilizing a single preferred product could never produce the same results

because different people react to different medicines in different ways. So from the perspective of cost-effectiveness, access restrictions through preferred drug lists and prior authorizations can impede improved health and financial outcomes.

Why ensuring access to new medicines is important in the context of the quality of patient care and improved health outcomes.

As with most of mankind's innovation, medical advances are usually made in a series of small steps rather than great leaps. This is also true for advances in the safety and effectiveness of medicines. Once on the market, a breakthrough medication inevitably displays some deficiencies. Incremental innovations lead to the development of improved compounds. Incremental advances in drug development represent the evolution of safer and more effective drug therapy. The dismissal of new drugs within an existing class as "me-too'' drugs predicated on the belief that these products merely duplicate original products in that class reflects one of the greatest misunderstandings of the process of drug discovery and development. The benefits of incremental improvements to existing medications are far reaching.

New drug products that are the result of incremental innovations often:

- Have fewer side effects;
- Have improved drug safety and effectiveness;

- Display greater ease of use which facilitates compliance;
- Are less expensive than existing agents;
- Provide alternatives that permit treatments to be better tailored to individual patient needs.

Physicians need to have a variety of treatment options because some individuals will experience a greater number of side effects, others will have a greater sensitivity to the drug, still others will find that the drug is not as effective for them as for others taking the same drug. Having a number of drugs available from the same drug class provides physicians with a number of options for their patients. If one drug does not prove to be effective for their patient, having a variety of drugs within the same therapeutic class ensures that they have the ability to try different options.

Non-Steroidal Anti-Inflammatory drugs (NSAIDs) are an older and well-established drug class that has a number of options available for physicians. NSAIDs all have similar effectiveness and side effects profiles; however, it is very difficult to predict individual patients' response to these drugs. Physicians will not know how a particular patient will react to a given NSAID, and therefore most rheumatologists use a range of 8-12 NSAIDs to treat their patients. Similarly, studies have shown that physicians will change the NSAID that their patient is taking 2-3 times before they find the one that is most appropriate for that patient (one that produces an optimal effect with minimal side effects). Incremental improvements help physicians tailor treatment to older adults.

Having a variety of medicines available within the same drug class can help decrease hospital admissions through (a) more effective care; (b) decreased

side effects; and (c) decreased drug interactions. Many studies have shown that using newer (and occasionally more expensive medicines) will reduce hospital readmissions and the cost of inpatient care, thus saving health care resources.

- To determine if newer medicines are cost effective, a recent study examined the impact of drug age. The study concluded that while newer drugs tend to be more expensive than older drugs, using newer drugs decreases overall health care costs. Drug age was determined by the number of years since the drug received FDA approval, and other health care expenditures were calculated using data from the Medical Expenditure Panel Survey (MEPS) for 1996, 1997, and 1998. The study concluded that when the age of the drug prescribed was decreased from one that was 15 years old to one that was 5.5 years old, non-drug expenditures were reduced 7.2 times as much as drug expenditures were increased. While drug spending increased by $18.00, other spending decreased by $129, yielding a $111 net reduction in total health costs. Decreases in hospitalization expenditures ($80) and physician-office visit expenditures ($24) were the greatest reductions. These results were more marked when an older population (Medicare) was examined. This study highlights the importance of providing access to a wide variety of drugs.

- In another study (Stroupe et al), it was found that while the cost of a newer generation diuretic was higher than the price of the older drug, patients treated with the newer diuretic had significantly fewer hospitalizations than those treated with the older drug (18% versus 34% for coronary heart failure, 38% versus 58% for all cardiovascular

admissions). "Owing largely to reduced readmission to the hospital, the cost of inpatient care for patient with CHF is significantly lower with torasemide than with furosemide, despite the higher acquisition costs of torasemide".

The availability of a variety of medicines within a drug class allows physicians to find the right drug therapy that safely and effectively meets the needs of individual patients. For example to treat depression, a class of drugs called selective serotonin re-uptake inhibitors (SSRIs) is often used. All the drugs within the SSRI class are effective in the treatment of depression, but the challenge for physicians lies in the wide variation in how individual patients respond to specific drugs.

In one study of patients treated with SSRIs for depression, 26% of patients who did not respond to fluoxetine did respond to sertraline. Conversely another study concluded that 63% of patients who failed to respond to setraline responded to fluoxetine. And a third study concluded that the overall success rate from switching from one SSRI to another was 51%. The fact that physicians have a choice of treatments for their patients allows them to find the most appropriate drug for each individual.

The availability of a variety of medications within a drug class increases price competition, since the newer, advanced drug must compete for market share with the existing drugs. Therefore, rather than adding to the expense of a drug class, a variety of drugs within the same class often serve to drive down the price of drugs.

An analysis of pricing trends of 20 new entrants to drug classes in eight therapeutic areas that account for more than half of total retail drug expenditures in 1999, reveals that the majority of new drugs were launched at discounts (often substantial) to the average price of existing drugs within the therapeutic class.

Anything that makes it easier for a patient to take their drugs will improve compliance. Think of taking antibiotics ten years ago: the process was long, involved, and complicated: pills had to be taken four times a day, with (or without) food, for a ten-day period. Today, some antibiotics are taken once a day for a maximum of 3-4 days.

Increased compliance helps maintain patient health, and thus decrease the need for physician visits and hospitalization. This fact is especially important for older adults who are often taking multiple medications (and who often are more forgetful than younger adults).

A variety of drug therapy options are especially important for the optimal treatment of elderly patients, because their diverse response to medications requires individualized care." (Wertheimer et al 2001) Elderly patients require individually tailored care because of the variations that exist from patient to patient, due to the presence of multiple chronic diseases and the physiological changes that accompany aging. The evolution of drug

pages missing

MENTAL HEALTH ASSOCIATION
IN NORTH DAKOTA

"Touching a Life"

Executive Director
Allan Stenehjem

Past Presidents, National Mental Health Association
Richard Weber
Bismarck, 1995-96
Michael Unjhem
Fargo, 1987-88
Geridee Wheeler
Bismarck, 1967-68

HB 1430

Senate Human Service Committee

Mental Health Association in North Dakota

Allan Stenehjem

March 17, 2003

Madam Chair and members of the committee, my name is Allan Stenehjem. I am the executive director of the Mental Health Association in North Dakota. The MHA is a non-profit volunteer citizens organization affiliated with the National Mental Health Association.

One of the primary missions of the Mental Health Association in North Dakota is to ensure the availability of appropriate, accessible, and adequately funded treatment and support services for persons with mental illnesses throughout the state of North Dakota. During the last 3 - 4 decades, our organization has worked closely with the legislature, the Department of Human Services, consumers and their families to move our state's delivery system from an over reliance on institutional or custodial care to a community-based system of care that enables them to be independent productive citizens.

One of the greatest challenges government faces is how it incorporates, or fails to incorporate, areas of progress and success into fiscal planning. That is largely the result of the constitutional structure and function of the legislative and executive branches in our state.

Each year, the executive branch produces an executive budget proposal. In creating that, each agency is individually asked to submit its budgetary requirements for consideration. Each agency provides its own framework, absent any input or reflection upon

United Way Agency

State Office • Mental Health Association in North Dakota, 1459 Interstate Loop PO Box 4106, Bismarck, ND 58502-4106 (701)255-3692•Fax (701)255-2411
Regional Office • Mental Health Association in North Dakota, 124 North 8th Street, Fargo, ND 58102-4915 (701)237-5871•Fax (701)237-0562
A private, non-profit 501(c)(3) agency. "The only non-governmental organization concerned with all aspects of mental health for all citizens of North Dakota."
Visit our website at www.mhand.org **HELP-LINE 1-800-472-2911**

programmatic implications in other agencies. Thus, the proposed state budget often times does not recognize that while an increase in medication expenses in DHS's Medicaid budget is offset many times over by millions of dollars being saved in the State Hospital's budget as it is able to continue to downsize it's psychiatric hospital. Conversely, as access to medications that are critical to the treatment of persons with mental illness in the state is restricted to save scarce resources in the Medicaid budget, it is offset by millions of dollars needed to support the State Hospital.

During the budget hearing this session on the State Hospital, the superintendent stated, "the daily patient census and admissions to the hospital continues to decline." He cited the *number one* reason for this decline as being "The decrease in population was made possible because of the availability of psychotropic medications." The other is the state's commitment to developing community-based services for the treatment of mental illness.

Without effective medications, the trend toward community-based treatment and recovery cannot continue. Admittedly, additional dollars have been spent in North Dakota for new drugs to treat mental illness. But they have helped save millions of dollars in in-patient admissions to the State Hospital and other in patient treatment centers.

Throughout the country, and North Dakota is no exception, state legislators are grappling with the issue of how pharmacy expenditures under Medicaid and other public health programs can be effectively managed.

Under consideration are various management techniques that will restrict access to expensive drugs. The most prevalent of these techniques is the establishment of preferred drug lists (PDLs) and the creation of prior authorization (PA) limitations or restrictions for all drugs on the preferred list.

The question for you today is: what is an appropriate, effective and fair public management policy for access to psychotropic drugs? Psychotropic drugs work

differently from other drugs. Pharmacy benefit management procedures such as prior authorization may not cause problems for the treatment of physical illness; however, they will **adversely** affect the treatment of persons with mental illness.

There are several fundamental considerations that indicate that the drugs used for the treatment of mental illness, psychotropic drugs, should be afforded full PDL status and be **exempted** from prior authorization requirements.

The Mental Health Association in North Dakota urges you to consider not including Psychotropic drugs in the Preferred Drug List and Prior Authorization as proposed in SB 2088 for the following reasons:

1. **Psychotropic Drugs Are Different From Other Drugs.**
   a. The average patient response time for psychotropic drugs is from 3 to 6 weeks, and can be even longer. Most other medications have a response time of hours or even minutes. The necessary time for eliminating the effects of psychotropic drugs is similarly lengthy.
   b. Psychotropic drugs are far more likely to induce distinctive treatment responses in patients than are other medications.
   c. Psychotropic drugs are associated with a considerable number of adverse side effects, especially when medical co-occurring conditions, treated and untreated, are present.
   d. Compliance is a significant issue when treating persons with mental illness with drugs, and all the preceding factors contribute to making compliance even more difficult.

2. **<u>Restrictions to Medication Impair Clinical Decision Making/Patient Care</u>**
   a. The special complications for clinical decision making created by psychotropic drugs demand that interference with physician choice be minimized.

b. Restrictions imposed by formulary management will interfere with clinical choices necessary to provide the most appropriate medical care, i.e. the most tolerable and effective treatment for each individual patient.

c. Physician, not third parties, should make medical decisions.

3. **Effective Psychotropic Drugs Are Essential to Maintain Persons with Mental Illness in the Community.**

a. Patients who do not receive the appropriate psychotropic drugs are often unable to function as members of the general community and may require hospitalization.

b. Failure to adequately provide access to psychotropic drugs may create an ADA violation (Olmstead) because the state will not be providing the necessary services for all individuals that will keep them from unnecessary institutionalization.

c. The goals of mental health system reform, i.e. community-based placement and treatment, will be undermined if patients access to appropriate drug treatment in restricted.

4. **Negative Fiscal Impact Created by Restriction of Access to Medications.**

a. It is well established that restricting access to drugs often fails to achieve the intended goal of cost containment because unanticipated problems are created that necessitate greater utilization of the overall health system.

b. Initiatives to reduce Medicaid and other public health program pharmacy expenditures must take into account the effect of 1) reduced federal financial participation for decreased state expenditures on pharmaceuticals and 2) increased state expenditures for more costly hospitalizations and other intensive outpatient services.

c. Mental illnesses are often chronic conditions that create substantial disability. The illnesses are often correlated with other costly social

problems such as unemployment, homelessness, and incarceration. Inappropriately treated mental illness clearly has consequences for the community at large as well as for the individual diagnosed with the disorder.

Madam Chair, for these reasons I would like to offer the following amendment to exempt Psychotropic Drugs from Preferred Drug Lists and Prior Authorization requirements.

TESTIMONY BEFORE THE SENATE HUMAN SERVICES COMMITTEE
REGARDING HOUSE BILL 1430
MARCH 17, 2003

Chairman Lee, members of the committee, I am David Zentner, Director of Medical Services for the Department of Human Services. I appear before you to provide information and support the need for the Department to have the authority to implement a prior authorization process for prescription drugs paid through the North Dakota Medicaid Program. However, the Department cannot support this bill in its present form.

As you are aware, North Dakota like most other states are faced with making difficult decisions regarding the funding of many services including health care for its low-income citizens. In preparing the budget for the next biennium the Department looked for ways of reducing the cost of the Medicaid Program without compromising the quality of services provided to Medicaid recipients.

One of the tools that is utilized by most state Medicaid Programs to ensure the delivery of quality services and at the same time reduce the overall cost of prescription drugs is to implement a prior authorization process for certain drugs. The Department included savings of $1.0 million in general funds when we prepared the budget in anticipation of receiving authority from the Legislature to implement such a program. The Department introduced Senate Bill 2088 to accomplish this goal. It was designed to use a private sector process that was already in place as a basis for establishing our prior authorization program. The Drug Use Review Board consisting of physicians and pharmacists would make the final recommendation as to what drugs would require prior authorization. This bill was defeated in the Senate.

The remaining mechanism available to implement a workable prior authorization process is the bill you have before you today. The bill in its present form creates

many administrative and legal issues that will slow and possibly prevent the implementation of prior authorization. If sufficient changes are not made to this bill, the Department would recommend it be killed and the legislature add back the $1.0 million in general funds in projected savings for the 2003 – 2005 biennium.

I now want to tell you the parable of three individuals in line to pick up their prescriptions at the local pharmacy.

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

TESTIMONY BEFORE THE SENATE HUMAN SERVICES COMMITTEE
REGARDING HOUSE BILL 1430
MARCH 17, 2003

Chairman Lee, members of the committee, I am Dr. Brendan Joyce, Administrator of Pharmacy Services for the Department of Human Services. I appear to provide testimony regarding this bill. Due to certain parts of the bill as it stands, I must reiterate that the Department is against HB 1430.

Prior authorization is explicitly allowed by the Centers for Medicare and Medicaid Services (CMS) and in fact it is encouraged as a tried and true method for cost effective medication utilization. Prior authorization is often perceived with a negative connotation; however, it serves many purposes.

First and foremost, it serves as an educational vehicle for physicians and other prescribers. National studies have shown that physicians do not know the relative cost effectiveness of all medication. In order of importance, cost will fall behind effectiveness and safety, as it should. Fortunately, the majority of prescriptions are written for conditions where multiple products would work equally well and therefore cost is the only differentiating factor. A properly structured prior authorization program provides the missing information for the physician.

Second, prior authorization serves as an educational vehicle for patients. Medicaid recipients do not typically remain on Medicaid for extended periods of time. A properly structured prior authorization program will help the patient understand that many different products are equally effective for certain indications, despite what the endless television advertisements say. This will help ensure that the patient will be taking the most cost effective products when they are no longer eligible for Medicaid. This will prevent some of the 'sticker shock' when they pay for their medicine in the private sector.

Third, prior authorization programs can improve the health of the recipients and avoid medication errors and side effects. Currently, there are many prospective and retrospective processes that work to reduce medication errors and interactions. Despite this being used universally through all pharmacies, medication interactions still claim thousands of lives yearly. Pharmaceutical companies, with their millions of dollars spent towards education, still could not prevent many products from being used with interacting medications or without the necessary lab monitoring. A large number of medications had to be removed from the market because of these issues. A properly structured prior authorization program can prevent many of these problems and assist pharmaceutical companies in keeping life saving drugs on the market. It may also save some of our citizen's lives.

Representatives from PhRMA have brought up tragic scenarios from other states. I have contacted these other states. They do not prior authorize anti-rejection drugs for liver transplant patients. They don't prior authorize cancer or HIV medication. Any delay in their therapy can be traced to misinterpretation or misunderstanding. For instance, per federal law, if a physician or pharmacist feels that the product is necessary, the patient can receive 72 hours supply; therefore, no patient will ever go without medicine if the providers utilize the available safeguards. A prior authorization process is not a process for denying care; it is a process for guiding appropriate, cost-effective care.

By developing this prior authorization process through the input of the ND Medical Association, ND Hospital Association, and the ND Pharmacy Association, with the safeguards guaranteed by the federal and state governments, the citizens of ND can rest assured that the Medicaid recipients will receive excellent, cost effective care.

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

TESTIMONY BEFORE THE SENATE HUMAN SERVICES COMMITTEE
REGARDING HOUSE BILL 1430
MARCH 17, 2003

Chairman Lee, members of the Committee, I am Krista Andrews, Attorney for the Department of Human Services. I am here today to express concerns with Sections 8 & 9 of this bill, and therefore cannot support this bill.

Section 8 of HB 1430 raises numerous concerns. First, it creates a new cause of action against the Department. Second, section 8 does not limit the instances in which a person could bring an action against the Department when their health care may have been denied or delayed as a result of an "administrative procedure." Under the current wording a person could conceivably bring as many such actions as he or she wants. Also, under the current language there is no limit to the "administrative procedures" that could be challenged in court. Finally, section 8 enables courts to award attorneys' fees and court costs to persons suing the Department at the Department's expense.

In short, this section creates a "remedy" that is unnecessary, unwarranted, and precarious. It is unnecessary and unwarranted because HB 1430 itself establishes the procedures that must be followed by the drug utilization review program and the drug prior authorization program. It is also unnecessary because the Medicaid law already requires the North Dakota Medicaid program to give an appeal right to any Medicaid recipient who is denied benefits or whose benefits are reduced. These appeals may be taken from the administrative level to the district court, and ultimately up to the North Dakota Supreme Court. Finally, this section is precarious because it will expose the Department and consequently the taxpayers of

North Dakota to additional costs and claims. Therefore, the Department respectfully requests that Section 8 be removed in its entirety from HB 1430.

Even with the amendments proposed by PhRMA, section 9 of HB 1430 is surplusage. Pharmaceutical manufacturers already have the remedy that they propose, as they can already sue the state if an agency violates state or federal law in a way that harms the manufacturer. For this reason, the Department again respectfully requests that Section 9 be removed in its entirety from HB 1430.

Sections 8 & 9 have the potential of substantial costs to the Department. As sections 8 & 9 were amended into the bill, the potential costs were not included when the fiscal note was prepared.

There is one other area on which the Department would request clarification. In several places in the bill, notice is required to be given to the public 30 days before certain decisions about drugs are made. The Department seeks clarification on how this notice is to be given. Also, the bill sometimes states that notice has to be "furnished" to the public, and in other places it states that notice must be "published." If there were an intended difference, the Department would ask what was intended by this difference and request clarification.

This concludes my testimony. I would be happy to try to answer any questions the committee members may have. Thank you.

NORTH DAKOTA PHARMACEUTICAL ASSOCIATION

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Testimony before the Senate Human Services Committee
HB 1430
Monday, March 17, 2003
Galen Jordre – Executive Vice President

On behalf of the North Dakota Pharmaceutical Association (NDPhA), an organization that represents 700 pharmacists practicing in the state, I want to indicate opposition to HB 1430 in its present form.

While our Association has gone on record in support of a prior authorization program for the Medicaid program, we feel that the process outlined in this bill is cumbersome and does not improve the ability of the Department to design safe and effective programs for Medicaid recipients.

I will outline specific areas that are problematic to us.

- The definition of "compendia" in Section 1 includes clinical information submitted to the department by pharmaceutical research companies. This type of information is not included in the definition of compendia contained in 42 U.S.C. 1396r-8(g)(2) the federal regulation that sets permissible standards for developing drug use review programs. Development of programs based on this type of information may cause the program to be in non-compliance with federal requirements.
- In Section 2 the establishment of an eighteen person drug utilization review (DUR) board creates a large board that will add to administrative expense to the Department. Inclusion of non-professional members would not add significant value to the clinically based decisions made by the board.
- In Section 3 (3) the inclusion of outside information provided by interested parties goes beyond the federal standards for developing drug use review programs as outlined in 42 U.S.C. 1396r-8(g). Development of programs based on this type of information may cause the program to be in non-compliance with federal requirements.
- In Section 4 (3) the prospective review process provides that when a pharmacist reviews prescriptions at the point of sale for potential drug therapy problems no changes can be made in the prescription. We would understand the requirement for a new prescription for any alterations would mean that the pharmacist could not change any prescription without consulting the prescriber, as is required by pharmacy law. However the requirement for patient approval is not consistent with medical practice. This would appear to give the patient veto power over any decisions that prescriber and pharmacist make in relation to prescribed therapy.
- In Section 5 we feel that the duties of the pharmacy and therapeutics committee could be combined with those of the DUR board. If the physicians and pharmacists making up the pharmacy and therapeutics committee were chosen from the DUR board, that would mean that those members would be attending 12 meetings annually. If the members are chosen outside the DUR board, it may become difficult to recruit sufficient members to fill both boards. We do feel that the membership of this type board should be made up only with physicians and pharmacists, as is done for formulary committees in hospitals and institutions around the state.

- In Section 7 (2) we feel that the requirements may complicate the process. The requirement to develop total health care costs in (c) may be beyond the capabilities of the Department in a practical manner. The opportunity for oral presentations in (d) could lead to lengthy meetings. We would support the ability of any party to submit written information prior to the meeting where a decision is made. The inclusion of a grievance process in 7 (3) regarding decisions of the committee gives many different entities an avenue to delay decisions and increase cost to the Department.
- In Section 8 the language would appear to give recipients ability to by-pass any appeal processes that are currently in place and could open new costs to the Department.
- In Section 9 the language provides a right to appeal that is based on language related to formularies (42 U.S.C. 1396r-8(d)(4). The prior authorization process approved in federal regulations does allow single source drugs to be included without meeting formulary requirements.

While there are portions of this bill that may make it difficult to implement, we do support the idea of formulating a strong structured DUR board that is made up of physicians and pharmacists. A strong board will provide legitimacy to processes utilized by the Department and insure that proper medication use is the foremost concern when any decisions are made. We feel that with these professionals providing recommendations to the Department that patients will be protected and that the processes developed will be efficient for the prescribers and pharmacists that will have to carry them out.

The function of the DUR Board is to provide education to physicians and pharmacists about appropriate drug use within the Medicaid program based upon data prepared by the department or its contractors. In the same light, the prior authorization process can serve to be an education process by providing prescribers the tools to make appropriate prescribing decisions. History from other states shows that the prior authorization process is not effective through denial of treatment, but through education. The prior authorization process does not affect the majority of prescribers on a routine basis. Information provided by the state of Maine with 77 drugs subject to basic prior authorization and 60 drugs subject to dose consolidation prior authorization provides the following statistics for January to September of 2002:

- Total volume of prior authorizations processed was 31,169, amounting to 0.9% of total claims.
- 93% of the claims were approved
- 91% of determinations were made within 24 hours with an average time of 2.08 hours.
- Only 3.5% of providers were affected by prior authorization program on any day (17.5%/week).
- The program produced 8.3% annualized savings.

The NDPhA realizes that an efficient prior authorization program can produce savings to the state Medicaid program. However it must be established with strong structured input from the physicians and pharmacists that must work with it. The DUR Board made up of practicing physicians and pharmacists can provide this input. In addition, there must be a mechanism for the public to provide information and comment on decisions. Provider input through the DUR Board can also assist the Department in designing the process to insure that there is a minimum of interference to patient care.

We would be very happy to work with the bill sponsors, Department, other provider groups, and the pharmaceutical industry to work on any revisions that you feel are necessary to protect patients and provide savings for the Department to meet budget goals.

orth Carolina Prior Authorization Program

Therapeutic Class Code: S2B
Therapeutic Class Description: Non-Steroidal Anti-Inflammatory Drugs Including COX-2 Inhibitors

Medication	Generic Code Number(s)
Vioxx (Rofecoxib)	93181, 93191, 93161, 93351, 42222
Celebrex (Celecoxib)	42001, 42002
Bextra (Valdecoxib)	15475, 15481

Criteria:

1. Patient must have a diagnosis of osteoarthritis, rheumatoid arthritis, degenerative joint disease, or chronic pain of greater than 3 months duration **AND**

2. At least one of the following documented under "Justification" on the PA form:

   a. history of GI bleed or gastric or duodenal ulcer
   b. history or symptoms of PUD, gastritis, or GERD while on conventional NSAIDS
   c. concurrent use of corticosteroids
   d. concurrent use of warfarin or heparin
   e. history of platelet dysfunction or coagulopathy **OR**

3. Patient's age is 60 or greater.

Approval length: 1 year for patients 60 and over; all other criteria for 6 months

References:

1. Merck & Co., Inc. Vioxx package insert. Whitehouse Station (NJ): 2001 Jul.
2. Pfizer Inc. Celebrex package insert. New York (NY): 2001 Oct.
3. Bextra package insert.
4. Noble SL, King DS, Olutade JI. Cyclooxygenase-2 enzyme inhibitors: place in therapy. Am Fam Phys 61(12).
5. Schoenfeld P. An evidenced-based approach to the gastrointestinal safety profile of the COX-2-selective anti-inflammatories. Gastroenterol Clin North Am. Dec 2001 30(4):1027-1033.
6. Celecoxib for arthritis. Med Lett Drugs Ther 1999;1045:11-12.
7. Rofecoxib for osteoarthritis and pain. Med Lett Drugs Ther 1999;1056:59-62.

Minnesota Department of **Human Services**

PPI prior authorization criteria recommended by the DFC on December 17, 2001:

Prior authorization is required from Day 1 for all proton pump inhibitors except pantoprazole.

Authorization criteria are dependent on the diagnosis:

Gastric/duodenal ulcer: Patient must have had a documented assessment for H. pylori. If the patient tests positive for the bacteria, pantoprazole may be used as part of a H. pylori eradication regimen. Other proton pump inhibitors may be used for this purpose for up to 4 weeks only if there is a documented history of pantoprazole treatment failure or intolerance. If the patient tests negative, a documented trial of either an H2 antagonist (including a high dose trial at the manufacturer's recommended maximum dose) or pantoprazole is required before authorization to use another proton pump inhibitor will be granted

Gastroesophageal reflux disease (GERD): A patient with erosive esophagitis, history of an esophageal stricture, and a documented failed pantoprazole trial may receive authorization to use another proton pump inhibitor for up to one year. Patients without erosive esophagitis or an esophageal stricture who have failed a pantoprazole trial due to lack of efficacy may receive authorization to use another PPI for up to one year. Patients without erosive esophagitis or an esophageal stricture who have failed a pantoprazole trial due to an adverse reaction must also have failed a high-dose H2-blocker trial before PA will be granted.

Pathological hypersecretory conditions: (Zollinger-Ellison Syndrome). Prior authorization may be granted for up to one year. No trial of pantoprazole is required.

Recipients who can't swallow (aphagic adults, children, persons with g-tubes, etc) – use of omeprazole or lansoprazole may be authorized. No trial of pantoprazole is required.

Example Brand Name	Generic Name
Allegra®	Fexofenadine
Clarinex®	Desloratadine
Claritin®	Loratadine
Zyrtec®	Cetirizine

NOTE:

- All new LSA's marketed after the effective date of this bulletin shall also be subjected to the criteria in this document.
- Combination low or non-sedating antihistamine products containing pseudoephedrine shall be covered as two separate prescriptions; one prescription for the low or non-sedating antihistamine and one prescription for OTC pseudoephedrine.
- Examples of antihistamines that do NOT require prior authorization when prescribed generically: clemastine, chlorpheniramine, brompheniramine, diphenhydramine.

AGE EXCEPTION TO THE PRIOR AUTHORIZATION PROCESS: Prior authorization is not needed

1. if the patient is 65 years of age or older; or
2. if the patient is between 6 months and 19 years of age and the prescribed low sedating antihistamine is indicated for child's age. See attached age criteria chart to determine prior approval/coverage status. Special consideration may be requested when age criteria are not met (see end of page 2).

HOW IS AUTHORIZATION REQUESTED?

PRESCRIBER ---

By Contacting First Health Directly: The prescriber may request authorization by phone directly from First Health Services Managed Access Program (MAP) Help desk by calling or faxing the patient's diagnosis and the other required information.

1. Phone: 1-800-780-6465
2. FAX: 1-800-229-3928

(A fax request form is enclosed and is also available at www.hhs.state.ne.us/med/medindex.htm .)

OR

By Providing the Pharmacist with the Needed Information: In certain situations, as noted on the next page, the prescriber may write the needed information on the prescription. The pharmacist will call or fax the information to First Health.

PHARMACIST ---

The dispensing pharmacist may use medical information provided by the prescriber to request authorization by phone directly from First Health Services Managed Access Program (MAP) Help desk by calling or faxing the patient's diagnosis and the other required information. The pharmacy must maintain this written information for the same length of time as the prescription record is required to be maintained by statute or regulation. Electronic storage/imaging shall meet this requirement.

1. Phone: 1-800-780-6465
2. FAX: 1-800-229-3928

(A fax request form is enclosed and is also available at www.hhs.state.ne.us/med/medindex.htm .)

Prepared by the Department of Human Services for Senator Judy Lee and the Senate Human Services Committee. All dollar figures for savings (or cost) are pre-drug rebate total (state plus federal) dollars.

MAC List

The department implemented a Maximum Allowable Cost (MAC) list for reimbursement of many drugs. This process began in September of 2002. Between September and December, enough products were placed on the MAC list to save approximately $133,000 per month in pharmacy payments. In January, after negotiating with the ND Pharmaceutical Association (NDPhA), the entire list (1,103 drugs) was implemented for an additional $200,000 per month savings.

Dispensing Fee

The department raised all dispensing fees (brand and generic) by $0.50. This was a result of negotiation with the NDPhA as part of the MAC list implementation; by giving the increased dispensing fee, we were able to fully implement the MAC list 5 months ahead of schedule.

- Previously, pharmacists collected an average of $4.01 for dispensing fees (87% of allowed $4.60)
  - $4.20 for brand (91.3% of allowed)
  - $3.80 for generic (82.6% of allowed)
- Generics are now reimbursed at much lower (MAC) levels, therefore the cost of the increased dispensing fee will only truly be felt on brand name drug side
  - Theoretically, increased dispensing fee for generics will cost $19,000 – $21,000
- 46,000 brand name scripts per month
- $0.4565 per prescription (91.3% of $0.50 allowed amount)
- $20,999 per month cost for increase in dispensing fee for brand name scripts
- $200,000 per month savings with completed MAC list implemented as a result of negotiations ($333,000 per month total)
- Intent is to shift the dispensing fee increase to only generic drugs as an incentive to pharmacies to increase generic dispensing. This incentive is a very common practice in both private and government pharmaceutical plans.

Edits

The department has implemented a large number of edits during the past year with excellent results.

- One dispensing fee per month = $193,000 per year maximum savings
- Tablet splitting = $200,000 per year maximum savings
- 80% utilization = $250,000 per year maximum savings
- Early refill over-ride limitations = $100,000 per year maximum savings

- Proton Pump Inhibitor edits (e.g. Prilosec®, the Purple Pill™) = $800,000 per year maximum savings
- Quantity limits = $500,000 per year maximum savings

The department is always looking at new areas for edits without compromising patient care and will continue to make appropriate changes and modifications to the above edits and any additional edits that may be brought to our attention. Two of the above edits came from NDPhA (tablet splitting and proton pump inhibitor edits).

Co-pays

The department implemented a co-pay of $3.00 per brand name prescription in August of 2002. This is the maximum allowed under federal law 42 CFR Ch.IV § 447.55 (see table).

States Payment for the service	Max co-pay
$10 or less	$0.50
$10.01 to $25	$1.00
$25.01 to $50	$2.00
$50.01 or more	$3.00

No co-pay was imposed on generic drugs for two reasons. First, the maximum allowed would be $1.00, which was not considered to be significant for cost savings. Second, we don't want to provide a disincentive for patients to use the less expensive alternatives.

The co-pays were anticipated to save $1 million in pharmacy payments per year based solely on the patients' portion of payment. What has happened, however, is that the percentage of generic use has increased from 45% to 49%, which translates into a savings of roughly $2.8 million because of the overall cheaper cost of generic drugs (as illustrated below).

- 1.1 million prescriptions yearly
- Old 45% generic / 55% brand expenditures
  - 605,000 brand prescriptions at $85.70 per Rx = $51,848,500
  - 495,000 generic prescriptions at $20.65 per Rx = $10,221,750
  - Total = $62,070,250
- New 49% generic / 51% brand expenditures
  - 561,000 brand prescriptions at $85.70 per Rx = $48,077,700
  - 539,000 generic prescriptions at $20.65 per Rx = $11,130,350
  - Total = $59,208,050
- Savings resulting from increased generic use = $2,862,200

If co-pays were placed on generics, it is likely that a portion of the savings from the above would disappear.

TESTIMONY BEFORE THE SENATE APPROPRIATIONS COMMITTEE
REGARDING HOUSE BILL 1430
MARCH 31, 2003

Chairman Holmberg, members of the committee, I am David Zentner, Director of Medical Services for the Department of Human Services. I appear before you to provide information regarding the fiscal note and support the amended version of this bill.

The Department submitted Senate Bill 2088 in order to develop a prior authorization and preferred drug list process to assist the Department in assuring that Medicaid recipients receive appropriate drug therapy in the most cost effective manner possible. The Senate defeated Senate Bill 2088. This bill is the remaining avenue available for the legislature to authorize this tool to better manage the drug program in the North Dakota Medicaid Program.

The Department had originally contemplated using the private sector information as a basis for development a list of drugs that would require prior authorization. Based on that assumption that we could implement such a program in a short period of time, we estimated a general fund savings of $1 million and built that savings into the Governor's Executive budget.

The bill that you have before you today requires the Department with the assistance of physicians and pharmacists to independently develop a list of drugs that will require prior authorization before the Department will pay for the prescribed drug. As a result, there will be a delay in the time it will take to implement the prior authorization process.

The fiscal note that you have before you reflects that difference. We would request that if this bill is passed that you restore $227,000 in general funds to the Department's Medicaid budget.

While the Senate version of this amended bill does not meet all our original expectations, we believe it will accomplish the main goal of establishing a prior authorization process that will ensure that our recipients will continue to have access to needed drug therapy in the most cost effective manner possible.

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

TESTIMONY

HB 1430 – PROTECTION AND ADVOCACY PROJECT

SENATE APPROPRIATIONS

HONORABLE RAY HOLMBERG, CHAIRMAN

MARCH 31, 2003

Chairman Holmberg, and members of the Senate Appropriations Committee, I am Bruce Murry, an employee of the North Dakota Protection and Advocacy Project. P&A opposes Senate Bill 2083 in its current engrossed form.

Recent amendments to HB 1430 removed due process provisions that allowed an individual to obtain an emergency 72-hour prescription and have expedited due process to review the propriety of the prescription. Those provisions allowed the best of both worlds – the cost savings of a preferred drug list and a method to obtain a specific medication if the physician firmly believes it necessary.

Without a short term, emergency prescription, the patient may receive a medication the physician feels is inferior. Without an expedited due process method, the patient may need to resort directly to the judicial system. Either of these problems could lead to increased expenses for the state and a poor result for the patient.

Thank you for this opportunity and I will address any questions you may have.

Howard Anderson #3

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Testimony before the Senate Appropriations Committee
HB 1430
Monday, March 31, 2003
North Dakota Pharmaceutical Association

On behalf of the North Dakota Pharmaceutical Association (NDPhA), an organization that represents 700 pharmacists practicing in the state, I want to indicate support for HB 1430 in its present form. Our Association has gone on record in support of a prior authorization program for the Medicaid program and we feel that the process outlined in HB 1430 as engrossed provides a responsible way for the Department of Human Services to design safe and effective medication use programs for Medicaid recipients.

We do support the concept of a strong and structured Drug Use Review (DUR) board made up of physicians and pharmacists practicing in the state. The proposed amendments to Engrossed HB 1430 provide this control, allow for public input, and allow for institution of an efficient process. A strong board will provide legitimacy to processes utilized by the Department and insure that proper medication use is the foremost concern when any decisions are made. We feel that with these professionals providing recommendations to the Department that recipients will be protected and that the processes developed will be efficient for the prescribers and pharmacists work with them.

The function of the DUR Board is to provide education to physicians and pharmacists about appropriate drug use within the Medicaid program based upon data prepared by the department or its contractors. In the same light, the prior authorization process can serve to be an education process by providing prescribers the tools to make appropriate prescribing decisions. History from other states shows that the prior authorization process is not effective through denial of treatment, but through education.

The prior authorization process does not affect the majority of prescribers on a routine basis. Information provided by the state of Maine with 77 drugs subject to basic prior authorization and 60 drugs subject to dose consolidation prior authorization provides the following statistics for January to September of 2002:

- Total volume of prior authorizations processed was 31,169, amounting to 0.9% of total claims.
- 93% of the claims were approved
- 91% of determinations were made within 24 hours with an average time of 2.08 hours.
- Only 3.5% of providers were affected by prior authorization program on any day (17.5%/week).
- The program produced 8.3% annualized savings.

The NDPhA realizes that an efficient prior authorization program can produce savings to the state Medicaid program. However it must be established with strong structured input from the physicians and pharmacists that must work with it. We are ready to work under the structure of this bill to improve the effectiveness of the Medicaid prescription drug program.