MICROFILM DIVIDER

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

ROLL NUMBER

DESCRIPTION

2284

2005 SENATE HUMAN SERVICES

SB 2284

2005 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. SB 2284

Senate Human Services Committee

☐ Conference Committee

Hearing Date January 25, 2005

Tape Number	Side A	Side B	Meter #
1		x	4298-6225
2	x		00-4990
3	x		3110-end
Committee Clerk Signature			

Minutes:

Chairman Lee opened the public hearing on SB 2284. All members were present.

Testimony in favor of SB 2284

Senator Karen Krebsbach, District 40 in Minot was the main sponsor of this bill and introduced it. See written testimony (Attachment 1)

Chairman Lee made note of the fiscal note.

Bruce Levi, North Dakota Medical Association See written testimony (Attachment 2)

Sen. Warner: Can you elaborate why the psychotropic drugs were left off?

Levi: There's been a lot of discussion on these drugs and the specific population and what these drugs mean to that population. The drug use review board has been careful in looking at that area. There was a 24-month program with CNS, it has an education program in place that is going over the data and giving information to providers they might need.

Neutral testimony on SB 2284

Dr. Brendan Joyce, Administrator of Pharmacy Services for the Department of Human Services. See written testimony (Attachment 3, 3A, 3B)

Chairman Lee: I have concern because I was told that a physician had "dispense as written" on his prescription pad. An astute pharmacist would at least require that it be initialed. But drug companies are eager to supply physicians with these pads.

Joyce: That is a common complaint.

Dr. Joyce went on to explain the methods drug companies use to keep medicines from becoming generic by changing patent information. This is called "evergreening" which is a way of protecting the patent on a drug. Chairman Lee talked about Medicaid paying for over the counter (OTC) drugs but private insurance doesn't.

Chairman Lee: How do we do a preferred drug list and prior authorization. If we're going to end up with the elderly and disabled going to part B and they're going to have a PDL anyhow, that a big component in the Medicaid drug cost.

Joyce: Unfortunately, the folks on part B, when they move over, its still going to be a very large part of the drug costs. We have no control over it. To make it less burdensome, there are some great systems out there to where its computerized and invisible. About 70% of prior authorizations that could be done, if we could get it set up and actually have it in a draft or fee, for the new MMIS system, we have in that requirement that there be a smart prior authorization system. Which means, pharmacy sends in a claim, if we require that they try another drug within two years, it will look to see if they tried that drug in the claims history--as that claim comes in, before they send a response to the pharmacy. If it sees it (that they've tried the other drug required) there's no paperwork for the physician. It would be invisible to the patient and the

only time prior authorization is required is if they don't meet the criteria based on claims history. And then, if they're required to try something else first, that's when they'd do that first. The pharmacy and the physician would work together and this would cut down on paperwork for prior authorizations by 50-60%. That would be the ideal situation to cut down on paperwork. This is where I'm hoping to take this to, to improve efficiencies.

Dr. Joyce explained the criteria for prior authorization versus PERS patient. (Tape 2 side A meter 2400-2860)

Neutral testimony on SB 2284

Linda Wurtz, Associate State Director for Advocacy for AARP North Dakota

Wurtz: I signed in as being neutral, but I am a big fan of evidence based research that is unbiased. We recognize the benefits of a preferred drug list and prior authorization but we have a couple of concerns with this particular bill. One is the "dispense as written" problem; the other is that this seem to have a blanket exemption for drugs prescribed for mental health and although we realize that there are some special previsions for prescribing drugs for mental illness, I would caution the committee to give them a forever blanket exemption. Perhaps a sunset on that exemption, and continue to look at ways we could find evidence based research that would support some kind of prior authorization in this area as well, because it's an ever developing area of study and because we would like to see our dollars put back to use, they could meet the demands of more people.

Testimony in opposition to SB 2284

Joel Gilbertson, Pharmaceutical Research Manufacturers of America (PhRMA), introducing Linda Carroll-Shern, Regional Director PhRMA See written testimony (Attachment 4, 4A)

No further testimony.

Chairman Lee closed the hearing on SB 2284.

Chairman Lee offered to provide the committee with any additional information needed to help with this bill.

Sen. Warner: I'd like to put a sunset clause on just a specific exemption on psychotropic drugs. Just so we review it again in two years.

Sen. Brown: I agree with what you're trying to do, but by the same token, I'm concerned that we give a blanket exception to those. It's a *huge* part of Medicaid, couldn't there be some kind of control, cost savings of some kind.

Sen. Lyson: I'm surprised, the mental health people were here and didn't say anything.

Chairman Lee: They want the exemption; they asked for it last time, but we assured them that nobody was going to be deprived of an appropriate psychotropic drug. Their worry was that the people wouldn't get the drugs they wanted. We assured them that wasn't going to happen if they were left in so all drugs were open to consideration. And there hasn't been a problem with that so they can't say they've been poorly treated. The mental health concerns are not causing them to say they have any problems. The only two types of drugs that have yet been approved for prior authorization are the proton pump inhibitors and antihistamines; and they're looking at doing additional classifications of drugs. The drug utilization review board have been working hard at

this, but they just really got going about a year ago because it got a long time to get through administrative rules, which was controversial.

There was general discussion on the task force, preferred drug lists and prior authorization and the effect of this bill the budget. (Tape 3 side A meter 300-1390). Sen. Warner asked a question of Dr. Robert Beattie from Hettinger concerning prior authorization. (Tape 3 side A meter 1400-1480).

Discussion continued after lunch. (Tape 3 side A meter 3110-4065). Dr. Beattie was asked about the difficulty dealing with Medicaid patients and how some physicians will not accept them because they can only recover about 50% of their costs. Medicaid puts up road blocks when dealing with these patients. The committee also discussed preferred drug lists, the time spent with patients due to Medicaid rules and how some Medicaid patients doctor shop and pharmacy shop to get multiple prescriptions.

Chairman Lee was concerned that the bill, being written as it is, is like a blank check for Medicaid patients. Maybe there could be an electronic benefit card. How can we keep patients from pharmacy shopping, without making it hard for the physicians.

There was also discussion on more efficient drug administration taking place. Also, how advertising effects what drugs people ask for.

Chairman Lee mentioned the dual-eligible problem coming into effect January 1, 2006. Discussion ended on SB 2284.

2005 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. SB 2284

Senate Human Services Committee

☐ Conference Committee

Hearing Date February 1, 2005

Tape Number	Side A	Side B	Meter #
3	x		2130-2400
Committee Clerk Signature			

Minutes:

Chairman Lee reopened the discussion on SB 2284. All members were present.

Chairman Lee: There are going to be significant changes January 2006 having to do with dual-eligibiles having Medicaid and Medicare will be under the federal formulary and we will not have a lot of say about that.. I asked the speaker what he thought about changing now from prior authorization to preferred drug list and he said it would be more important to do something with the Medicare modernization act than making adjustments now. Why make changes now when its coming up in January.

Sen. Dever: He said this is something we'd be better looking at a few years from now.

Chairman Lee: My thought is that this is something we might not pass now and bring back again in two years after we have the part B Medicaid kind of squared away because we need to figure out what we're going to do with all the people who aren't going to get their bills paid.

Senator Lyson moved DO NOT PASS, Senator Brown seconded

Vote: 5 yeas, 0 nays, 0 absent

Carrier: Senator Lyson

Chairman Lee closed the meeting.

FISCAL NOTE

Requested by Legislative Council
01/19/2005

Bill/Resolution No.: SB 2284

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

	2003-2005 Biennium		2005-2007 Biennium		2007-2009 Biennium	
	General Fund	Other Funds	General Fund	Other Funds	General Fund	Other Funds
Revenues	$0	$0	$0	$4,118,807	$0	$5,693,813
Expenditures	$0	$0	$2,231,917	$4,118,807	$3,553,584	$5,693,813
Appropriations	$0	$0	$507,727	$930,775	$0	$0

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

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

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

This bill would create and enact a new section to NDCC chapter 50-24.6 relating to a medical assistance preferred drug list; it would amend and reenact section 50-24.6-01, subsection 2 of section 50-24.6-02, and sections 50-24.6-03, 50-24.6-05, and 50-24.6-07 of the NDCC relating to medical assistance drug use review; and would repeal section 50-24.6-04 of the NDCC relating to the medical assistance prior authorization program.

There are three areas of fiscal impact of this bill. Section 7 of the bill repeals the prior authorization program. Section 5.2 would require that the department remove existing limits on prescription drugs used to treat mental illness; and the last sentence of Section 5.2 would require the department of continue the psychiatric pharmacy program study of current prescribing practices and scientific efficacy of drugs prescribed for the treatment of mental illness.

The appropriation authority relates to the agency's regular 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.*

Removing the limitations of certain prescription drugs would result in $921,335 of addtional federal title XIX revenue at FMAP rates for 2005-2007 and $1,091,983 for 2007-2009

Continuing the psychiatric pharmacy program study would result in federal title XIX revenue at the 50% administration rate; revenue would total $256,440 for 2005-2007 and $264,184 for 2007-2009.

Repealing prior authorization would result in removing $550,000 of title XIX revenue at the 50% administration rate for 2005-2007. However the PDL contract would allow the department to draw down federal funds at the 50% administration rate; this amounts to $303,000 in 2005-2007 and $315,241 in 2007-2009. Additionally repealing prior authorization would eliminate prescription drug savings caused by prior authorization resulting in higher drug costs. At FMAP for 2005-07 additional federal title XIX revenue would be received in the amount of $3,188,032; for 2007-2009 $4,022,404 could be received in title XIX 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.*

Expenditures in the operating line for 2005-2007 would be reduced by $1,100,000 as a result of eliminating the prior authorization contract; 50% or $550,000 of that amount is general funds. The PDL contract that would replace the prior authorization contract would offset those savings by $606,000 in 2005-2007 ($303,000 general funds) and $630,482 in 2007-2009 ($315,241 general funds). Repealing prior authorization would conversely increase medical assistance grants expenditures since prescription drug costs would increase; for 2005-2007 this would mean and increase of $4,912,222 ($1,724,190 general funds); for 2007-2009 expenditures would increase $6,361,544 ($2,339,140 general funds).

Operating expenditures would increase as a result of taking over responsibility for the psychiatric pharmacy program study which is currently funded by an outside party. The cost of this study for 2005-07 would be $512,880 ($256,440 general funds); for 2007-2009 the cost would be $528,369 ($264,184 general funds).

Medical assistance grants expenditures would need to increase as a result of removing limits on drugs used to treat mental illness. For 2005-07 expenditures would increase $1,419,622 of which $498,287 is general funds after applying FMAP; for 2007-09 expenditures would increase $1,727,002 of which $635,019 after FMAP.

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.*

Operating line appropriations for 2005-2007 would be reduced by $1,100,000 as a result of repealing prior authorization; 50% or $550,000 of that amount is general funds. The PDL contract that would replace the prior authorization contract would offset those savings by $606,000 in 2005-2007 ($303,000 general funds) and $630,482 in 2007-2009 ($315,241 general funds).

Operating line appropriations would increase as a result of taking over responsibility for the psychiatric pharmacy program study which is currently funded by an outside party. The cost of this study for 2005-07 would be $512,880 ($256,440 general funds); for 2007-2009 the cost would be $528,369 ($264,184 general funds).

Medical assistance grants appropriations would need to increase as a result of removing limits on drugs used to treat mental illness. For 2005-2007 appropiations would increase $1,419,622 of which $498,287 is general funds after applying FMAP; for 2007-2009 expenditures would increase $1,727,002 of which $635,019 after FMAP.

Name:	Brenda Weisz	**Agency:**	Human Services
Phone Number:	328-2397	**Date Prepared:**	01/24/2005

Date: 2-1-05
Roll Call Vote #: 1

2005 SENATE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. SB 2284

Senate **Human Services** Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken Do not Pass

Motion Made By Sen Lyson Seconded By Sen Brown

Senators	Yes	No	Senators	Yes	No
Sen. Judy Lee - Chairman	✓		Sen. John Warner	✓	
Sen. Dick Dever - Vice Chairman	✓				
Sen. Richard Brown	✓				
Sen. Stanley Lyson	✓				

Total (Yes) 5 No 0

Absent 0

Floor Assignment Sen Lyson

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

REPORT OF STANDING COMMITTEE

SB 2284: Human Services Committee (Sen. J. Lee, Chairman) recommends **DO NOT PASS** (5 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). SB 2284 was placed on the Eleventh order on the calendar.

2005 TESTIMONY

SB 2284

Attachment 1

Sen. Karen Krebsbach

SB 2284
Senate Human Services Committee
Tuesday, January 25, 2005

During the interim between legislative sessions, a working group was convened to explore different ways of addressing the needs of low-income people in North Dakota who participate as beneficiaries in the Medicaid program, as well as the operation of the Medicaid program itself. A large number of organizations and individuals were involved in that group process, which resulted in a number or recommendations to both the Governor and the Legislative Assembly. One of those recommendations of the Group centered on the issue of the rising cost of prescription drugs and the strategy the state should pursue in its cost containment efforts.

The recommendation of the Group was to ensure beneficiary access to medically necessary prescription drugs without undue administrative burdens. "Specifically, DHS should redirect its cost containment strategy from one of identifying drug categories for prior authorization to the establishment of an evidence-based preferred drug list. This effort should include revision of the statute (NDCC Ch. 50-24.6) creating the Drug Use Review Board."

I understand that there are various bills introduced to address the direction the state will take in addressing the role of the Medicaid Drug Use Review Board and what cost containment strategy will work best without undue administrative burdens on physicians, pharmacists and other professionals who serve the Medicaid population, and without unduly interfering in the physician-patient relationship. Senate Bill 2284 would implement the working group's recommendation by requiring the Department of Human Services, in consultation with the Drug Use Review Board, to develop an evidence-based preferred drug list, which would be a list of prescription drugs within designated therapeutic classes selected by the Department for which the Department would not require a prior approval process. A majority of states have now implemented a Medicaid preferred drug list, which is what the various organizations involved in the Medicaid working group determined would be an appropriate direction for our state.

Thank you Senator Lee and members of the committee. I believe there are others here who will more fully explain the purpose of the bill, and I will defer to them.

Attachment 2

Testimony in Support of Senate Bill No. 2284
Senate Human Services Committee
January 25, 2005

Madam Chairman and Committee Members, I'm Bruce Levi representing the North Dakota Medical Association. NDMA is the professional membership organization for North Dakota's physicians, residents and medical students.

The Medical Association supports SB 2284 in its current form. The bill would require the Department of Human Services to establish a preferred drug list. By definition, a preferred drug list, or formulary, is a list of drugs that have been carefully selected by a committee of health care professionals as the safest and most clinical and cost effective drugs within a given therapeutic class. The purpose of a preferred drug list is to enhance clinical outcomes and increase cost-effectiveness. Most commercial insurance plans currently use a preferred drug list, formulary or similar mechanism.

In summary, SB 2284 would replace the current prior authorization program in the Medicaid Drug Use Review Board with a preferred drug list. The Department of Human Services would be authorized to implement the preferred drug list using scientific, evidence-based standards. A physician or other prescriber would be allowed to prescribe a drug not on the preferred drug list without requiring additional medical justification or prior authorization by documenting on the prescription that the drug is medically necessary. The Department would not be authorized to establish a preferred drug list for drugs used to treat mental illness. Instead, the Department would be required to continue its ongoing psychiatric pharmacy program study of current prescribing practices and the scientific efficacy of drugs prescribed for the treatment of mental illness. The Department would be authorized to contract with a vendor or one or more states for the purpose of participating in a multi-state preferred drug list and would be authorized to administer the preferred drug list as part of the administration of a supplemental drug rebate program.

Let me provide the background on why SB 2284 is before you.

About fifteen months ago, the Medical Association adopted a resolution directing the Association to support efforts to sustain the Medicaid program in North Dakota, including active participation by NDMA in a Medicaid work group comprised of a number of North Dakota organizations, and in the Legislative Council's 2003-04 interim Medicaid study.

Over the interim, the Budget Committee on Health Care reviewed Medicaid's pharmacy assistance program and discussed various cost containment initiatives in both North Dakota and the country, including the use of preferred drug lists. A copy of that interim study is attached. The study also described efforts of the Medicaid Drug Use Review Board, in which several physicians in North Dakota participate. The Department, in consultation with the DUR Board, has now required prior authorization for two classes of drugs – antihistamines and proton pump inhibitors, used to treat acid reflux disease. Others categories are being considered. The Department has also initiated the ND Psychiatric Pharmacy Program using a consultant, Comprehensive NeuroScience, Inc., that recommends to physicians changes in their prescribing patterns based on "best practice" prescribing guidelines.

At the same time, over the interim, NDMA along with various other organizations and individuals in North Dakota, participated in a work group to provide recommendations to the Governor and the Department relating to the 2005-07 Medicaid budget. A copy of the final report of the group is also attached to my written testimony.

On page 11 of the report, there is a discussion regarding Medicaid prescription drug benefits:

> "As an optional Medicaid benefit in North Dakota, outpatient prescription drugs constitute over 28% of all mandatory and optional medical services. While Medicaid has experienced increases in drug payments in excess of 10% per year in fiscal years 2001 and 2002, payments actually dropped by 2% in fiscal year 2003. Medicaid credits new initiatives implemented in 2002 for "stabilizing and limiting" the growth in prescription drug costs. These initiatives included a $3 copayment imposed on brand name drugs, which resulted in the greater use of generic products.
>
> "Physicians have the primary responsibility for ensuring that Medicaid prescription drug cost containment programs support the provision of medically necessary care. While costly, prescription drugs improve the quality of life for many Medicaid recipients and are less costly than hospitalization, surgery or other therapies. Therefore, choice of drugs should be based on clinical criteria and not solely on cost.

"The provider response to the current prior authorization program implemented by the new Medicaid Drug Use Review Board is mixed. Providers are increasingly opposed to the administrative burdens imposed by "piece-meal" cost containment efforts which equate to additional financial responsibilities for providers.

"While there was reduction in prescription drug spending in 2002-03, expenditure growth is projected in the low double digits for the immediate future. With respect to cost containment programs, thirty states have implemented or plan to implement a preferred drug list (PDL) to control Medicaid fee-for-service prescription drug spending – lists of preferred prescription medications that recipients generally may receive without first obtaining prior authorization from a state. North Dakota has not implemented a PDL program, but the topic of PDLs with supplemental rebates is being considered by the Legislative Council's interim Budget Committee on Health Care. The Department has expressed the view in testimony to the interim committee that supplemental rebates allow a program to offer more medication choices, thereby reducing the administrative burden by decreasing the number of prior authorizations."

The work group recommended that the state consider establishing a preferred drug list – that "DHS ... redirect its cost containment strategy from one of identifying drug categories for prior authorization to the establishment of an evidence-based preferred drug list." The purpose of the recommendation is to ensure beneficiary access to medically necessary prescription drugs without undue administrative burdens.

Senate Bill No. 2284 would replace the current prior authorization program in the Medicaid Drug Use Review Board with a preferred drug list. There are other bills introduced this session addressing prescription drug cost containment strategies, including HB 1465 which would require the Department to consider implementing the prescription drug formulary of the federal Medicare reform law, as well as HB 1470 which addresses the composition of the Drug Use Review Board and places limits on prior authorization.

NDMA supports SB 2284 because drugs selected for a preferred drug list by the Department in consultation with the Drug Use Review Board would be determined based on an evidence-based approach used by a committee made up of practicing physicians and pharmacists. Under SB 2284, the patient-physician relationship would remain of primary importance, and drugs that are not included on the preferred drug list would be covered by the program if a patient's physician determines that the drug is medically necessary. The process for prescribing a drug off the preferred drug list would be minimally invasive.

In addition, since cost effectiveness is one of many factors used to select drugs for the preferred drug list, pharmaceutical manufacturers may discount their drugs for the program to enhance their positioning for inclusion on the preferred drug list. SB 2284 recognizes this by authorizing the Department to contract with a vendor or one or more states for the purpose of participating in a multi-state preferred drug list and would be authorized to administer the preferred drug list as part of the administration of a supplemental drug rebate program.

On behalf of NDMA, I urge you to support SB 2284 with a "do pass" recommendation.

Attachment 3

TESTIMONY BEFORE SENATE HUMAN SERVICES COMMITTEE

SB 2284

JANUARY 25, 2004

Chairman Lee, members of the committee, I am Dr. Brendan Joyce, Administrator of Pharmacy Services for the Department of Human Services. I appear before you to provide testimony regarding SB 2284.

It appears that the intent of this bill is to replace the current prior authorization process with a preferred drug list (PDL). This is a bill that seeks to have the Department implement a PDL, and a preferred drug list exists in concert with a prior authorization program, it would be imperative that section 50-24.6-04 not be repealed, or at a minimum, language added to SB 2284 specifically authorizing, and guiding the Department in the prior authorization process that must accompany the PDL. Also, by retaining prior authorization language, if PDL's fall out of favor once Medicare Part D is implemented, the Department would still be able to pursue efficiencies through prior authorization.

Section 5, 1.e. includes language for a physician to include on a prescription to bypass any PDL enforcement (presumably prior authorization). Oregon is the only state that I am aware of that has utilized this process (initially PDL, prior authorization, and MD ability to bypass PA/PDL by writing 'dispense as written' on the prescription), and according to information I received from Oregon, their savings with this process was 75% less than what other states achieved with their PDL's. This process only lasted for a short period of time in Oregon, as they are now the only state that has a PDL but does not enforce it with any prior authorization. The fiscal note reflects the estimated increase in drug expenditures if the Department no longer has the ability to use prior authorization as a tool to control drug costs within the Medicaid Program.

The bill does authorize the Department to seek supplemental rebates from drug manufacturers. However, without a prior authorization process, there is no incentive for drug manufacturers to agree to additional rebates since the payer (the Department) cannot influence market share.

Section 5.2 includes language to exempt mental health drugs from any PDL. As a reminder, mental health drugs account for roughly 50% of our drug spend. Also, exemptions from PDL's are a slippery slope, and it is difficult to define exactly what should be exempted. Overall, most states trust the practicing physicians and pharmacists on the DUR Board to make the appropriate decision. The Department has already implemented quantity limits for some mental health drugs. The fiscal note identifies the additional costs to the program if we are no longer able to apply limits to this class of drugs. Also in section 5.2, the Department is instructed to continue the psychiatric pharmacy program. For the moment, Eli Lilly is funding the program. Once the funding ends, the Department would have to take over funding at a cost of $256,440 per year (current costs). Currently, there is no other state that is funding the program without assistance from a pharmaceutical company.

The Department implemented the prior authorization process in April 2004 for proton pump inhibitors and anti-histamines. The Drug Review Board has recommended additional drug classes to be subject to prior authorization, and it is logical to assume further recommendations will come. We would suggest that the Legislature allow the current process to continue during the next biennium, so that we can get a clear picture of the results of implementing this process, that is also used by most other Medicaid programs and will be used by Part D plans.

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

inspections are required annually, while the State Building Code inspections are only necessary for new construction or remodeled buildings. North Dakota Century Code Chapter 54-21.3 provides for a State Building Code but does not require cities, counties, and townships to enforce the code. The law permits cities, counties, and townships to amend the State Building Code to meet local needs. The committee learned most local governments do not have the capacity to enforce the State Building Code and thus the Life Safety Code survey may be the first onsite inspection that occurs at a nursing home.

Nursing Home Deficiency Citations

The committee received testimony from representatives of nursing homes regarding the nursing home survey process and the issuance of deficiency citations, including:

1. The survey process is an adversarial relationship between the State Department of Health and each nursing home, instead of a relationship with a team of professionals who have the same common goal.
2. The survey process sometimes generates unnecessary costs to a nursing home.
3. Nursing homes that have repeat citations within certain areas have experienced significant increases in general liability insurance rates.
4. Many nursing homes believe the informal dispute resolution process does not work.

When a State Department of Health survey team determines that a nursing home does not meet a specific regulation, the department issues a deficiency citation based on the scope and severity of the violation. The State Department of Health has 10 working days to send the deficiency citation to the nursing home and a nursing home has to respond with a written plan of deficiency correction to the State Department of Health within 10 calendar days.

If a plan of deficiency correction is not acceptable, the Centers for Medicare and Medicaid Services is consulted and must concur with survey findings before the Centers for Medicare and Medicaid Services will impose a remedy or action necessary for the nursing home to correct the deficiency. Depending on the nature of the deficiency citation, various remedies are enforced against the nursing home, ranging from Category 1 remedies, which include state monitoring, directed plans of correction, or directed inservice training to Category 2 remedies, which include civil penalties of $50 to $3,000 per day and deny Medicaid payment for new admissions or all residents. The State Department of Health follows up with the nursing home to verify that the concerns were corrected and once verified, the nursing home receives recertification. If problems are not corrected, the Centers for Medicare and Medicaid Services may terminate its agreement with the nursing home or assign additional penalties of up to $10,000 per day.

The committee learned the Centers for Medicare and Medicaid Services mandates a Category 2 remedy for a nursing home that for two consecutive years receives a Level G deficiency rating--an isolated case that results in a negative outcome that has negatively affected a resident's ability to achieve his or her highest functional status. The State Department of Health will notify the nursing home 15 days prior to the actual enforcement of the ban or denial of payment for new admissions. The nursing home may use that period to fill resident vacancies and if the deficiency is corrected during the period, the ban will be rescinded.

The committee learned the State Department of Health is required to follow federal regulations when conducting surveys of nursing homes and is subject to annual review by the regional office of the Centers for Medicare and Medicaid Services. Approximately 98 or 99 percent of deficiency citations are related to federal requirements. If the state surveyors do not follow federal regulations, the state survey team will receive a low review score and the state could possibly lose federal Medicaid funds. State surveyors are not allowed to make informal recommendations to health care facilities during the survey process.

Informal Dispute Resolution Process

The informal dispute resolution process provides an opportunity for nursing homes to present evidence to the State Department of Health that will refute deficiencies or correction orders. According to the state operations manual, which is based on a federal publication that defines the requirements for the informal dispute resolution process, the state survey agency makes the final decision. The Centers for Medicare and Medicaid Services has issued directives to state survey agencies providing that an independent, informal dispute resolution process may serve only as a recommendation to the state survey agency and the Centers for Medicare and Medicaid Services will not reimburse state agencies for costs associated with an outside review process.

Recommendations

The committee encourages the State Department of Health to review Life Safety Code inspection procedures and provide options, within available resources, to the 59th Legislative Assembly (2005) for the State Department of Health to provide for any construction inspections necessary to ensure compliance with the Life Safety Code upon completion of a construction project.

PHARMACY ASSISTANCE PROGRAM STUDY

The 58th Legislative Assembly (2003) approved House Bill No. 1430 which provided for the establishment of a medical assistance drug use review program and drug prior authorization program in the Department of Human Services and authorized the creation of a 15-member Drug Use Review Board. The board's duties include cooperating with the department to create and implement a prospective and retrospective drug use review program for outpatient prescription drugs for the

medical assistance or Medicaid program. Section 11 of 2003 House Bill No. 1430 directed a study of the value of the medical assistance program's 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.

North Dakota's Medicaid Prescription Drug Costs

The 58th Legislative Assembly appropriated $95,207,239, which includes $25,712,069 from the general fund, for prescription drug costs in the Medicaid program. This represents an increase of $16,091,517, or 16.9 percent more than the 2001-03 biennium appropriation. The increase in Medicaid prescription drug costs is attributed to increased drug costs, the changing structure of health care, the development and use of more expensive drug treatments, and the increasing number of prescriptions.

The committee learned that as of January 2004, the average cost of a prescription paid for by the North Dakota Medicaid program was $55. The average cost of a brand name drug prescription was $95, compared to the average cost of a generic drug prescription of $19. Approximately $4.8 million is paid monthly for Medicaid prescription drugs, with approximately 22,000 Medicaid recipients having at least one prescription filled each month. Each recipient has an average of four prescriptions filled each month.

The North Dakota Medicaid program began requiring a $3 recipient copayment for brand name drugs in August 2002. A copayment is not required for generic drugs. Prior to the copayment requirement, 55 percent of Medicaid medication purchases were for brand name drugs and 45 percent were for generic drugs. In June 2004, 48 percent of medication purchases were brand name drugs and 52 percent were generic drugs. Every 1 percent increase in the use of generic drugs saves the Medicaid program approximately $850,000 a year, of which $269,000 is from the general fund.

North Dakota's Medicaid pharmaceutical reimbursement rates are based on the average wholesale price less 10 percent for brand name drugs and the maximum allowable cost for generic drugs. The dispensing fee rate paid pharmacies is $5.60 for generic drugs and $4.60 for brand name drugs.

North Dakota currently has over 300 Medicaid recipients on a "lock-in" or "coordinated care" program. These individuals are required to select one physician, one pharmacy, and one dentist to assume primary responsibility for their care. This program allows all providers of care to gain more insight into a patient's overall care and to prevent misutilization of medical services.

An applicant or enrollee has a right to appeal to the Department of Human Services if there is a reduction, termination, or denial of Medicaid benefits. A grievance is a process of appealing to the Department of Human Services a Medicaid-related decision other than coverage of health services or payment of benefits, including matters such as not including a drug on a preferred drug list or requiring prior authorization for a particular drug.

Drug Use Review Board

The Drug Use Review Board is an advisory board consisting of 15 members. The pharmacy administrator of the Department of Human Services and the medical consultant to the department are ex officio nonvoting members. The remaining 13 members of the board are appointed by the executive director of the Department of Human Services and include physicians and pharmacists residing in varying locations throughout North Dakota with various areas of expertise. The board members serve staggered three-year terms. The board meets at least quarterly and may meet at other times by teleconference or electronically.

The federal statutory authority for the Drug Use Review Board is contained in the Code of Federal Regulations. These regulations require states to establish a Drug Use Review Board and prescribe the professional makeup of the Drug Use Review Board. The Code of Federal Regulations provides that the state Medicaid agency is ultimately responsible for ensuring that the drug use review program is operational and conforms with the regulations. The state Medicaid agency has the authority to accept or reject the recommendations of the Drug Use Review Board.

Prior Authorization Program

Prior authorization is a process in which certain drugs cannot be prescribed until authorization is received from a Medicaid agency or insurer. The Department of Human Services provides related medical and clinical criteria, cost information, and utilization data to the Drug Use Review Board for review and consideration. The board considers the department's data and information from other sources in deciding whether to place a drug on the prior authorization list.

The committee learned there is very little difference between a preferred drug list and a prior authorization program. A preferred drug list is a newer term describing a broad prior authorization program. North Dakota's prior authorization program does not allow "supplemental rebates" or additional discounts from drug manufacturers in exchange for keeping medications off the prior authorization list, which is the primary difference between a preferred drug list and a prior authorization program. The committee heard testimony from representatives of the Department of Human Services indicating that additional Medicaid cost-savings could be realized if the state allowed supplemental rebates.

North Dakota's prior authorization program permits a pharmacy to issue a five-day supply for new prescriptions, which is intended to cover the time needed for the pharmacy to complete the prior authorization form, receive documentation from the physician, and submit the form to the Department of Human Services. The Department of Human Services is required to respond to the prior authorization request within 24 hours.

The committee learned that as of August 2004, the Drug Use Review Board has required prior authorization for two classes of drugs--antihistamines and proton pump inhibitors, used to treat acid reflux disease. Any medication within these drug classes that is not on the approved list requires authorization from the Department of Human Services before it can be prescribed to a Medicaid recipient. The savings per dose realized from the preapproved medications as compared to the medications that require prior authorization are $1.70 for the antihistamines and $3.58 for the proton pump inhibitors. The Medicaid program currently pays for more than one million doses per year in each of these two drug classes.

The 58th Legislative Assembly appropriated $1,450,000, of which $725,000 is from the general fund, for the Department of Human Services to contract with a vendor to provide prior authorization services for the 2003-05 biennium. The committee learned that because of the limited number of drug classes requiring prior authorization, the Department of Human Services was initially able to internally operate the prior authorization program. However, the Department of Human Services plans to issue a request for proposals for prior authorization services prior to December 31, 2004. The anticipated cost for a vendor to operate the prior authorization program for the 2005-07 biennium is approximately $1,450,000.

Prescription Connection for North Dakota Program

The committee received information on the Prescription Connection for North Dakota program administered by the Insurance Commissioner's office, pursuant to NDCC Section 26.1-01-11. Prescription Connection for North Dakota is a program that connects qualified, low-income people with discount prescription drugs direct from the pharmaceutical manufacturer. The goal of the program is to provide as much access to information on pharmaceutical assistance programs as possible to residents while also providing one-on-one assistance, if necessary. There are over 150 volunteers statewide providing program assistance to individuals. As of May 2004 approximately 5,000 North Dakota residents received assistance from the Prescription Connection for North Dakota Program, with total benefit savings realized of approximately $2.5 million. The web site address for the program is *www.rxconnectnd.org.*

Federal Medicare Prescription Drug, Improvement, and Modernization Act of 2003

The committee received information on the federal Medicare Prescription Drug, Improvement, and Modernization Act of 2003, including its impact on the state Medicaid program. Phase 1 of the federal program, in place from June 2004 to December 2005, provides for the issuance of a prescription drug card and an annual $600 drug credit to certain low-income Medicare beneficiaries. Eligible Medicare beneficiaries who do not have other prescription drug coverage may receive one of several cards offered by various entities which provide discounts of up to 25 percent for certain prescription drugs. The discount cards vary as to the types of drugs covered in each class and may cost up to $30. Medicaid recipients already receive drug coverage and thus will not be eligible for a discount card.

Phase 2 of the federal program, referred to as Medicare - Part D, begins in January 2006 and establishes a drug payment program for Medicare recipients. Phase 2 provides subsidies to pay for all or part of monthly insurance premiums, deductibles, cost-sharing, and coverage limits based on an individual's income and assets. The Medicare program will be required to pay for dual-eligible recipients, or individuals who receive Medicare and also some form of Medicaid assistance, enrolled in Medicare - Part D. However, state Medicaid programs are required to pay a portion of related Medicaid savings to the federal government. This "clawback" provision requires states to originally pay 90 percent of the estimated state savings back to the federal government, which is gradually reduced to 75 percent of savings by 2014.

Other information and Testimony

The committee received information from Dr. Randy Seifert, PharmD, Seifert and Associates, Santa Barbara, California, on prescription drug cost containment programs. The committee learned there has been an increase in the use of tiered pharmacy benefit programs, with three-tiered programs being the most common. A tiered program requires varying copayments based on the drug utilized. A three-tiered program consists of generic drugs, preferred brand name drugs, and nonpreferred brand name drugs, with generic drugs having the smallest percentage copayment and nonpreferred brand name drugs the largest. Increases in copayments generally result in reduced utilization of prescription drugs, with the greatest impact on individuals who make less than $25,000 per year.

The committee learned advertising by pharmaceutical companies provides consumers with a better awareness of disorder treatment; however, it may also increase unnecessary drug utilization. It is estimated 13 percent of adults in the United States have received a specific prescription in response to a drug advertisement.

Several factors have been identified that increase prescription drug utilization and costs, including:

- Greater public perception of the value of pharmacies.
- Increase in disease identification.
- Changes in treatment options.
- Changes in demographic - An older population.
- Increases in direct consumer advertising.
- Changes in physician practice patterns.
- Increases in outpatient treatment, made possible by drug treatments.
- Increases in new pharmaceuticals.

Private insurers are able to negotiate significant discounts with pharmaceutical manufacturers for certain classes of drugs based on the insurer's volume of purchases or "market share." Private insurers do not

negotiate for discounts on other types of drugs, such as antipsychotic medications, in which the Medicaid program has a large "market share." Because price rebates received by states are often based on the private payer's negotiations with drug manufacturers, states have formed purchasing pools to negotiate additional volume discounts.

Dr. Seifert informed the committee pharmacies commonly purchase drugs in bulk, repackage the drugs, and receive a new National Drug Code number for the repackaged product. Each National Drug Code number is assigned a new average wholesale price, which may result in the pharmacy receiving a larger Medicaid reimbursement than provided by the original or "innovator" National Drug Code. The committee learned a state Medicaid program could limit reimbursement to pharmacies based on the average wholesale price provided by the "innovator" National Drug Code, rather than the repackaged product.

The committee received information from a representative of Outcomes Pharmaceutical Health Care regarding Outcomes medication therapy management services, a prescription drug cost containment program. The program is a health care benefit offered in Florida, Iowa, and other states which provides covered members with services from specially trained local pharmacists. These services include comprehensive medication review, medication cost management, drug dosage and compliance monitoring, drug information, and over-the-counter medication consultation. Fees for the program are based on a per member per month basis. The fees collected are placed in a "risk pool" to pay pharmacists for providing covered services and for administrative costs. Cost-avoidance savings, based on a cost-avoidance model, are guaranteed by Outcomes Pharmaceutical Health Care to exceed the annual program costs or the company will refund the difference.

The committee learned that the Department of Human Services is evaluating alternatives for a quality assurance program to be recommended for possible implementation during the 2005-07 biennium. The department will recommend a program that will achieve the most desired results within available resources.

Recommendations

The committee makes no recommendations relating to its pharmacy assistance program study.

MEDICAID PROGRAM STUDY

Section 16 of 2003 Senate Bill No. 2012 directed a study of the feasibility and desirability of establishing an advisory council for the Medicaid program of the Department of Human Services. The committee received approval from the chairman of the Legislative Council to expand the study to include a review of Medicaid payments, access to services, and utilization.

Medical Assistance Program Advisory Council

The North Dakota Medicaid program was authorized in 1966, pursuant to NDCC Section 50-24.1-01, for the purpose of strengthening and extending the provisions of medical care and services to people whose resources are insufficient to meet such costs. Pursuant to Title 42, Code of Federal Regulations, Section 431.12, the Department of Human Services is required to have a Medical Care Advisory Committee for the purpose of advising the department about health and medical services, including participating in policy development and program administration.

The Medical Care Advisory Committee reviews and makes recommendations regarding any major changes the department intends to implement in the Medicaid program. The committee consists of both providers and recipient members who are appointed for either two-year or three-year terms.

Medicaid Program

Medicaid is a joint state/federal program established by Congress in 1965 and designed to pay for the health care of certain low-income citizens. The program is optional; however, states that decide to participate must abide by federal laws and regulations. Participating states are required to maintain a state plan that describes the groups covered, types of services provided, the method of payment used for each type of service, and other administrative aspects of the program. The Medicaid program must include certain services, while other services can be provided at the state's option. Coverage of certain categories of recipients are also mandatory.

The federal government shares in the cost of providing services to recipients based on the federal medical assistance percentage for each state. The federal medical assistance percentage is a complicated formula that uses a three-year average of per capita income in each state compared to the national average. North Dakota received an enhanced federal medical assistance percentage as federal temporary fiscal relief to states, from April 1, 2003, through June 30, 2004. The Department of Human Services received $19.6 million as a result of the enhanced federal medical assistance percentage. North Dakota's federal medical assistance percentage rate, however, decreased from 71.31 to 68.31 percent on July 1, 2004, and is projected to decrease to 67.49 percent on October 1, 2004, and 65.85 percent on October 1, 2005. The potential impact of this reduction is an estimated reduction of $34 million for the 2005-07 biennium.

The total 2003-05 Department of Human Services appropriation for medical assistance services is $902.6 million, of which $265.4 million is from the general fund. The 2003-05 appropriation for long-term care services, including nursing home services, is $358 million, of which $122.4 million is from the general fund.

States are required to provide Medicaid services to certain categorically eligible recipients, including:

- Children and adult caretakers if deprivation exists because of parental absence, incapacity, unemployment, or underemployment.

Attachment 3B

REPORT OF THE

MEDICAID WORKING GROUP

AUGUST, 2004

MEDICAID WORKING GROUP
AUGUST 2004

PREFACE

The Medicaid Working Group resulted from ongoing discussions with Governor John Hoeven regarding North Dakota's Medicaid program. The working group was formed by representatives of a number of professional, service, and advocacy organizations for the purpose of providing the Governor, the Department of Human Services (DHS), and policymakers with recommendations on how to improve the Medicaid program in North Dakota.

The working group members all have some connection to the Medicaid program as providers of service or otherwise. Special thanks to DHS and ND Health Department staff who provided information requested by the working group. All costs associated with the working group were incurred by professional, service, and advocacy organizations involved in the effort.

In many respects, the recommendations are specific in nature as to need or purpose, but may not include all details as to how each recommendation may be implemented. The working group felt strongly that the Governor, DHS, and policymakers should be allowed maximum flexibility in implementing the recommendations, consistent with the working group's goal of addressing the long-term sustainability of the Medicaid program in North Dakota.

We are at a crossroads in North Dakota with respect to our state's Medicaid program – fewer federal resources, increased cost shifting to other payers resulting from under funding of Medicaid, the need for an enhanced information systems infrastructure, more enrollees and greater needs of Medicaid recipients, growing cost pressures on service providers -- all these factors and more contribute to the need to address the long-term sustainability of the Medicaid program. The Working Group believes these recommendations can begin to address these issues while improving the quality of life for the recipients.

While the working group deliberated for about a year, one of the key recommendations is to foster improved Medicaid management through the expansion of the current Medical Care Advisory Committee. If this recommendation is implemented, the Advisory Committee is a logical vehicle for continuation of the important process of initiating improvement in the Medicaid program.

The working group expresses its appreciation to Governor John Hoeven, DHS staff, and our legislative participants, Sen. Judy Lee and Sen. Richard Brown, for their leadership in encouraging this collaborative effort.

MEDICAID WORKING GROUP
MEMBER AND STAFF LISTING

MEMBERS:

Susan Bosak	MeritCare
Sen. Richard Brown	ND Legislature
Janis Cheney	AARP ND
Joe Cichy	ND Dental Association
John Doherty	MeritCare
Karen Hagel	PrimeCare health group & ND Medical Group Management Association
Dr. Patricia Hill	ND Pharmacists Association
Kathy Hogan	Cass County Social Services
Janelle Johnson	Community Health Care
John Johnson	Options
Galen Jordre	ND Pharmacists Association
Betty Keegan	AARP ND
Kim Krohn, M.D.	Minot Center for Family Medicine
Karen Larson	Community Health Care
Sen. Judy Lee	ND Legislature
Bruce Levi	ND Medical Association
James M. Moench	ND Disabilities Advocacy Consortium
Barb Murry	Pride Inc. & ND Association of Community Facilities
Bruce Murry	Protection and Advocacy
Shelly Peterson	ND Long Term Care Association
Rod St. Aubyn	Noridian
Al Stenehjem	ND Mental Health Association
Chip Thomas	ND Health Care Association
Mike Tomasko	PrimeCare health group & ND Medical Group Management Association
Dan Ulmer	Noridian
Mary Wakefield	UND Center for Rural Health
Les Wietstock	Towner County Memorial Hospital
John Windsor, D.O.	ND Medical Association
Tim Yellow	Indian Health Services

STAFF SUPPORT:

Rod Backman	Covenant Consulting Group
Dr. John Baird	ND Health Department
Barb Fischer	ND Department of Human Services
Celeste Kubasta	ND Office of Management and Budget
Dave Zentner	ND Department of Human Services

MEDICAID WORKING GROUP
FINDINGS AND RECOMMENDATIONS

The Medicaid Working Group (MWG) was formed in August of 2003 for the purpose of providing recommendations, to the Governor and the Department of Human Services (DHS), to improve Medicaid in North Dakota. The group's Charter is as follows:

"To provide information, from the perspective of providers and consumers of health care working together, that the Governor and Department of Human Services may use in developing the '05-'07 budget for Medicaid. To be useful, the information provided should present ways the group had concluded Medicaid services could be most effectively delivered, recognizing the limitations of resources."

The Medicaid program in North Dakota is approaching a $1 billion biennial state/federal appropriation. The provision of Medicaid benefits is complex. It requires an appropriately high level of management, administration, operation and advisory oversight that befits a program of such major significance to the overall state budget in North Dakota and, more importantly, to the approximately 53,000 eligible North Dakotans who benefit from the program (in the year ended 6-30-03 there was a monthly average of 53,134 eligible individuals with an average of 38,324 recipients served per month) see appendix C. The challenge for our state's policymakers is to put recipients first in assuring the long-term sustainability of the state's Medicaid program.

I. Medicaid Management

- Expand Medical Care Advisory Committee
  Expand the role and composition of the federally-mandated Medical Care Advisory Committee to report directly to the Governor or the Governor's designee at least annually on all aspects of the Medicaid program, and to report to legislative leaders or committees at their request. The composition of the Committee should be expanded from its present form to include appropriate representatives of hospitals, clinics and other service providers. In addition to its current scope of responsibilities, the role for this Medical Care Advisory Committee should include a consultative role in development of the executive biennial budget for Medicaid, and also include:

  (a) An annual review of the Medicaid fee schedules and program expenditures with a report of its findings and recommendations as needed to DHS, Legislative Council's Budget Section, and the Governor.

(b) An annual review of program administration, including program case management (including the current lock-in program), vendor relationships, and quality assurance programs and measures.

(c) An annual review of enrollment, service utilization and other program trends.

(d) An annual review of clinical performance profiles of providers and recipients, with assistance from the state's peer review organization or similar entity.

(e) Identification of state and federal rules and regulations unnecessary to operating an efficient and effective Medicaid program.

(f) An annual cost/benefit analysis of the current mandatory and optional services.

(g) An assessment of current behavioral health policies and procedures.

Narrative: Timely and appropriate access to quality health care is essential to the health and well being of the North Dakotans enrolled in the Medicaid program. To ensure this access, it is vital that the DHS receive meaningful, participatory input and advice from providers including long term care, home and community based service providers, health professionals, hospital and clinic administrators, Medicaid recipients, and others regarding Medicaid policy development and program administration.

Federal law requires DHS to have a Medical Care Advisory Committee for the purpose of advising the DHS about health and medical services, including participating in policy development and program administration (42 CFR, Section 431.12). However, the purpose and composition of the committee under the federal mandate is currently narrow in scope. In addition, the current committee does not meet often and provides limited input on a department-driven agenda.

The Medical Care Advisory Committee should be given a broader mandate and composition to focus on all aspects of the medical assistance program, including consideration of innovative approaches to care delivery. States have considerable discretion under current law to administer their Medicaid programs through state plan amendments and seeking waivers; however, the waiver/amendment has been viewed more as an insurmountable barrier to change in North Dakota. The Medical Care Advisory Committee can be structured in a manner that provides a positive force for addressing challenges, ensuring access for Medicaid recipients, and achieving long-term financial sustainability for the program.

II. Medicaid Budget Process and Payments

- Develop Actuarially-Based Budget and Payments
  Develop actuarially-based methodologies for setting Medicaid payment rates and developing agency budget recommendations, performing and reviewing data analyses, tracking program service utilization, and determining the effectiveness of quality and cost containment initiatives. These methodologies should lead to development of the underlying basis for:

  (a) An actuarially-based executive budget process resulting in recommendations to the Legislative Assembly;

  (b) A fair and equitable payment system that funds services to appropriate levels, helping to ensure quality services can be delivered.

  (c) Periodic payment adjustments that reflect inflation, technology and overhead costs;

  (d) Establishment of service priorities (benefits and eligibility) actuarially linked to funding sources, including analyses of the relative level of spending by sector compared to other states; and

  (e) Consideration for implementing insurance concepts, including stop loss insurance.

- Address Expected FMAP Decrease
  For the 2005-07 budget cycle, address the expected decrease in FMAP (Federal Medical Assistance Percentage) in North Dakota by considering the allocation of additional funds, including federal funds made available to North Dakota pursuant to the Jobs and Growth Tax Relief Reconciliation Act of 2003. (FMAP is the process that the federal government uses to allocate Medicaid funds to the states. It bases the federal percentage on the economic growth of each state. States with per capita personal income growing faster than average will see their federal share decrease; conversely states with slower growth will see their share increase. Because North Dakota has seen better than average economic growth we are expecting a decrease in the Federal share. The current FMAP in North Dakota is 68.31%; however, the enhanced FMAP which ended on June 30, 2004, was 71.31%. The percentage dropped to 68.31% on July 1, 2004, and will further decline to 67.49% for the 2005 fiscal year beginning on October 1, 2004.) Other FMAP strategies include:

  (a) In consultation with the state's Congressional Delegation, the executive branch should lead in developing a private/public sector federal Medicaid advocacy strategy. Consideration should be given to advocating for bold change in the Medicaid structure as encouraged by the National Conference of State Legislatures and other organizations.

  (b) DHS should forgo implementation of proposed new service limits and co-payments and exercise existing budget authority to spend available FMAP funds to meet its budget obligations.

- Consider Other Budget-Related Initiatives
  Other initiatives that should be pursued include:

  (a) Develop a payment system whereby providers will not be compensated less than their cost.

  (b) Investigate taking full financial advantage of the federal disproportionate share program.

  (c) Investigate taking full financial advantage of federal SSI provisions applied to Medicaid recipients.

  (d) Continue the North Dakota Healthy Steps program (SCHIP) as a separate program directed to maximize coverage for the uninsured with maximum federal financial support.

Narrative: For the future, North Dakota faces significant funding challenges in the Medicaid program that will directly impact the ability of the state to assure continued access to community, long term and acute care for Medicaid recipients. The willingness of providers to accept Medicaid recipients is threatened by confusion regarding eligibility and inappropriate presentation for care, low reimbursement rates that do not recognize all costs of providing care, and continued delays in claims payments, increased paperwork, new service limitations and other administrative burdens.

The executive budget process for the Medicaid program should result in budget recommendations that are actuarially sound and reliable. Currently, DHS sets payment rates based on expenditures from the prior complete year that is then trended forward based on price and utilization factors used in the Department's budget request. Various considerations may be left out of the equation, including the current health status of the Medicaid population and other major factors. The budget process should be taken to a higher level of financial sophistication, to assure legislators, participating hospitals, long term care, home and community based service providers, clinics, physicians, other health professionals, and taxpayers that the program is actuarially sound.

Payment schedules for all providers should cover the provider's cost of service delivery and should also be actuarially linked to benefit coverage and program eligibility thresholds. The current fee schedules do not account fully for the direct and indirect costs incurred. Many Medicaid providers receive payments significantly below their standard rates and in some cases below their actual cost. Adjustments that are made are piecemeal, with no apparent underlying payment philosophy, policy or framework.

In addition, as North Dakota's economy grows, federal funding support for North Dakota's Medicaid program will decrease significantly under the current FMAP financing structure, providing a new challenge in the need for additional funding to maintain the current level of recipient benefits or benefit reprioritization and provider payments in 2005-07. At the same time, health related expenditures continue to grow faster than the growth in per capita Gross Domestic Product, even though state funds supporting DHS have not kept pace with the growth in the number of recipients. See appendix C for Eligibles, Recipients and expenditures by year.

III. Medicaid Administrative Functions

- Enhance Administrative Support Systems
  After thorough analysis, implement options in a timely manner for building better administrative support systems, including assurance of an adequate DHS infrastructure of technology and personnel. The options considered should include outsourcing current administrative functions to experienced entities subject to adequate protections for maintaining Department control of medical and utilization information.

  (a) In developing a new CMS-certified Medicaid Management Information System (MMIS), a request for proposal/bid process to qualified entities should be employed in assisting the Department to define, develop, implement and operate its administrative support systems.

  (b) Standards should be adopted for the promptness and accuracy of Medicaid claim payments. The claim processing function should be included in any request for proposal/bid process.

- Explore Risk Sharing or Capitated Service Delivery Options
  Explore options for Medicaid service delivery including direct contracting with systems and/or consortia and other third party payors as appropriate for Medicaid acute care service, and expansion of managed care, risk-sharing, or capitated service delivery arrangements. These options would require DHS to provide service providers with access to information to evaluate the benefits of such arrangements.

- Provide Access to Fee Schedules and Administrative Assistance
  DHS should enhance its provider service function. Medicaid fee schedules should be readily available through electronic means to providers for budgeting and other purposes. Other provider services should include a Medicaid website for referrals, preauthorizations and claim follow-up and, if problems cannot be resolved, Medicaid should make available a representative that can be called upon for assistance. The current appeals process should be reviewed.

Narrative: Medicaid program administration should be efficient and encourage participation by providers. However, the current MMIS is not adequate to support existing and future program administration demands, and unacceptable claims delay is currently a disincentive for provider participation in the Medicaid program. DHS is facing major capital challenges to upgrade its claims management capability, and is currently working with a consultant to identify MMIS options.

Sufficient financial resources, including access to necessary technologies, should be available for program administration, in a manner appropriate to the $1 billion biennial state/federal appropriation for the Medicaid program. The technical advantages available to commercial insurers should be available to the management and administration of the state's Medicaid program. DHS must have the management, administrative, and technology tools necessary to perform its role and functions appropriately.

IV. Medicaid Benefits and Eligibility

- Establish a Single Point of Entry (SPE).
  To address the confusion and lack of consistent information, DHS should establish a single point of entry for community and long term care services. The SPE should provide the public with consistent and accurate information about:

  (a) Services available and how to access,
  (b) Funding options,
  (c) Screening and uniform assessment.

- Strike an Appropriate Balance in Pursuing the Long-Term Sustainability of the Program
  In pursuing the long-term sustainability of the state's Medicaid program, strike an appropriate balance between the needs of recipients, the state's ability to pay, and health care providers ability to absorb the cost of providing service, including:

  (a) An initial review of the current benefit and eligibility program by the Medical Care Advisory Committee to determine appropriateness of the current level of mandatory and optional services, and capacity for coordinating care.

  (b) A recognition that current Medicaid benefits will not be enhanced unless there is a change in commitment by either the state or federal government; new benefit commitments and changes in eligibility thresholds should not be made until an actuarial assessment and cost-benefit analysis have been completed and funding sources identified.

- Consider Wellness, Disease Management and Self-Care Initiatives
  Consider wellness, disease management, and self-care initiatives, including:

  (a) Review and expand as appropriate the current lock-in case management program, and

  (b) Consider appropriate initiatives developed by the Governor's Healthy North Dakota program's Third Party Payor Committee that support and promote healthy lifestyles of Medicaid recipients.

Narrative: The aging of North Dakota's population suggests increasing demands for health care services in the next five to ten years, especially specialized services by an older population with increased health care needs. Providers will see increasing numbers of clients with several chronic diseases. These clients will require improved coordination of care.

A lack of consistent information is a problem. In addition to multiple sources of information, there also appears to be differences in the various regions of the state and differences between rural and urban access to both services and information. Another issue that arose was the inability for some sources of information or services to be of assistance if they did not cater to the specific need presented. There are many levels of systems entry from simply receiving

information and referral (211 or Senior Info-line) to preliminary screening and finally comprehensive assessment. If there is to be one single point of entry for screening or assessment for all levels of care, it will need to be adequately funded.

Closely related to this issue is the need for an initial uniform assessment process. As individual's assessed needs change, there is a need for the money to follow the individual, to the most appropriate, least restrictive setting.

On the acute care side, Medicaid recipients should access benefits at the appropriate level of care. However, while the extent of the problem may vary by facility, there exists a substantial misuse of the emergency room as a point of presentation by Medicaid beneficiaries.

North Dakota's eligibility thresholds are more restrictive than surrounding states, while Medicaid program benefits in North Dakota are comparable with surrounding states. While enrollment in North Dakota's Medicaid program is at an all time high, claim trends are more stable.

The Medicaid program should use incentives to encourage positive health and lifestyle choices by Medicaid recipients. There is a wellness/prevention component in the Medicaid program. The program includes preventative / wellness services, including nutrition counseling (morbid obesity), tobacco cessation counseling and medications, the Health Tracks program for children, care management for pregnant women, and wellness services provided in the Altru managed care plan.

DHS should be the lead agency for educating and informing the public about Medicaid services and access. Coordination to ensure consistent information is presented is critical. DHS should partner with other public service interests including local public health units to promote healthy lifestyles as an important way to improve health and to reduce costs. In addition, efforts should be made to work with the financial, provider, insurance and legal communities to better inform the public on how to properly plan for LTC needs and costs.

DHS & the ND Health Department should be encouraged to develop pilot projects in the area of disease management. The State agencies should also encourage local entities with flexibility so as to promote new and creative approaches to providing services.

V. Medicaid Prescription Drug Benefits

- Ensure Access to Prescription Drug Benefits
  Ensure beneficiary access to medically necessary prescription drugs without undue administrative burdens. Specifically, DHS should redirect its cost containment strategy from one of identifying drug categories for prior authorization to the establishment of an evidence-based preferred drug list. This effort should include revision of the statute (NDCC Ch. 50-24.6) creating the Drug Use Review Board.

Narrative: As an optional Medicaid benefit in North Dakota, outpatient prescription drugs constitute over 28% of all mandatory and optional medical services. While Medicaid has experienced increases in drug payments in excess of 10% per year in fiscal years 2001 and 2002, payments actually dropped by 2% in fiscal year 2003. Medicaid credits new initiatives implemented in 2002 for "stabilizing and limiting" the growth in prescription drug costs. These initiatives included a $3 copayment imposed on brand name drugs, which resulted in the greater use of generic products.

Physicians have the primary responsibility for ensuring that Medicaid prescription drug cost containment programs support the provision of medically necessary care. While costly, prescription drugs improve the quality of life for many Medicaid recipients and are less costly than hospitalization, surgery or other therapies. Therefore, choice of drugs should be based on clinical criteria and not solely on cost.

The provider response to the current prior authorization program implemented by the new Medicaid Drug Use Review Board is mixed. Providers are increasingly opposed to the administrative burdens imposed by "piece-meal" cost containment efforts which equate to additional financial responsibilities for providers.

While there was reduction in prescription drug spending in 2002-03, expenditure growth is projected in the low double digits for the immediate future. With respect to cost containment programs, thirty states have implemented or plan to implement a preferred drug list (PDL) to control Medicaid fee-for-service prescription drug spending – lists of preferred prescription medications that recipients generally may receive without first obtaining prior authorization from a state. North Dakota has not implemented a PDL program, but the topic of PDLs with supplemental rebates is being considered by the Legislative Council's interim Budget Committee on Health Care. The Department has expressed the view in testimony to the interim committee that supplemental rebates allow a program to offer more medication choices, thereby reducing the administrative burden by decreasing the number of prior authorizations.

VI. Housing, Assisted Living and Other Community Based Services

These recommendations for benefit enhancements should be considered only in recognition of the previous recommendation that changes in government commitments should be made before additional benefit commitments are made

- The State needs to develop a long term plan for housing for the elderly and disabled.

  (a) Develop plan to address changing demographics.

  (b) Consider funding assistance for assisted living arrangements.

Narrative: Helping the elderly and the disabled to live as independently as possible in the community of their preference is a key component of a least restrictive environment. Core services are necessary to support independent living. Transportation, affordable housing and adequate support to remain in the setting (Home and Community Based Services) are three core services identified as critical, but not universally available.

Transportation is an issue that affects both housing and medical access. Without adequate transportation, a person may have to choose a more restrictive setting to access services and remain safe. While it sometimes is an issue in the cities, it is more of a problem in rural areas.

Affordable assisted living is in short supply in North Dakota. In recent years, entities in the cities have begun to offer assisted living accommodations; however, these facilities tend to be upscale and not affordable to many people. The success of these entities points to the appeal such living arrangements have for elderly persons. On the surface it appears that assisted living facilities of a more affordable level would see significant usage if they were available.

A serious shortage of services through the Individualized Supported Living Arrangement (ISLA) program and Qualified Service Provider (QSP) program results in people living with inadequate support or remaining institutionalized. Additionally, low salaries for support staff lead to a shortage of workers.

The State needs to develop a long term plan for housing for the elderly and disabled. Demographics of an aging population and longer life expectancies indicate that this problem will only accelerate in years to come and it is important to begin to plan for the future.

People of moderate income fall into a housing gap when their home is no longer appropriate yet they do not need nursing home services. DHS should consider a program to subsidize assisted living facilities to a cost level that is somewhat comparable to basic care. Such a move could stimulate private sector interest in providing such living arrangements to a larger percentage of the elderly by making it more affordable.

CONCLUSION

In North Dakota an aging population, longer life spans and accelerating medical and long term care costs are all combining to create a challenge for Medicaid in the near future. In order to avert significant financial problems, best practices in administration and programming will be required We believe the recommendations in this report are all a part of and can assist with implementation of those best practices. We are also very concerned that actions need to be taken soon. The issues are urgent, but manageable if they are addressed in a timely fashion.

APPENDIX A

MEDICAL CARE ADVISORY COMMITTEE

Pursuant to Title 42, Section 431.12 of the Code of Federal Regulations, the Department of Human Services is required to have a Medical Care Advisory Committee for the purposes of advising the department about health and medical services, including participating in policy development and program administration. The committee is to consist of physicians and other representatives of the health profession who are familiar with the medical needs of the low-income population and the resources available and required for their care; members of consumers' groups, including Medicaid recipients, and consumer organizations such as labor unions and cooperatives; and the director of the State Department of Health (State Health Officer). North Dakota currently has a Medical Care Advisory Committee and the members are as follows:

July 31, 2004

MEDICAL CARE ADVISORY COMMITTEE MEMBERSHIP

Terry Dwelle, M.D.
State Health Officer
Bismarck, ND

Terry Johnson, M.D.
Archway Mental Health Services
Bismarck, ND

Lynn Blakeman
St. Vincent's Care Center
Bismarck, ND

Alison Fallgatter, DDS
Bismarck, ND

Amy Fleck, O.D.
Family Vision Clinic
Bismarck, ND

David Peske
ND Medical Assoc.
Bismarck, ND

Delores Farrell
Public Member
Bismarck, ND

Connie Glasser
Public Member
Bismarck, ND

Gary Bettig, M.D.
Medical Consultant
Medical Services, DHS
Bismarck, ND

Howard Anderson, R.Ph.
Turtle Lake, ND

APPENDIX B-1

Overview of North Dakota's MR/DD Waiver Program

North Dakota received approval to begin implementation of its Home and Community Based Services Waiver program serving individuals with mental retardation and developmental disabilities beginning April 1,1983. North Dakota's MR/DD Waiver allows individuals to receive case management, homemaker, personal care, adult day health, habilitation, family support services, respite, family training-infant development and adult family foster care.

The populations that are served on this waiver are the following: individuals who have a diagnosis of mental retardation and developmental disability, require the level of care provided in an Intermediate Care Facility for the Mentally Retarded (ICF/MR), be financially eligible for Medicaid (for this waiver the eligibility is the aged, blind or disabled who meet requirements that are more restrictive than those of the Supplemental Security Income (SSI) program and the medically needy) and require home-based services which are no more costly than institutional services.

The Disabilities Services Division, Developmental Disabilities Unit, directly operates the waiver, however; the State Medicaid Agency (Medical Services) exercises administrative discretion in the administration and supervision of the waiver. The philosophy of the DD Unit regarding operational status of this waiver involves input from a variety of individuals who function as a team and who have different responsibilities for ensuring the operational functioning of the waiver program.

Based on the assurances North Dakota had provided the Centers for Medicaid and Medicare Services, our request for renewal of our waiver was approved for a 5-year period, effective April 1, 2004. Currently, there are approximately 2,600 recipients of waiver services.

1915(c) MEDICAID WAIVERS FOR HOME AND COMMUNITY BASED SERVICES FOR THE AGED AND DISABLED

A home and community-based services (HCBS) waiver is an agreement between the Centers for Medicare and Medicaid (CMS) and the State's Medicaid Agency. HCBS waivers enable the eligible individual to choose between institutional care or, if his/her needs can still be met, living in community. In 1981 the federal government acknowledged the Medicaid Program had a bias toward funding institutional care, such as nursing homes. HCBS waivers were developed as a means of countering that bias, with the stipulation that the cost of community support services cannot cost more than institutional care. The Waiver provides federal matching funds for needed services otherwise not available under the State's Medicaid Program. A maximum of $2,400 per recipient per month is allowed.

ELIGIBILITY FOR AGED & DISABLED WAIVER

- Medicaid recipient, and
- Screened at nursing facility level-of-care, and
- At least 65 years of age OR disabled by Social Security Disability criteria, and
- Capable of directing his/her own care or legal authority, and
- Lives in own home/apartment (not dormitory or other group housing), and
- Has service/care need(s) that can be met within scope of this Waiver.

SERVICES AVAILABLE UNDER AGED & DISABLED WAIVER

HCBS Case Management
Personal Care Service
Chore Service
Adult Day Care
Specialized Equipment
Respite Care
Adult Family Foster Care
Homemaker
Non-Medical Transportation
Environmental Modification
Training Family Members
Adult Residential Service

PROVIDER REQUIREMENTS

Clients select their provider(s) from the "QSP LIST" issued by the Aging Services Division to the county social service office for each service provided in that county.

12/

1915(c) MEDICAID WAIVERS FOR HOME AND COMMUNITY BASED SERVICES TBI

A home and community-based services (HCBS) waiver is an agreement between the Centers for Medicare and Medicaid (CMS) and the State's Medicaid Agency. HCBS waivers enable the eligible individual to choose between institutional care or, if his/her needs can still be met, living in community. In 1994 North Dakota received approval for a Medical Waiver for TBI.

ELIGIBILITY FOR TBI

- Receiving Medicaid, AND
- Screened in need of nursing facility level-of-care AND
- Disabled by social security criteria AND
- 18 years of age and over (does not have IEP) AND
- A diagnosis, which is not degenerative or congenital, of traumatic brain injury or acquired brain injury (e.g. anoxia, infections, CVA, aneurysms, tumors which are not expected to result in death, toxic chemical reactions) resulting in significant emotional, behavioral, or cognitive impairments AND
- Be capable of directing care as determined by inter-disciplinary team or, if not, legal party to act in their behalf AND
- Neuropsychological Evaluation

SERVICES AVAILABLE UNDER AGED & DISABLED WAIVER

TBI Case Management
Personal Care Service
Chore Service/ERS
Transitional Care
Specialized Equipment
Respite Care
Prevocational Services
TBI Residential Care
Supported Employment
Non-Medical Transportation
Environmental Modification
Training Family Members
Substance Abuse Counseling
Behavior Management

PROVIDER REQUIREMENTS

Clients select their provider(s) from the "QSP LIST" issued by the Aging Services Division to the county social service office for each service provided in that county.

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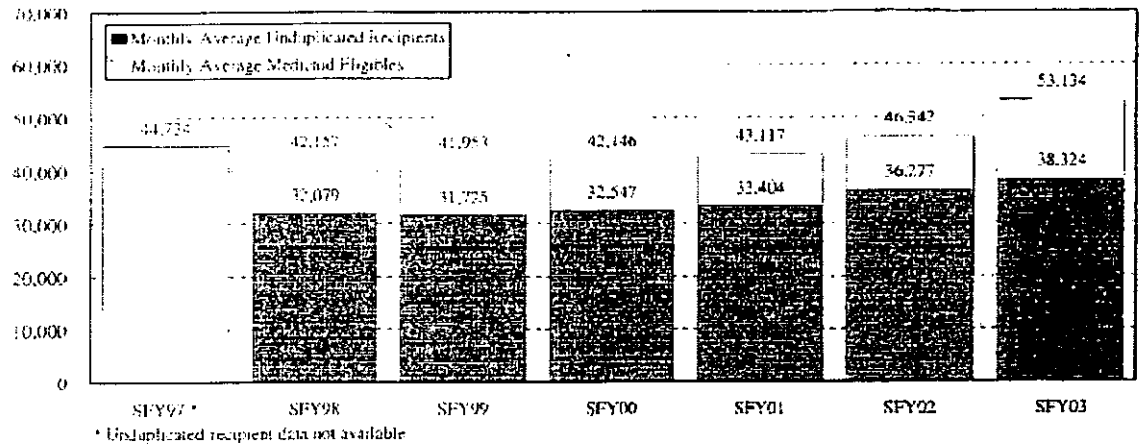
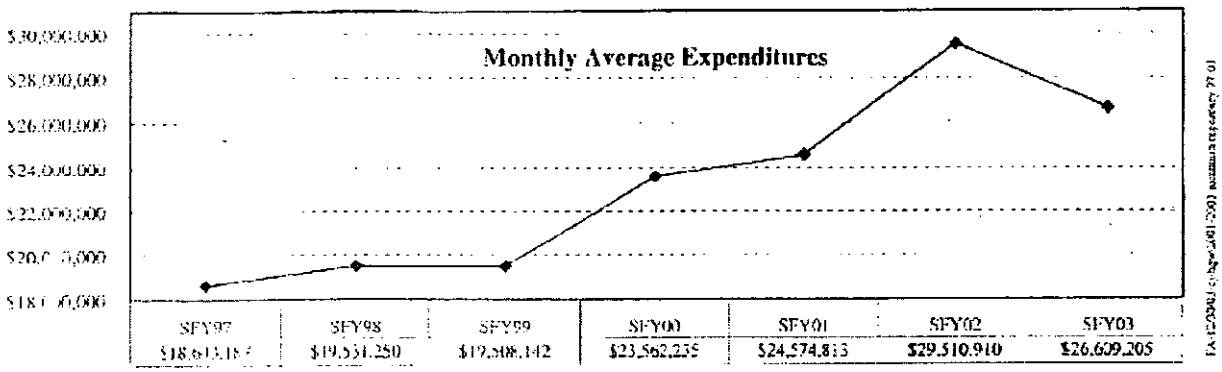
North Dakota Department of Human Services

Medicaid

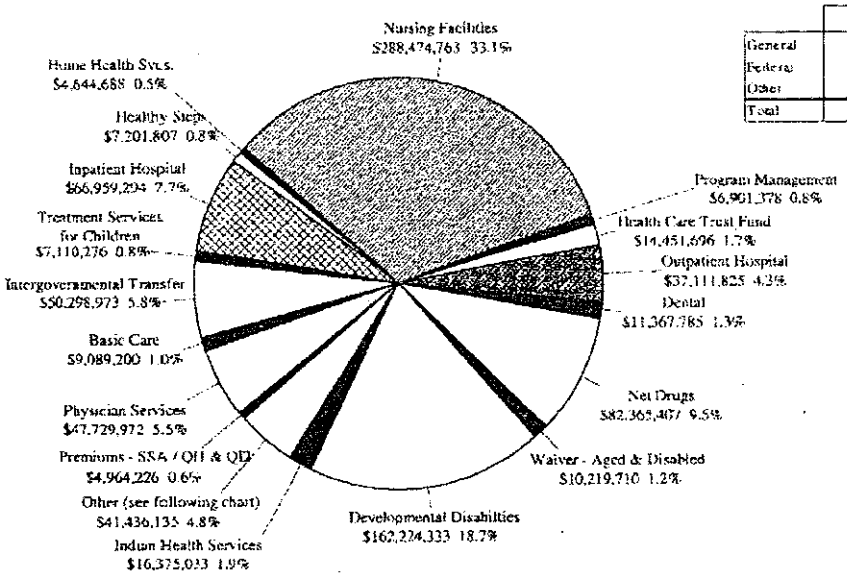
Monthly Average Number of Eligibles, Recipients, and Expenditures by State Fiscal Year





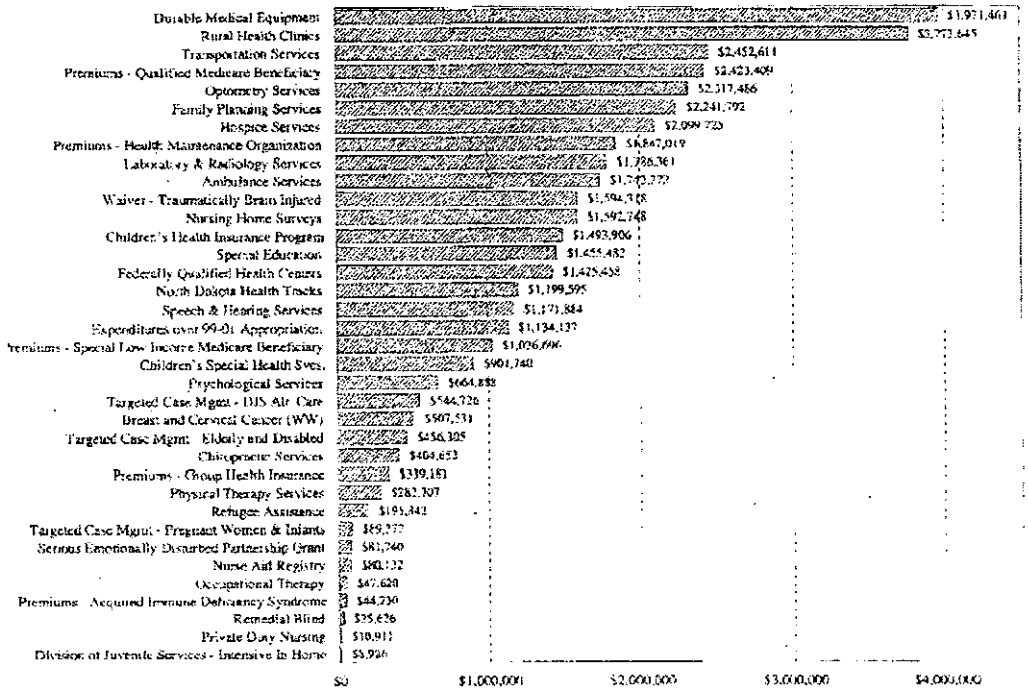
Source- DHS 2001-2003 Biennial Report

Medical Services Expenditures
2001-2003 Biennium



	Funding	Percent
General	$224,566,916	25.8%
Federal	$592,288,875	68.2%
Other	$52,070,710	6.0%
Total	$868,926,501	100.0%

Total of "Other" Expenditures ($41,436,135)
Medicaid Division (Including DD Grants)
2001-2003 Biennium



Source- DHS 2001-2003 Biennial Report

Attachment 4

Statement PhRMA

Statement in Opposition to North Dakota Senate Bill 2284

January 23, 2005

Position: PhRMA supports unrestricted access to pharmaceutical care for all patients, including those in Medicaid. We respectfully oppose North Dakota SB 2284 and the use of preferred drug lists in the state Medicaid pharmacy program for economic purposes because it jeopardizes the health of patients and is not sound fiscal public policy.

Senate Bill 2284 proposes to implement a preferred drug list (PDL) for North Dakota Medicaid patients. In addition, the legislation seeks to allow the department to enter into a multistate PDL for the purpose of purchasing drugs, as well as imposing supplemental rebates on the industry.

What many don't realize is that the new federal Medicare drug benefit law can substantially decrease a state's possible savings from a new PDL and multi-state purchasing initiative because dual-eligible beneficiaries, those individuals eligible for benefits under both Medicaid and Medicare, will now be covered by Medicare after January 1, 2006. As a result, the potential savings for these patients will accrue over a diminishing period of time. Also, the number of prescriptions from which savings can be derived (subject to a PDL) will be greatly reduced. The likelihood that a PDL makes sound fiscal policy is slim.

Preferred Drug List (PDL) and Multi-State Initiative

PhRMA supports unrestricted access to medications to all patients, particularly those on Medicaid, who are among the most vulnerable in society. While we commend the authors of the legislation for including important patient protections such as due process, continuity of care, and "dispense as written" requirements, these protections do not solve all the difficulties with a PDL. Patients may still be left without coverage if the Department makes categorical decisions about their drugs prior to the drug being prescribed. Many physicians only know coverage requirements for specific drugs they often prescribe and would only know to write "dispense as written" (DAW) on specific medications when necessary. While PhRMA agrees with the importance of DAW policies, we do not believe they go far enough in protecting the patients. DAW is a band-aid response for an otherwise broken system. PDLs interfere with the physicians' professional judgment and responsibility to deliver quality medical care, regardless of the legislation's attempt at evidence-based decisions.

Regardless of what the legislation states about evidence-based decisions, PDLs are being considered if based upon cost-containment purposes. Physicians feel this is true. According to a recent survey, over 90 percent of physicians believe Medicaid prior drug approval leads to substandard treatment and endangers patients.[1] The survey reports that "nearly all primary care physicians feel that prior authorization will have a negative impact on the overall health of patients who need acute care or rescue medications, and that patients won't have access to the best available treatment (92 and 95 percent, respectively)." Consequently, prior authorization can cause health care spending to grow. The Arkansas Medicaid program reduced prescription drug costs by more than five percent; however, all other healthcare costs increased, including the cost of hospitalization and nursing home care, which resulted in a net increase in costs to the state of $59 million.[2] In addition to being poor health policy, it is inappropriate fiscal policy.

Critics sounding the alarm over increases in pharmaceutical spending and the use of new drugs are not taking into consideration the economic benefits associated with newer drugs. Research demonstrates that use of newer drugs increases life expectancy, improves quality of life, and can mean lower health care spending overall. A recent study prepared for the U.S. Department of Health and Human Services reported, "new medications are not simply more costly

[1] American College of Allergy, Asthma and Immunology (ACAAI) Survey, November 2002.
[2] "Prescription policy saves North Dakota money, Medicaid official says."(July 14 1999). The Charleston Gazette.

than older ones. They may be more effective or have fewer side effects; some may treat conditions for which no treatment was available."[3] Another recent study published in the journal *Health Affairs* stated, " . . . estimates indicate that use of newer drugs tends to reduce all types of non-drug medical spending, although the reduction in inpatient [institutional] spending is by far the largest. This reduction of $71.09 in non-drug spending is much greater than the $18 increase in prescription cost, so using a newer drug results in a substantial net reduction in the total cost of treating a condition."[4]

The state must also keep in mind that protecting its patients may not be easy if it intends to enter into a multistate agreement because other state PDLs may not have the same protections as it. When purchasing for multiple populations and for multiple states it is difficult to meet a state's various populations' needs, as well as program requirements. As a result, the quality of care of North Dakota patients may not be properly addressed.

Moreover, A proposed multi-state program could impact the Medicaid best price rule. While it is not possible to predict what individual companies may do in negotiations, the Medicaid best price law, coupled with a proposed multi-state program, could create uncertain consequences in those negotiations.

Supplemental Rebates

Rebates and discounts are a form of government-mandated price controls that are not in the best interest of patients. Currently, at least 20 percent of the U.S. pharmaceutical market is subject to price controls through federal and state level programs (Public Health Service, Veterans Administration, Medicaid, state pharmacy assistance programs). Price controls lead to an erosion of the free market and discourage innovation, resulting in fewer treatments for patients. Of all U.S. industries, the pharmaceutical industry reinvests the largest share of its revenues back into research and development. With such a commitment to innovation, the pharmaceutical industry can continue to bring new medicines to market to prevent, cure, and better treat disease.

Pharmaceutical manufacturers already pay the state millions of dollars each year in federally-mandated Medicaid rebates. In 2004, pharmaceutical manufacturers paid an estimated $11.4 million in prescription drug manufacturer rebates for the State of North Dakota. If the State insists on attempting to increase rebate amounts through implementation of supplemental rebates, other health care purchasers such as managed care plans, private plans, and patients without drug coverage may be forced to pay higher costs because of market forces.

To continue developing innovative medicines, pharmaceutical companies must be able to attract the investment needed to sustain and enhance its vital research. With the average cost of bringing a drug to market at 800 million dollars, pharmaceutical companies must realize a reasonable return on their risky efforts – only 1 of 5,000 compounds tested finds its way into the nation's medicine cabinets and only 3 of 10 are sufficiently profitable to cover average research and development costs.[5] Although most European countries have established price controls, this has had a deleterious effect on their investment and research. "Although clinical trials occur in almost every country, most of the basic research on new drugs is concentrated in a few areas of the world, the United States, Europe, and Japan. The U.S. accounted for 45% of 152 globally marketed products developed from 1975 to 1994, compared to the next highest, 14% accounted for in the United Kingdom."

For these reasons, PhRMA urges the North Dakota Senate to oppose SB 2284.

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[3] Merlis, Mark, "Explaining the Growth in Prescription Drug Spending: A Review of Recent Studies," *A background report prepared for the Department of Health and Human Services, Conference on Pharmaceutical Pricing Practices, Utilization and Costs*, August 8-9, 2000.

[4] Lichtenburg, Frank R., "Are the Benefits of Newer Drugs Worth Their Cost? Evidence from the 1996 MEPS," Health Affairs September/October 2001): 241-251.

[5] Joseph A. DiMasi, Ph.D., *Risks in New Drug Development: Approval success rate investigational drugs.* Tufts Center for the Study of Drug Development, Tufts University, November 2001.

Attachment 4A

EXECUTIVE SUMMARY

STATE MEDICAID PROGRAM ISSUES: PREFERRED DRUG LISTS – CONDUCTING A COST BENEFIT ANALYSIS

Prepared by:
Mary Kay Owens, RPh, CPh, President, Southeastern Consultants, Inc. and
Linda Schofield, BSN, MPH, Schofield Consulting,
July 2004

A preferred drug list (PDL) is a list of selected drugs that health care providers are permitted to prescribe without prior authorization. Providers must obtain prior authorization from the state Medicaid agency (or its contractor) before any drug that is not included on the PDL can be dispensed.

PDLs primarily focus on drugs used to treat chronic illnesses, which are refilled on a regular basis. These include drugs for diabetes, gastrointestinal conditions, high blood pressure, heart disease, arthritis, asthma, epilepsy, cancer, mental illness, and high cholesterol. Elderly and disabled patients tend to feel the impact of a PDL disproportionately because they suffer from more chronic illnesses than younger and non-disabled patients.

While several states have implemented a PDL in their Medicaid program and others are considering or planning to implement a PDL in the coming year, the new Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) significantly reduces the state's potential for savings from new PDL initiatives. The MMA shifts responsibility of prescription drug benefits for dual eligible patients[i] from Medicaid to Medicare effective January 1, 2006. Therefore:

- Potential savings for dually-eligible patients will accrue over a diminishing period of time, and
- The number of prescriptions from which savings can be derived (subject to a PDL) will be greatly reduced.

This means that the cost of a PDL implementation is amortized over a smaller base of savings opportunities.

In addition, few states recognize the unintended and usually un-monitored costs of a PDL implementation. The mandatory switches in drug therapy associated with a PDL can result in:

- Additional physician office visits,
- Lab work for monitoring and titrating new prescriptions,
- Increased concomitant medications, and
- More treatment failures.

These costs are shown to have a substantial negative impact on the true valuation of net PDL savings.

Recently, a white paper was prepared by the authors of this brief that provides a framework for states to estimate the potential first year return on investment from a PDL implementation, in light of the impending Medicare drug benefit. In the paper, two sample calculations illustrate that *savings from a PDL are reduced by as much as 60 percent when all implementation costs and indirect non-pharmacy costs are accounted for* (and the PDL is implemented within six months of the Medicare drug benefit effective date of January 1, 2006). A reduced savings expectation may make the decision to invest in a PDL unattractive in terms of its return on investment. *The savings may be further eroded depending upon the state's Federal Medical Assistance Percentages (FMAP)* [ii] since there are minimal savings to a state with a large federal match. (See Table 1.)

The sample calculations in the white paper include assumptions based on data from the literature and from other states; however, each state should input its own data in order to determine their respective return on investment. In addition to the state's estimate of return on investment, the state should also consider the following before making the decision to implement a PDL:

- There can be significant disruption to **patients** who are required to switch from a trusted, effective drug to a new, as yet untried drug. There are real quality of care and cost concerns associated with the five to six percent of drug switches that fail to achieve an acceptable therapeutic outcome.
- The return on investment for alternative cost containment strategies, such as **disease and targeted case management**, may equal or exceed the return on investment for a PDL without any of the aforementioned quality-of-care concerns.
- The cost impact of dealing with prior authorization requirements and denials is significant for

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[i] *A dual eligible is a beneficiary who is eligible for Medicaid and entitled to Medicare, the federal health insurance program.*

[ii] *The federal government and the states share responsibility for financing Medicaid. The portion of the Medicaid program paid by the Federal government, known as the Federal Medical Assistance Percentage (FMAP), varies by state with an authorized rate of between 50 and 77 percent, depending on the state's per capita income. (Financing the Medicaid Program: The Impact of Federal Fiscal Relief. Kaiser Commission on Medicaid and the Uninsured. April 2004.)*

physicians and pharmacies.

- The cost impact to the **Medicare** program is significant, and indeed, dwarfs the impact on state coffers. This is because the direct and indirect cost of drug switches for dually eligible patients (including physician, laboratory, and emergency room services) are paid by Medicare, not Medicaid. While a state may save money in the pharmacy budget, the federal government may experience large increases in other medical costs to support the drug switches, as well as additional medical costs when some of the drug switches fail.

In summary, it is important that the decision to implement a PDL not be based on over-simplified and over-sold estimates. In light of the new Medicare drug benefit, states need to look carefully at whether a PDL is an effective way to invest their time and money in order to achieve savings in Medicaid.

Table 1 — First Year PDL Costs and Savings

Tangible Costs	**Savings for Medicaid-Only Recipients**
State staffing costs (to oversee P&T committee and hire & manage vendors, etc.) Vendor costs for PDL: • Development • Implementation • Prior authorization processing MMIS costs for duplicate claims when prior authorization results in a claim denial Non-drug benefit costs for physician office visits and lab work necessary to switch patients to PDL drug Non-drug benefit costs when new PDL drug fails to work or causes adverse results and patient must be switched back or needs emergency care services for treatment failures	Lower drug ingredient costs for each new PDL prescription and/or refill for 12 months of the year
Intangible Costs from State Perspective	**Savings for Dual Eligible Recipients**
Labor costs for pharmacies and physicians to handle prior authorization requirements Patient inconvenience and time loss to respond to prior authorization requirements Quality of life impact when prior authorization process results in: • Loss of symptom control • Treatment gaps • Treatment failures Non-drug benefit costs to Medicare	Lower drug ingredient costs for each new PDL prescription and/or refill for however many months before January, 2006

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