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Theresa A. Lee — 10-16-03

Operator's Signature — Date

2003 SENATE HUMAN SERVICES

SB 2088

2003 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. SB 2088

Senate Human Services Committee

☐ Conference Committee

Hearing Date January 29, 2003

Tape Number	Side A	Side B	Meter #
1		X	2260 - end
2	X		0-2852
Committee Clerk Signature	Donna Kramer		

Minutes:

SENATOR JUDY LEE called the public hearing to order on SB 2088 relating to development of a pharmacy best practices and cost control program and to authorize additional prescription drug cost containment strategies in the medical assistance program.

DAVID ZENTNER, Director of Medical Services for the Department of Human Services, appeared to provide information regarding this bill. (Written testimony with attached letter) (Proposed Amendments attached) (Meter # 2420 - 2865)

DAVID ZENTNER: Explanation of what drugs are in the formulary process. (Meter #2870 - 3110)

GALEN JORDRE, Ex. Vice President of the ND Pharmaceutical Association, testified in support of SB 2088. (Written testimony) (Meter 3210 - 3451)

DAVE PESKE, Lobbyist for ND Medical Association, testified in support of the bill. (Copy of proposed amendments attached) (Meter # 3519 - 3930)

AL STENEHJEM, Ex. Director of the Mental Health Association, testified in support of bill.

(Written testimony provided with an amendment) (Meter # 3940 - 5078)

DAVID BOECK, a state employee and lawyer for the Protection & Advocacy Project, testified.

He indicated this bill provides no immediate process to challenge the Department's "prior authorization" decisions. This bill provides no opportunity to meaningful challenge a Department decision when a patient needs immediate treatment. He offered to work with the Committee to design appropriate amendments. (Meter # 5238 - 5895)

SENATOR BROWN: Formularies have worked for the general population. Why are you so concerned about the Medicaid population?

DAVID BOECK: Many people covered by general insurance policies have the wherewithall to pay the difference between a formulary drug and a drug that is more expensive. Continued discussion. (Meter # 5939 - 6185)

CARLOTTA McCLEARY, works with the Federation of Families for Childrens Mental Health, testified in favor of the bill. (Tape 1, Side B, Meter # 6234 to end and Tape 2, Side A, 0-68)

CALVIN ROLFSON, Legislative counsel to the Pharmaceutical Research and Manufacturers of America, testified in opposition to the bill. (Written testimony attached with suggested amendments) (Medicaid Drug Rebates States list attached) (Meter # 166 - 1088)

CHRIS WARD, Independent Counsel to PhRMA, testified in opposition. (Attachment given on graphs and charts) His testimony focused on health policy issues relating to prescription drug access for both pharmaceutical industry and for a variety of diseased patients' societies. Stated preferred drug list ... barrier to patient access. (Meter # 1130 - 2750)

SENATOR LEE closed the public hearing for SB 2088. (Meter # 2852)

2003 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. SB 2088

Senate Human Services Committee

☐ Conference Committee

Hearing Date February 4, 2003

Tape Number	Side A	Side B	Meter #
4	X		5775 - 0
		X	0 - 86
Committee Clerk Signature	Donna Kramer		

Minutes:

SENATOR JUDY LEE opened the committee discussion on SB 2088 regarding the development of a pharmacy best practices and cost control program and to authorize additional prescription drug cost containment strategies in the medical assistance program.

She said that there were two bills in the House that have to do with prescription drugs. We may end up kind up nullifying one another. Senator Lee suggested that consideration be given to not passing this bill so that we can work with the House bill. It has much of the same stuff, but rather than focusing on the preferred drug list which the Dept. of Human Services would prefer, it would be a formulary ... drugs first choice. (Tape 4, Side A, Meter # 5775 - end and Side B, 0 - 70)

SENATOR ERBELE made a motion to Do Not Pass

SENATOR BROWN seconded the motion.

Roll call was read. 6 yeas 0 nays.

SENATOR BROWN will be the carrier. (Meter # 86)

FISCAL NOTE

Requested by Legislative Council
01/03/2003

Bill/Resolution No.: SB 2088

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

	2001-2003 Biennium		2003-2005 Biennium		2005-2007 Biennium	
	General Fund	Other Funds	General Fund	Other Funds	General Fund	Other Funds
Revenues				($2,933,895)		($3,261,577)
Expenditures			($1,000,000)	($2,933,895)	($1,178,316)	($3,261,577)
Appropriations						

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

2001-2003 Biennium			2003-2005 Biennium			2005-2007 Biennium		
Counties	Cities	School Districts	Counties	Cities	School Districts	Counties	Cities	School Districts

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

This bill permits the Department of Human Services to establish a prior authorization process for perscription drugs provided through the Medicaid Program. It would allow the Medicaid Program to establish a list of preferred drugs that would not require prior authorization. Drugs not on the list would require prior authorization before payment would be made by the Department. The fiscal impact of this bill has been included in the Executive Budget.

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

The reduction in other revenues relates to Federal Medicaid funds.

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

Grant expenditures have been decreased by $5,383,895, with $1,725,000 being general funds.

This anticipated savings is offset by an increase in operating expenditures of $1,450,000, with $725,000 being general funds for the contracting of program services.

This amounts to a net decrease in expenditures of $3,933,895 with $1,000,000 being general funds.

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

The 2003 - 2005 Executive Budget includes the prior authorization process for prescription drugs. **If this bill does not pass, $3,933,895 would need to be added to Medical Services budget, with $1,000,000 being general funds .**

Name:	Debra A. McDermott	**Agency:**	Human Services
Phone Number:	328-3695	**Date Prepared:**	01/15/2003

Date: 02-04-03
Roll Call Vote #: 1

2003 SENATE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 2088

Senate Human Services Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken Do Not Pass

Motion Made By Sen. Erbele Seconded By Sen. Brown

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

Total (Yes) 6 No 0

Absent _____

Floor Assignment Sen. Brown

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

REPORT OF STANDING COMMITTEE (410)
February 5, 2003 7:41 a.m.

Module No: SR-22-1665
Carrier: Brown
Insert LC: . Title: .

REPORT OF STANDING COMMITTEE

SB 2088: Human Services Committee (Sen. J. Lee, Chairman) recommends **DO NOT PASS** (6 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). SB 2088 was placed on the Eleventh order on the calendar.

2003 TESTIMONY

SB 2088

Medicaid Drug Rebates, 2000

State	Allocation of Drug Rebate Moneys[1]	Total Rebates[2]	Federal Share[2]
National Total		***$3,988,646,518***	***$2,280,371,488***
Alabama	Medicaid Drug Budget	$60,984,826	$42,485,689
Alaska	Medicaid General	$8,594,014	$5,139,221
Arizona[4]	-	-	-
Arkansas	Medicaid General	$40,814,931	$29,883,245
California	Medicaid Drug Budget	$600,895,711	$308,431,431
Colorado	Medicaid General	$28,832,989	$14,585,937
Connecticut	Medicaid General	$49,164,014	$24,602,011
Delaware	Medicaid General	$13,780,359	$6,965,075
District of Columbia	Medicaid General	$9,215,651	$6,451,065
Florida	Medicaid Drug Budget	$248,637,014	$141,212,269
Georgia	General Fund	$91,886,605	$55,206,228
Hawaii	General Fund	$10,947,632	$5,584,387
Idaho	Medicaid General	$13,984,004	$9,809,778
Illinois	Medicaid Drug Budget	$143,590,170	$72,263,431
Indiana	General Fund	$84,453,135	$52,141,365
Iowa	General Fund	$36,040,216	$22,801,180
Kansas	General Fund	$31,022,023	$18,676,788
Kentucky	Medicaid General	$93,688,165	$66,263,557
Louisiana	Medicaid Drug Budget	$84,800,897	$59,739,453
Maine	General Fund	$31,598,262	$20,941,814
Maryland	Medicaid General	$42,081,781	$21,144,564
Massachusetts	Medicaid General	$146,225,538	$73,686,348
Michigan	Medicaid Drug Budget	$75,687,945	$41,757,587
Minnesota	General Fund	$43,228,324	$22,253,941
Mississippi	Medicaid General	$61,260,326	$47,145,011
Missouri	Medicaid General	$110,025,619	$67,118,836
Montana	General Fund	$10,985,923	$7,975,111
Nebraska	Medicaid General	$31,004,940	$19,079,756
Nevada	Medicaid Drug Budget	$4,863,879	$2,441,096
New Hampshire	General Fund	$15,073,211	$7,565,378
New Jersey	Medicaid Drug Budget	$105,535,091	$53,012,631
New Mexico	General Fund	$8,901,456	$6,526,547
New York	General Fund	$470,317,992	$235,158,996
North Carolina	Medicaid General	$140,047,825	$87,687,234
North Dakota	Medicaid General	$6,503,601	$4,587,990
Ohio	Medicaid General	$171,685,793	$100,728,336
Oklahoma	Medicaid Drug Budget	$37,135,809	$26,464,341
Oregon	General Fund	$32,056,386	$19,420,533
Pennsylvania	Outpatient Appropriation	$118,989,849	$64,226,599
Rhode Island	General Fund	$19,223,034	$10,336,226
South Carolina	Medicaid Drug Budget	$73,052,676	$51,571,964
South Dakota	Medicaid General	$7,198,848	$4,975,389
Tennessee	General Fund	$41,302,450	$26,061,846
Texas	Medicaid Drug Budget	$222,314,531	$136,729,535
Utah	General Fund	$21,889,639	$15,708,314
Vermont	Medicaid General	$17,869,053	$11,144,557
Virginia	Medicaid Medical Budget	$75,630,717	$39,258,117
Washington	General Fund	$69,782,396	$36,262,361
West Virginia	Medicaid General	$46,762,149	$34,968,735
Wisconsin	Medicaid Drug Budget	$66,358,433	$39,156,515
Wyoming	Medicaid Drug Budget	$4,720,686	$3,033,170

[4]Does not apply for Arizona. Arizona has an 1115 waiver for which special rules apply.
Sources: [1]As reported by State drug program administrators in the 2001 NPC Survey.
[2]CMS, HCFA-64 Report, FY 2000.

TESTIMONY

BY
CALVIN N. ROLFSON
ON BEHALF OF
PHARMACEUTICAL RESEARCH AND MANUFACTURERS
OF AMERICA (PhRMA)
IN OPPOSITION TO
SENATE BILL NO. 2088

My name is Cal Rolfson, I am the legislative counsel to the Pharmaceutical Research and Manufacturers of America (PhRMA). I appear on PhRMA behalf in opposition to Senate Bill 2088.

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

PhRMA opposes Senate Bill 2088 to establish a preferred drug list, a prior authorization program, and supplemental rebate program within the Medicaid program of the Department of Human Services (DHS), because it could be deleterious to the health of some of North Dakota's most vulnerable citizens its

poor and elderly. It also would extract additional rebates from the pharmaceutical manufacturers when they already pay millions of dollars annually to the North Dakota Medicaid program. Senate Bill 2088 proposed to give to the Department of Human Services the authority to implement a preferred drug list (PDL), a prior authorization program (PA) and seeks to extract additional supplemental rebates from pharmaceutical manufacturers for the Medicaid program.

PhRMA recognizes the need to control the escalating health care cost in North Dakota. However, PhRMA remain opposed to programs that would impose additional Medicaid rebate requirements on pharmaceutical manufacturers, coupled with a prior authorization and preferred drug list program. This "triple-whammy" would be potentially dangerous to the vary vulnerable populations served by the Medicaid program.

According to Senate Bill 2088, the Department must cover non-preferred drugs if they are not on the PDL, if the patient's participating Medicaid physician prescribes them. We applaud the state's proposal for upholding the integrity of the patient-physician relationship and also for recognizing that the patient's healthcare practitioner is the only one that can truly access the patient's therapeutic options- not the government in Bismarck through a PA or PDL program.

According to the language in 2088, the Department must cover the patient's

drugs:

a. If the preferred choice has not been effective, or with reasonable certainty is not expected to be effective, in treating the patient's condition, or
b. When the preferred choice causes or is reasonably expected to cause adverse or harmful reaction in the patient.

These are important protections for the patient that should be in place. Nevertheless, even with these protections, the state should be wary of the dangers PA can present. When the state gets between the patient and the physician, just because they are poor and elderly, bad things can happen. Let me cite some examples:

1. **Restricting access to effective medication may cause patients to suffer medically and, additionally, require more costly treatments in the long run for this state.** According to a recent, November, 2002, survey conducted for the American College of Allergy, Asthma and Immunology (ACAAI), over 90% of physicians believe Medicaid prior drug approval leads to substandard treatment and endangers patients. The survey reports that: " . . . nearly all primary care physician feel that prior authorization will have a negative impact on the overall health of patients who need acute care or rescue

medication and that patients won't have access to the best available treatment (92% and 95% respectively.) Accordingly, prior authorization can cause healthcare spending to grow. The Arkansas Medicaid program reduced prescription drug costs by more than 5%; however, all other healthcare cost <u>increased</u>, including the cost of hospitalization and nursing home care, which resulted in a net increase in the cost to the state of $59 million.[1]

2. **<u>The interference with medical care has been the subject of a class action lawsuit brought in Florida.</u>** Medical patients allege that Florida's implementation of a Medicaid prior authorization program has resulted in dire medical consequences for certain Medicaid populations. As examples:

   a. In one circumstance, a liver transplant patient did not receive the appropriate immunosuppressant drug to treat a fungal infection because the drug was not on the prior authorization program. The patient began rejecting his liver and had to be hospitalized

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[1]"Prescription Policy Saves West Virginia Money, Medicaid Officials Said", July 14, 1999, the Charleston Gazette.

for two weeks. While in the hospital, he was able to obtain the appropriate drug and was stabilized. However, upon discharge, he was again unable to receive the appropriate drug and his health has deteriorated and remains precarious.

b. Another patient had to be hospitalized several times because of chest pains and hypertension after the appropriate drugs were denied to her because they were not on the prior authorized or preferred drug list.

c. Out of 1,827 drugs eligible for inclusion at the start of the Florida Medicaid prior authorization program, because of the federal rebate agreement, only 830 drugs were included in the Florida program.[2]

3. **Newer drugs save lives and cost.** 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

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[2]Bauman, Naomi Lopez, "Playing Doctor in Tallahassee: How Law Maker's Efforts to Save Money May Threaten Quality Care for Mentally Ill Medicaid Patients," James Madison Institute Policy Report #37, March, 2002.

expectancy, improves quality of life, and can mean lower healthcare spending overall. A recent study prepared by the United States Department of Health and Human Services reported: " . . . new medications are not simply more costly 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 far from the largest. This reduction of $71.09 in non-drug spending is much greater than the $18.00 increase in prescription cost, so using a newer drug results in a substantial net reduction in the total cost of treating a condition."[4]

In conclusion, I urge the committee to reject the restrictive and potentially

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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, conferences on pharmaceutical pricing practices, utilization and cost, August 8-9-2000.

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

harmful public policies proposed in Senate Bill 2088. PhRMA will be happy to work with the Department to help draft a better proposal that is more cost effective and reflects the dignity to which our poor and vulnerable citizens are entitled in North Dakota.

I would be pleased to respond to questions.

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

Senate Human Services Committee
Fifty-eighth Legislative Assembly of North Dakota
Senate Bill No. 2088
January 28, 2003

Good morning, Chairman Lee, and Members of the Senate Human Services Committee. I am David Boeck, a State employee and lawyer for the Protection & Advocacy Project. The Protection & Advocacy Project serves people with disabilities, many of whom receive Medicaid benefits.

Proponents of this bill have accepted an ambitious mission, guided by three key principles: (1) save money, (2) maintain high quality in prescription drug therapies; and (3) do not compromise the health of Medicaid recipients. If enacted, this legislation must serve all three purposes.

Several proposals in the bill appear particularly promising though many questions arise about how these provisions would work. Briefly, I summarize several concerns about the bill.

→ A drug formulary can be effective at reducing costs but there are disadvantages to some formulary practices. The law should eliminate or minimize those disadvantages. For example, a drug formulary might group many drugs together, though they are substantially different. For example, aspirin and morphine are both pain medications.

→ A drug formulary might clump together many diseases and conditions that respond quite differently to specific medications. An example is low blood glucose, which might arise from insulin-dependent diabetes, non-insulin dependent diabetes, or pancreatic cancer, among other diseases and conditions.

→ One patient may respond much differently to a medication than another with the same disease or condition. A patient with a migraine

headache may respond much differently to the same medication at different times. A patient with a migraine headache may respond differently to a medication in the very early stages of a migraine headache than later in the course of the migraine.

→ There are plans to reduce the census at the State Hospital. A patient's success at returning to the community may depend upon the availability of a specific psychotropic medication. One patient's mental illness may respond much differently to one psychotropic medication than another patient with the same mental illness.

→ Off-label uses of prescription medications are relatively common. For example, several antidepressant medications were widely prescribed to treat pain for years while it was an off-label use.

→ How long will it take to get a particularly promising new medication on the formulary? This is particularly important when there are no medications available that consistently provide successful treatment.

→ Controls over prescription practices could have a very significant impact on the practice of medicine. That is certainly a goal of this proposal. Will these controls be subject to oversight by physicians who specialize in the treatment of a particular disease affected by a preferred drug?

→ Controls over prescription practices could have a very significant impact on the practice of pharmacy. That appears to be a goal of this proposal. Will these controls be subject to oversight by pharmacists with relevant expertise?

It is especially important to have input from practicing pharmacists and specialty physicians. For many diseases and conditions, it is very important that the system be open to new medications. This bill needs some quality control over creation and implementation of the formulary.

This bill provides no immediate process to challenge the Department's "prior authorization" decisions. This bill provides no opportunity to meaningful challenge a Department decision when a patient needs immediate treatment. A process should be included in the bill.

I have not brought proposed amendments to this hearing. I offer to work with the Committee to design appropriate amendments.

Thank you. I am happy to answer any questions you may have.

50th Anniversary Celebration
Mental Health Association in North Dakota

SB 2088

Senate Human Service Committee

Mental Health Association in North Dakota

Allan Stenehjem

Madam Chair and members of the committee, my name is Allan Stenehjem. I am the executive director of the Mental Health Association in North Dakota. The MHA is a non-profit volunteer citizens organization affiliated with the National Mental Health Association.

One of the primary missions of the Mental Health Association in North Dakota is to ensure the availability of appropriate, accessible, and adequately funded treatment and support services for persons with mental illnesses throughout the state of North Dakota. During the last 3 - 4 decades, our organization has worked closely with the legislature, the Department of Human Services, consumers and their families to move our state's delivery system from an over reliance on institutional or custodial care to a community-based system of care that enables them to be independent productive citizens.

One of the greatest challenges government faces is how it incorporates, or fails to incorporate, areas of progress and success into fiscal planning. That is largely the result of the constitutional structure and function of the legislative and executive branches in our state.

Each year, the executive branch produces an executive budget proposal. In creating that, each agency is individually asked to submit its budgetary requirements for consideration. Each agency provides its own framework, absent any input or reflection upon programmatic implications in other agencies. Thus, the proposed state budget often times

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Each agency provides its own framework, absent any input or reflection upon programmatic implications in other agencies. Thus, the proposed state budget often times does not recognize that while an increase in medication expenses in DHS's Medicaid budget is offset many times over by millions of dollars being saved in the State Hospital's budget as it is able to continue to downsize it's psychiatric hospital. Conversely, as access to medications that are critical to the treatment of persons with mental illness in the state is restricted to save scarce resources in the Medicaid budget, it is offset by millions of dollars needed to support the State Hospital.

During the budget hearing this session on the State Hospital, the superintendent stated, "the daily patient census and admissions to the hospital continues to decline." He cited the *number one* reason for this decline as being "The decrease in population was made possible because of the availability of psychotropic medications." The other is the state's commitment to developing community-based services for the treatment of mental illness.

Without effective medications, the trend toward community-based treatment and recovery cannot continue. Admittedly, additional dollars have been spent in North Dakota for new drugs to treat mental illness. But they have helped save millions of dollars in in-patient admissions to the State Hospital and other in patient treatment centers.

Throughout the country, and North Dakota is no exception, state legislators are grappling with the issue of how pharmacy expenditures under Medicaid and other public health programs can be effectively managed.

Under consideration are various management techniques that will restrict access to expensive drugs. The most prevalent of these techniques is the establishment of preferred drug lists (PDLs) and the creation of prior authorization (PA) limitations or restrictions for all drugs on the preferred list.

The question for you today is: what is an appropriate, effective and fair public management policy for access to psychotropic drugs? Psychotropic drugs work differently from other drugs. Pharmacy benefit management procedures such as prior authorization may not cause problems for the treatment of physical illness; however, they will **adversely** affect the treatment of persons with mental illness.

There are several fundamental considerations that indicate that the drugs used for the treatment of mental illness, psychotropic drugs, should be afforded full PDL status and be **exempted** from prior authorization requirements.

The Mental Health Association in North Dakota urges you to consider not including Psychotropic drugs in the Preferred Drug List and Prior Authorization as proposed in SB 2088 for the following reasons:

1. **Psychotropic Drugs Are Different From Other Drugs.**
   a. The average patient response time for psychotropic drugs is from 3 to 6 weeks, and can be even longer. Most other medications have a response time of hours or even minutes. The necessary time for eliminating the effects of psychotropic drugs is similarly lengthy.
   b. Psychotropic drugs are far more likely to induce distinctive treatment responses in patients than are other medications.
   c. Psychotropic drugs are associated with a considerable number of adverse side effects, especially when medical co-occurring conditions, treated and untreated, are present.
   d. Compliance is a significant issue when treating persons with mental illness with drugs, and all the preceding factors contribute to making compliance even more difficult.

2. **Restrictions to Medication Impair Clinical Decision Making/Patient Care**

a. The special complications for clinical decision making created by psychotropic drugs demand that interference with physician choice be minimized.
b. Restrictions imposed by formulary management will interfere with clinical choices necessary to provide the most appropriate medical care, i.e. the most tolerable and effective treatment for each individual patient.
c. Physician, not third parties, should make medical decisions.

3. **Effective Psychotropic Drugs Are Essential to Maintain Persons with Mental Illness in the Community.**

a. Patients who do not receive the appropriate psychotropic drugs are often unable to function as members of the general community and may require hospitalization.
b. Failure to adequately provide access to psychotropic drugs may create an ADA violation (Olmstead) because the state will not be providing the necessary services for all individuals that will keep them from unnecessary institutionalization.
c. The goals of mental health system reform, i.e. community-based placement and treatment, will be undermined if patients access to appropriate drug treatment in restricted.

4. **Negative Fiscal Impact Created by Restriction of Access to Medications.**

a. It is well established that restricting access to drugs often fails to achieve the intended goal of cost containment because unanticipated problems are created that necessitate greater utilization of the overall health system.
b. Initiatives to reduce Medicaid and other public health program pharmacy expenditures must take into account the effect of 1) reduced federal financial participation for decreased state expenditures on pharmaceuticals

and 2) increased state expenditures for more costly hospitalizations and other intensive outpatient services.

c. Mental illnesses are often chronic conditions that create substantial disability. The illnesses are often correlated with other costly social problems such as unemployment, homelessness, and incarceration. Inappropriately treated mental illness clearly has consequences for the community at large as well as for the individual diagnosed with the disorder.

Madam Chair, for these reasons I would like to offer the following amendment to exempt Psychotropic Drugs from Preferred Drug Lists and Prior Authorization requirements.

50th Anniversary Celebration
Mental Health Association in North Dakota

"The department shall not prior authorize or otherwise restrict drugs prescribed for the treatment of:

1) a mental illness, as defined in the most recent publication of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders;

2) HIV/AIDS"

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PROPOSED AMENDMENTS TO SB 2088

Senate Human Services Committee
January 27, 2003

Page 1, line 9, after "services" insert ", with the concurrence of the drug utilization review board established under 42 U.S.C. part 1396,"

Page 2, line 4, after "The" insert "patient's health care provider has determined that the"

Page 2, line 6, after "The" insert "patient's health care provider has determined that the"

Page 2, line 11, after the period insert "This subsection does not apply to pharmacy benefit coverage of drugs for the treatment of mental health or human immunodeficiency virus conditions."

Page 2, line 12, replace "is authorized to" with "shall"

Renumber accordingly

NDPhA
NORTH DAKOTA PHARMACEUTICAL ASSOCIATION

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Testimony before the Senate Human Services Committee
SB 2088
Wednesday, January 29, 2003
Galen Jordre – Executive Vice President

My name is Galen Jordre and I am the Executive Vice President of the North Dakota Pharmaceutical Association (NDPhA) an organization that represents the 700 pharmacists practicing in the state. The NDPhA is here to support the intent of SB 2088.

The NDPhA has gone on record in support of a preferred drug list for the Medicaid program and the prior authorization program needed to implement the list. The purpose of this bill is to give the Department of Human Services the tools necessary to manage utilization of prescription drugs within the Medicaid program.

The intent of the bill is to provide the Department with the same type of tools that are used by private health insurance groups. Because of federal regulations the Department cannot provide standard industry practices such as differential or tiered co-payments to influence choice of prescription drugs. The prior authorization review process then becomes necessary to insure that the preferred drug list is utilized to the greatest extent.

While the bill gives the Department the authority to contract with a third party to implement the program, we feel that there should be language within the bill for the Drug Utilization Review (DUR) Board to provide input into the management process. This language should create a more formal role for the DUR Board in the process and establish parameters to insure that the practices implemented by the third party will meet federal requirements and act to achieve best therapeutic outcomes for Medicaid recipients. We are willing to work with the Department and other interested parties to develop amendments that will achieve those purposes.

We support the initiative shown by the Office of Management and Budget and the Department of Human Services to bring these controls to the prescription drug program. They are essential to the long-term provision of cost-effective prescription drug services to the Medicaid program. We ask for your favorable consideration of this bill.

PROPOSED AMENDMENTS TO SENATE BILL 2088

Page 1, line 12, after "include" insert "a pharmaceutical manufacturers drug access program for low income citizens" and remove "a preferred list of covered"

Page 1, remove line 13

Page 1, line 14, replace "particular diseases and conditions, including generic alterations," with "only those"

Page 1, line 15, remove ", including a prior authorization review process." and remove "any"

Page 1, line 17, after the period, add "in order to promote efficiency and savings, the department shall create and implement the broadest possible list of generic and multi-source drugs that can be acquired at the maximum allowable cost. The department shall also maximize utilization of all edit programs that pertain to payment of Medicaid pharmaceutical claims. The department shall disclose to the Legislative Assembly and any standing or interim committee of the Legislative Assembly requesting it, a complete listing of all such available department edit programs. Upon disclosure, the department shall provide to the Legislative Assembly and any committee of the Legislative Assembly requesting it, a final date for implementing such edit programs." and remove "The department of"

Page 1, remove lines 18 through 22

Page 2, line 4, replace "The" with "After a medically reasonable period of time, the" and after "is" insert "determined by the department, in consultation with the medical assistance recipient's health care provider,"

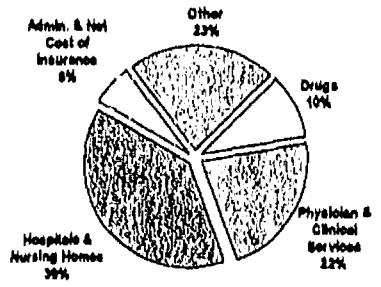
Page 2, line 6, replace "is reasonably" with "with reasonable certainty is"

Page 2, line 8, before "The" insert "The determinations required in subdivisions a and b must be made in writing as to each patient."

Page 2, remove line 12 and 13

Renumber accordingly

The Health Care Dollar 2001

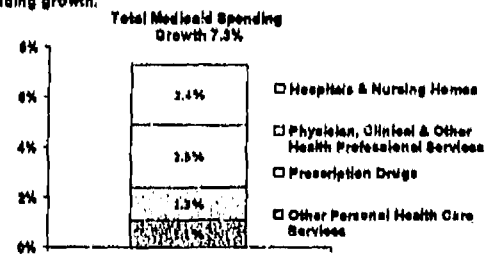


Source: Centers for Medicare and Medicaid Services, January 7, 2002

2

Medicaid Spending Growth 2000 – 2001

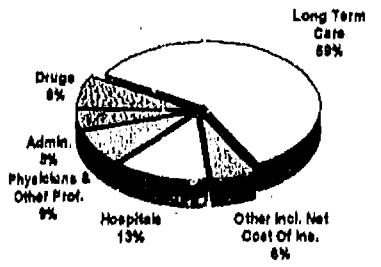
Institutional care and outpatient services continue to drive Medicaid spending growth.



Source: Based on data from Center for Medicare and Medicaid Services, National Health Expenditures, Table 10, Jan 7, 2002 and National Health Expenditure Projections 2000-2010 (published March 2001)

3

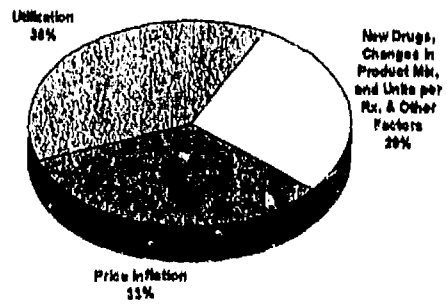
The North Dakota Medicaid Dollar 2001



Source: Centers for Medicare and Medicaid Services, 2000

3

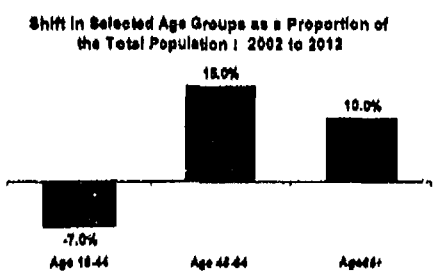
Components of Increase in Plan Member Drug Costs 2000 to 2001



Source: based on data from Express Scripts, 2001 Drug Trend Report

4

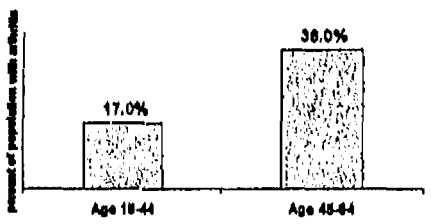
America's Population Is Aging



Source: U.S. Census Bureau

5

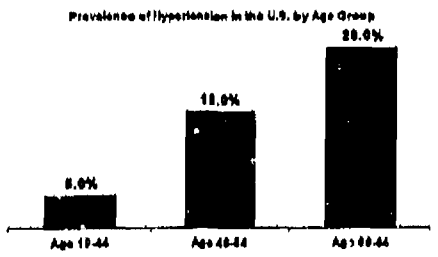
U.S. Prevalence of Arthritis by Age



Source: CDC, Behavioral Risk Surveillance Survey 1987-1988

6

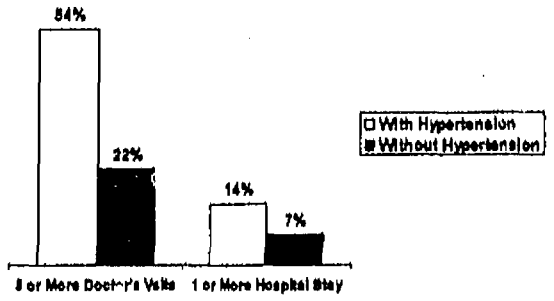
As the Population Increases so does the Prevalence of Chronic Conditions



Source: CDC, Behavioral Risk Surveillance Survey 1987-1988

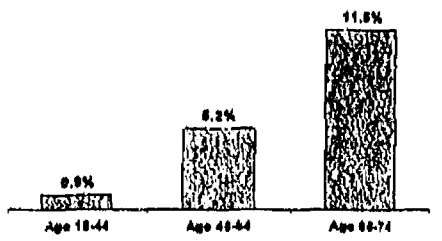
7

Health Service Use Among Those with Hypertension



8

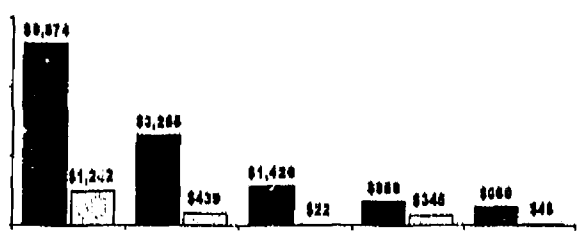
Prevalence of Diabetes in North Dakota by Age



Source: CDC, Behavioral Risk Surveillance Survey 1997-1998

9

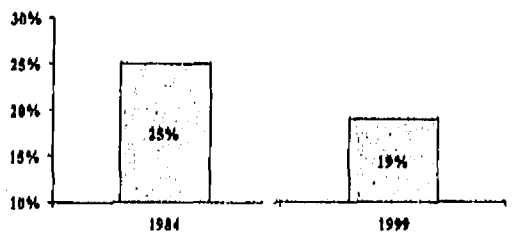
Per Capita Health Spending Age Elderly vs. Non-Elderly Population



Source: CMS, National Health Expenditure Data Base (1998 data)

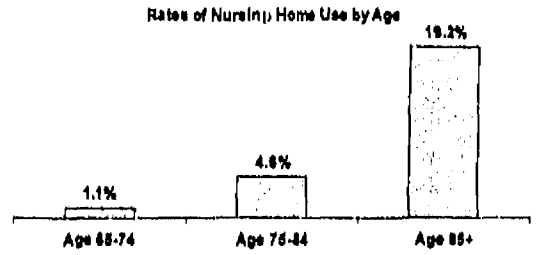
10

Percentage of Elderly Living with Disability



11

Nursing Home Use by Age

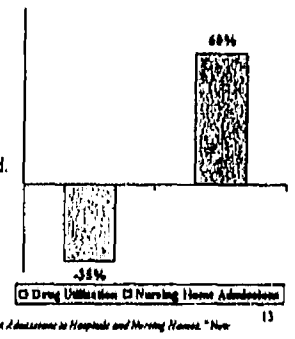


12

Drug Access Restrictions

The Impacts of Medicaid prescription caps on nursing home admissions.

- drug utilization decreased by 15% with prescription caps
- nursing home admissions increased by 60%
- overall health expenditures increased.
- when the restrictions were lifted, nursing home admissions decreased



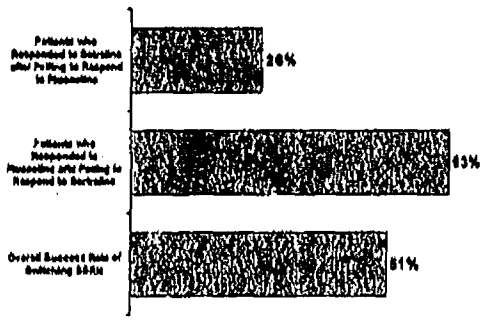
13

Source: Soumerai, et al. "Effects of Medicaid Drug Payment Limits on Admissions to Hospitals and Nursing Homes." New England Journal Medicine, Oct 10, 1991

Elderly patients require individualized care because of the variations from patient to patient

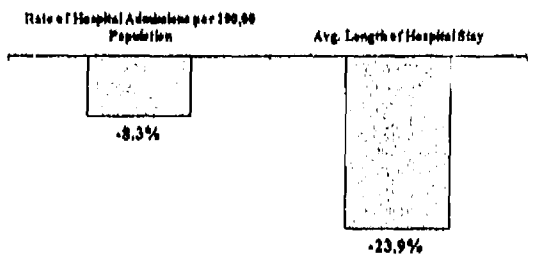
Patients with multiple conditions (Co-morbidity)	Potential Drug Interactions	Adverse Effects
Arthritis *and* High Blood Pressure	NSAIDs + ACE Inhibitors	Some NSAIDs may decrease the effects of some hypertension medications (ACE inhibitors)
High Blood Pressure *and* Heart Disease	Diuretics + Digoxin	Irregular heart beat (Arrhythmia) can result from using these two types of drugs together
Arthritis *and* Diabetes	Cortisone + Insulin	Harmful increase in blood glucose levels

Impacts of Switching Treatments for Depression



15

Hospital Utilization 1989-1999

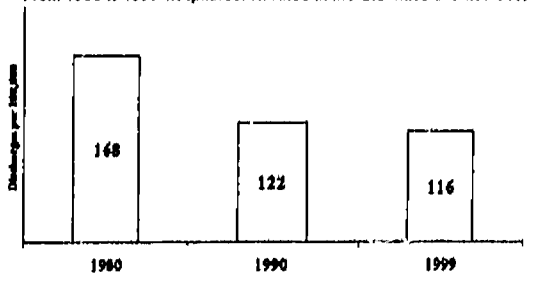


Source: OECD Health Data 2000

16

Saving Health Resources

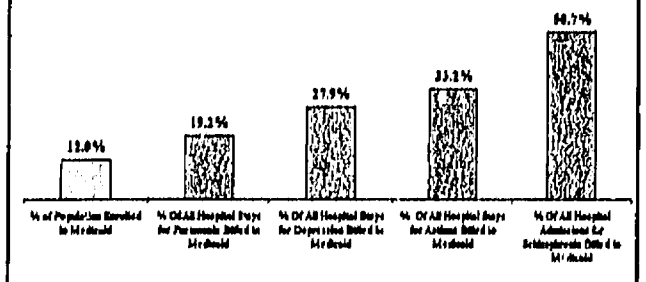
From 1980 to 1999 hospitalization rates in the U.S. have declined 31%



Popovic JR, Hall MJ. 1999 National Hospital Discharge Survey. Advance data from health and vital statistics, no 319. Hyattsville Maryland, National Center for Health Statistics

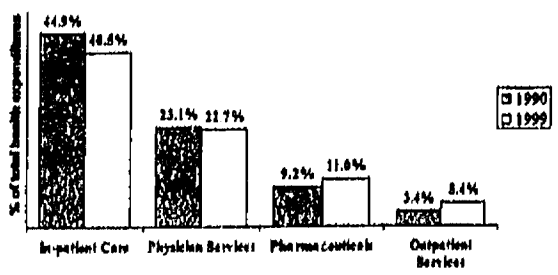
17

Percent Of Hospitalizations Billed to Medicaid



Source: Stranges E, Ye K., Barrett M, Hospitalizations in the United States, 1997. Rockville MD: Agency for Healthcare Research and Quality; 2000. HCUP Fact Book No. 1; AHRQ Publication No. 00-0031.

Shifts In Health Costs 1990 - 1999



19

Impacts of Innovation on Hospital Costs

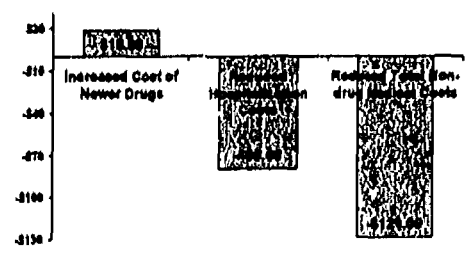
1990	1998
Cost of Hospital Bed Day	Cost of Hospital Bed Day
$694	$1273
No. Of Bed Days	No. Of Bed Days
299,359,200	243,223,200
Population	Population
249,466,000	270,248,000

Avoided costs from actual reduction of 63 million bed days $ 71.46 billion

Avoided costs adjusted for population growth and accounting for improvements length of stay and discharge rates 81.1 million bed days $103.24 billion

20

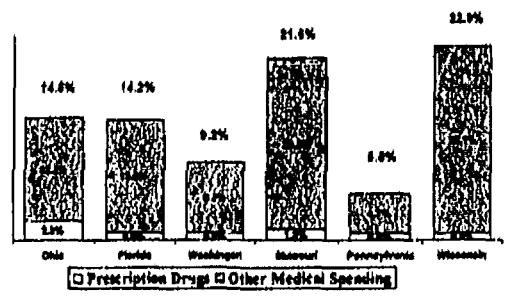
Overall Health Cost Implications of Newer Medicines



Source: Frank R. Lichtenberg, Are the Benefits of Newer Drugs Worth Their Cost? Evidence From the 1996 MEPS, Health Affairs, Volume 20, Number 5, September 2001.

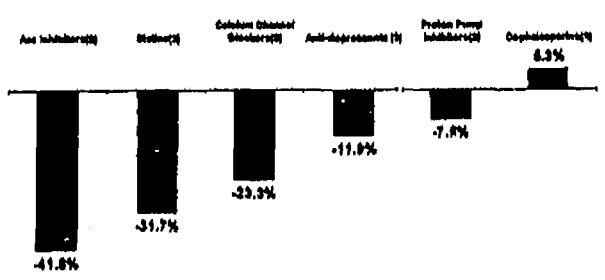
21

Medicaid Spending Growth In Selected States 2000-2001



22

Average Discount of New Drugs Launched in Existing Classes



23

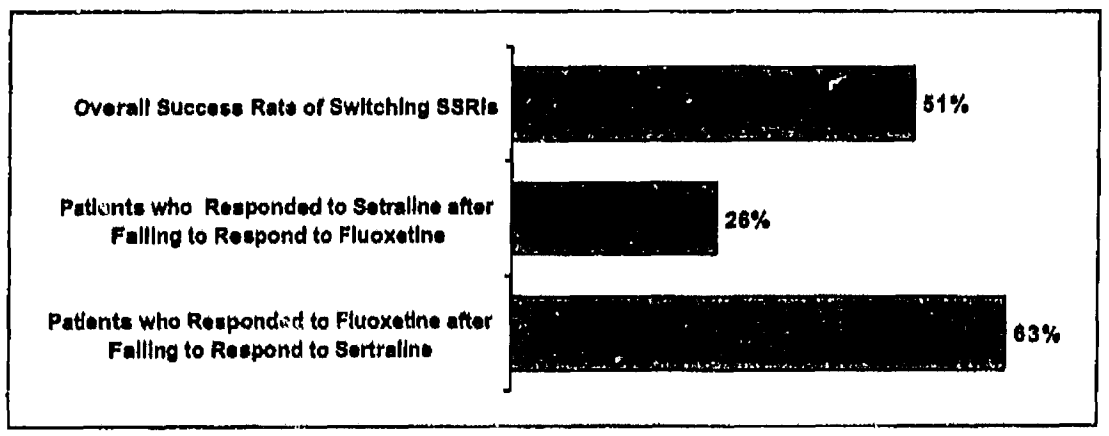
Ward Health
Strategies

Advancing Innovation

Incremental pharmaceutical innovation allows physicians to tailor treatments for depression to individual patient needs.

Incremental advances in drug development represent the evolution of safer and more effective drug therapy. One of the great misunderstandings about new drug development is the dismissal of new agents in a drug class as "me-too' drugs, predicated on the belief that these products essentially duplicate the original breakthrough product.[I] An important benefit of incremental pharmaceutical innovation is that it creates product alternatives that allow treatments to be tailored to individual patient needs. An example of why this is so important for patient care is found in the variation of how patients respond to selective serotonin re-uptake inhibitors (SSRIs), a widely-used drug class for the treatment of depression.

In one study of patients treated with SSRIs for depression 26% of patient who did not respond to fluoxetine did respond to sertraline.[II] Conversely another study concluded that 63% of patients who failed to respond to setraline responded to fluoxetine.[III]. And a third study concluded that the overall success rate from switching from one SSRI to another was 51%.[IV]



All of the drugs within this class are effective in the treatment of depression but the challenge for physicians lies in the wide variation in how individual patients respond to specific drugs. The availability of a variety of medications within this drug class allows physicians to find the right drug therapy that safely and effectively meets the needs of individual patients.

[I] A. Werhelmer, R. levy, T. O'Connor, *Too May Drugs? The Clinical and Economic Value of Incremental Innovations*. Investing in Health: The Social and Economic Benefits of health care Innovation Volume 14, Elsevier Science Ltd. 2001

[II] Zarate, C.A., et al. (1996) Does intolerance or lack of response with fluoxetine predict the same will happen with Setraline? *Journal of Clinical Psychiatry, 57*, 67-71

[III] Thase, M.E., et al, (1997) Fluoxetine treatment of patients with major depressive disorder who failed initial treatment with setraline. *Journal of clinical Psychiatry, 58*, 16-21

[IV] Joffe, R.T., et al.(1996) Response to an open trial of a second SSRI in major depression. *Journal of Clinical Psychiatry, 57*, 114-115.

Ward Health
Strategies

Access to Innovation

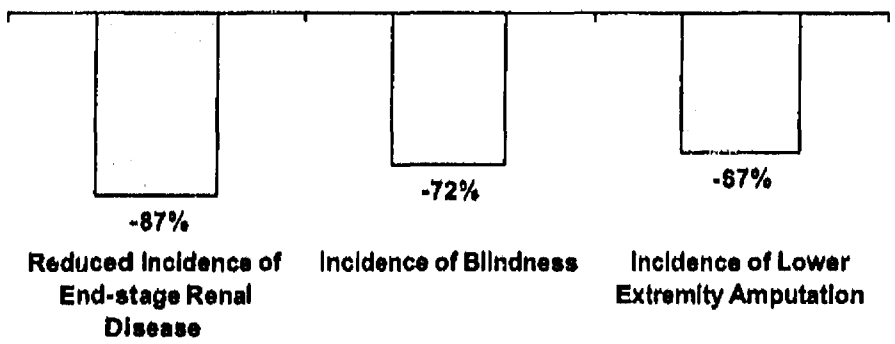
Policies that support incremental as well as breakthrough innovation are essential to improving clinical and economic outcomes in the treatment of diabetes.

Most medical advances come from incremental improvements on existing therapies—from a series of small steps forward rather than from great leaps or breakthroughs. Pharmaceutical research has yielded an array of incremental advances that offer substantial clinical and economic benefits in the treatment of diabetes.

Because of the many pharmaceutical options available, diabetes treatment can be tailored to individual patient needs. "Medications for diabetes reduce blood glucose levels in several different ways. Some increase the amount of insulin secreted from pancreatic cells. Others allow insulin that is already present to be used more effectively. A third group reduces the breakdown of carbohydrates in the gastro-intestinal tract so that less sugar is absorbed. No single currently available agent appears to be superior when used as monotherapy and combination therapy is often indicated." [I]

The primary cost of treating diabetes comes from short-term hyperglycemia and from long term complications. An analysis of intensive treatment of type II diabetes found that achieving normal blood sugar levels reduced the incidence of serious complications (see chart) and raised life expectancy by 1.4 years. [II]

The Impact of Achieving Normal Blood Sugar Levels in Reducing Diabetes Complications



Controlling diabetes demands individualized patient care because of the complex nature of the disease, the diversity of the diabetic population and the fact that diabetes often occurs concurrently with other medical conditions.[III] Improved diabetes management leads to quality, cost-effective outcomes and underscores the importance of policies that encourage and support the research that fosters incremental as well as breakthrough innovation. It also reinforces the importance of ensuring that patients have access to choices in drug treatments.

[I] D. Nash, et al., The Importance of Individualized Pharmaceutical Therapy in the Treatment of diabetes Mellitus. *Disease Management, Vol.4 , Supplement 1*, 2001
[II] Eastman R., et al, Model of complications of NIDDM. Analysis of the health benefits and cost-effectiveness of treating NIDDM with the goal of Normoglycemia. *Diabetes Care* 1997, 20:735-744.
[III] D. Nash et al.

Ward Health Strategies is a Division of Ward advocacy Communications Inc.

Ward Health
Strategies

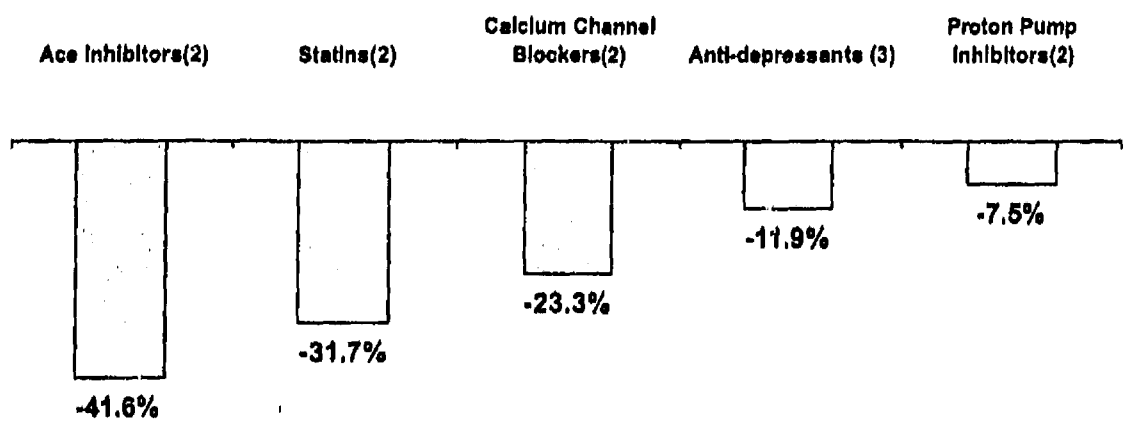
Advancing Innovation

Incremental advances in pharmaceutical innovation help lower drug costs while improving the quality of care.

Most major advances in drug therapies come from incremental improvements - the development on new agents within existing drug classes. The process of evolution of drug therapies results in the development of safer, more effective medicines that are usually easier to use, have fewer side effects and are less costly.

The availability of a variety of medications within a drug class increases price competition, since incremental innovations must compete for market share with existing drugs.

Average Discount of New Drugs Launched in Existing Classes*



**Source:* Adapted from DiMassi

An analysis of pricing trends of 20 new entrants to drug classes in eight therapeutic areas that account for more than half of total retail drug expenditures in 1999, reveals that the majority of new drugs were launched at discounts (often substantial) to the average price of existing drugs within the therapeutic class.[I] Of 20 drugs examined 13 were launched at prices at least 5% and as much as 53% below the average price, 5 were launched at a price ranging from parity to a 5% discount and 2 entered the market at a premium to the average price but still discounted relative to the price leader. "Over time, incremental innovation has resulted in striking improvements in existing drug therapy and patient care, and in some cases reduced total costs for therapy"[II]

[I] Joseph A. DiMassi, Ph.D, *Price Trends for Prescription Pharmaceuticals: 1995-1999*, A background report prepared for the Department of Health and Human Services Conference on pharmaceutical Pricing Practices, Utilization and Costs, August 2000

[II] A. Werhelmer, R. levy, T. O'Connor, *Too May Drugs? The Clinical and Economic Value of Incremental Innovations*. Investing in Health: The Social and Economic Benefits of health care Innovation Volume 14, Elsevier Science Ltd. 2001

PPTA
Plasma Protein Therapeutics Association

PPTA
Plasma Protein Therapeutics Association

January 17, 2003
Reference No.: PPSA03009

Honorable Judy Lee
Chairman
Senate Human Services Committee
State Capitol
600 East Boulevard
Bismark, ND 58505-0360

RE: Senate Bill 2088 of 2003 – An Act to Create a Pharmacy Best Practices and Cost Control Program

Dear Chairman Lee:

The Plasma Protein Therapeutics Association (PPTA) asks that the Senate Human Services Committee amend **Senate Bill 2088** to exempt plasma-derived and recombinant analog therapies (collectively, "plasma therapies") from prior authorization under North Dakota Medical Assistance, and to require that plasma therapies be included on the preferred drug list created under that legislation. Subjecting plasma therapies to prior authorization would compromise the access of North Dakota Medical Assistance recipients to the treatments necessary to treat bleeding disorders, immune system deficiencies, hepatitis, Alpha-1, and burns and shock, while doing little to reduce Medical Assistance expenditures.

PPTA is the primary advocate for the world's leading producers of plasma therapies. PPTA's member companies produce 80 percent of the plasma therapies used in the United States. While PPTA recognizes the need to control escalating prescription drug costs under Medical Assistance, we do not believe that plasma therapies, used to treat unique, life-threatening diseases and medical conditions, are driving those program costs. Plasma therapies constituted only 0.65 percent of annual expenditures under the North Dakota Medical Assistance program in 2001. The use of plasma therapies is not driven by mass media advertising, and they are not purchased at the corner pharmacy. Moreover, plasma therapies they do not have generic equivalents that can be substituted under a prior authorization system. Therefore, we believe that it was not the intention of the North Dakota Office of Management and Budget to capture plasma therapies in Senate Bill 2088 and subject them to prior authorization.

Plasma therapies are designed to treat highly unique, life-threatening, and often chronic diseases. They require a series of complex manufacturing steps, validation criteria, and

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Brussels Office: Boulevard Brand Whitlock 114/5 · 1200 Brussels · BELGIUM
tel: 202.789.3100 · fax: 410.263.1298 · e-mail: ppta@pptaglobal.org · www.plasmatherapeutics.org

constantly evolving viral inactivation processes, all to ensure safety and efficacy. It is crucial that, as a matter of public policy, the individuals threatened by the unique, life-threatening, and often chronic diseases that plasma therapies treat not be denied access in a timely manner to the treatments they need.

Plasma therapies are different from the commonly advertised, compound-based pharmaceutical products that are the target of the Medical Assistance program's cost-cutting efforts. Consumers are not rushing to their healthcare providers or their neighborhood pharmacies to seek plasma therapies after seeing the therapies advertised in the mass media, as with many of the products subject to prior authorization under Senate Bill 2088. It is important to understand that a patient with intracranial bleeding who is in need of a blood-clotting therapy cannot wait the 24 hours that prior authorization procedures could take to allow a healthcare provider to prescribe his or her therapy. Applying prior authorization to plasma therapies could have dire consequences for the patients relying on those therapies.

For these reasons, PPTA asks that the Senate Human Services Committee amend Senate Bill 2088 to exempt plasma-derived and recombinant analog therapies (collectively, "plasma therapies") from prior authorization under North Dakota Medical Assistance, and to require that plasma therapies be included on the preferred drug list created under that legislation.

Thank you for your attention to these issues. We are available to answer any questions that the Senate Human Services Committee or the Office of Management and Budget might have on plasma therapies.

Sincerely,

Christopher P. Healey
Executive Director
PPTA North America

cc: Ms. Pam Sharpe, Interim Director, North Dakota Office of Management and Budget

North Dakota Medicaid Program:

Prior Authorization of Prescription Drugs

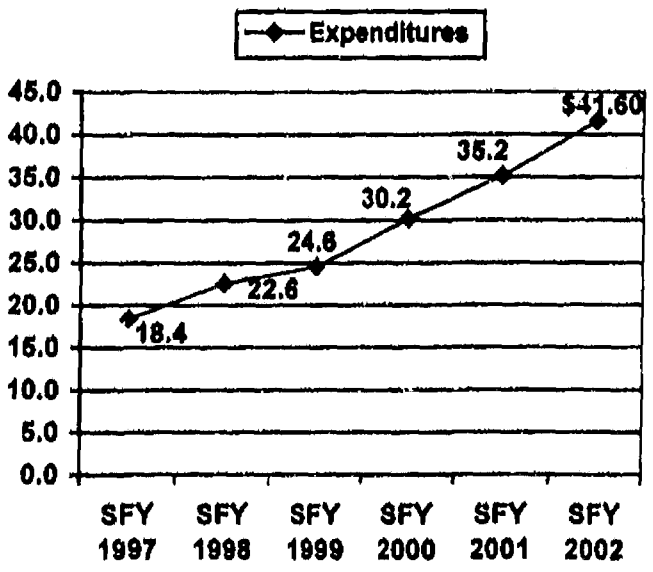
Background:

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

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

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

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



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

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

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

What is prior authorization?

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

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

OVER →

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

How would prior authorization affect people?

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

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

What does prior authorization mean for providers?

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

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

Prepared January 2003

How would North Dakota benefit by adopting prior authorization?

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

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

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

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

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

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David Zentner, Director

TESTIMONY BEFORE THE SENATE HUMAN SERVICES COMMITTEE
REGARDING SENATE BILL 2088
JANUARY 29, 2003

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

This bill would allow the Department to implement a prior authorization program within pharmacy services as well as collect supplemental rebates from drug manufacturers. These are two common cost containment procedures utilized by states as well as private industry. Currently, all but four states have a prior authorization process in place and at least six states (including Minnesota) are collecting supplemental rebates from drug manufacturers. Both processes are specifically allowed by CMS (see attachment).

When this bill is approved, the Department will partner with private industry and utilize an existing drug formulary for assistance in selecting products for prior authorization. For instance, the North Dakota PERS plan through Blue Cross Blue Shield (BCBS) of North Dakota has a drug formulary – formulary products cost less to the patient than non-formulary products. This formulary is selected by BCBS by first evaluating the drug for safety and efficacy and lastly for cost. The Department would have the Drug Utilization Review (DUR) Board evaluate the selected formulary and provide guidance to the Department for prior authorization actions.

Since it is not possible to require Medicaid recipients to pay more than a nominal co-payment, prior authorization is the only tool available to encourage the use of the most cost effective drugs that will meet the medical needs of Medicaid recipients.

There are many benefits for this approach. First, the physicians and pharmacists are familiar with private industry formularies. By utilizing an existing formulary, much less provider education needs to be done. Second, private industry currently has a prior authorization process with which the providers in the state are familiar. Once again, this decreases the need for education. Third, as part of our continuing efforts in education, North Dakota Medicaid recently came to an agreement with BCBS of ND to increase physician education. BCBS educates physicians throughout the state (face-to-face) and North Dakota Medicaid has assessed the educational program and agrees with the philosophy and content. That is why we have asked BCBS to include North Dakota Medicaid as a sponsor of this education. It is hoped that continued physician education will drive appropriate prescribing practices. By utilizing the same formulary, the educational message being delivered to the physicians will stay consistent and maximize compliance.

An additional justification for this process is that the utilization of an existing formulary will provide faster implementation of the program. This will generate savings for the program much faster than if the development and education had to be duplicated internally.

Anticipated savings from the prior authorization program will be $1,000,000 in general funds. Collection of supplemental rebates was not built into the proposed budget and the Department does not have plans for collection of these rebates. However, given the recent historic rise of drug expenditures (more than doubled between SFY 1997 and SFY 2002) and the increasing use of these rebates in other states, it may become necessary in the future.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES
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CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations

SMDL #02-014

September 18, 2002

Dear State Medicaid Director:

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

Medicaid Supplemental Drug Rebate Agreements

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

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

Prior Authorization Requirements Related to Supplemental Rebate Agreements

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

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

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

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

Non-Medicaid Supplemental Rebates and Medicaid Prior Authorization

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

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

Sincerely,

/s/

Dennis G. Smith
Director

cc:

CMS Regional Administrators

CMS Associate Regional Administrators
for Medicaid and State Operations

Lee Partridge
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Joy Wilson
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