

STUDY OF BENEFIT PURCHASING POOLS, PREFERRED DRUG LISTS, AND OTHER PHARMACY BENEFIT MANAGEMENT CONCEPTS

The 2003 Legislative Assembly approved House Bill No. 1430, attached as Appendix A. Section 11 of the bill provides for a Legislative Council study of the value of medical assistance program use of benefit purchasing pools, preferred drug lists, and other pharmacy benefit management concepts, including the fiscal impact of the appeals and grievance process on existing programs. The Budget Committee on Health Care has been assigned this responsibility for the 2003-04 interim.

Nationally, 9.9 percent of total Medicaid costs during federal fiscal year 2002 were for prescription drugs as compared to 7.6 percent during federal fiscal year 1999. The 2003 North Dakota Legislative Assembly appropriated \$95,207,239, \$25,712,069 from the general fund, for prescription drug costs under the medical assistance program, \$16,091,517, \$7,176,251 of which is from the general fund, more than the 2001-03 biennium appropriation of \$79,115,722. The increases in total Medicaid prescription drug costs have been 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 being written.

States have developed various diverse pharmaceutical assistance programs to contain costs and/or expand coverage. These programs have been based on the following, or a combination of the following, methods:

1. Using state funds to assist or subsidize the cost of pharmaceuticals for the eligible population, including direct benefit programs, insurance, and waiver programs.
2. Providing programs that offer discounts or price reductions to the eligible population, through state law or combining purchases (purchasing pools) among programs, agencies, or states.
3. Changing or creating pharmaceutical purchasing policies, including plans related to the use of preferred drug lists, generic products, and state-only rebates or tax credits based on pharmaceutical expenditures.

PHARMACEUTICAL PURCHASING POOLS

Purchasing pools (bulk purchases) may involve an interstate consortium of several states or an intrastate cooperative of state agencies or programs that consolidate pharmaceutical purchasing functions in order to obtain discounted prices and achieve administrative efficiencies. These programs involve voluntary, rather than mandatory, discounts negotiated with manufacturers.

Examples of purchasing cooperatives include the following:

- **The Northern New England tristate coalition** - The Northern New England tristate coalition is an executive branch initiative uniting the states of Maine, New Hampshire, and Vermont into a single entity for the purpose of gaining efficiencies in the administration of state prescription drug programs, including Medicaid. The states jointly selected a pharmacy benefits manager to negotiate price discounts and rebates, increase efficiency in pharmacy claims processing, reduce administrative costs, and prevent inappropriate drug dispensing through prospective drug utilization review. The tristate partners are also part of the **Northeast Legislative Association on Prescription Drug Prices**, a larger coalition also including Connecticut, Massachusetts, New York, Pennsylvania, and Rhode Island. The group wants to negotiate directly with drug firms for deep discounts instead of using high-volume purchase orders for savings.
- **The Texas Interagency Council on Pharmaceuticals Bulk Purchasing** - The Texas Interagency Council on Pharmaceuticals Bulk Purchasing combines pharmaceutical purchasing for the Texas Department of Health, Department of Mental Health, state employees and retirees, teachers, the correctional system, and other agencies that purchase pharmaceuticals.

PREFERRED DRUG LISTS

Preferred drug lists (PDL) have been implemented by several states to steer beneficiaries toward drugs that are therapeutically appropriate and less expensive. Under the preferred drug list model, state-appointed pharmacy and therapeutics committees recommend placing certain drugs, often lower-priced generics, on a preferred drug list for treating a particular condition. The committee makes recommendations based on a drug's evidence of effectiveness to the appropriate state agencies that then develop the preferred drug list. When no demonstrated advantage exists between one drug and another, generally the more cost-effective drug is selected for the list. Some states will also consider another manufacturer's drug for the preferred drug list if the manufacturer gives the state a supplemental rebate, usually equal to or close to the difference in price between that drug and the preferred drug.

In most cases, **prior authorization** is required in order for a physician to prescribe a drug that is not on the preferred drug list. Prior authorization is a process where certain drugs or services require authorization

from a Medicaid agency or insurer before prescribing a drug or obtaining those services.

Examples of various state approaches to implementing a preferred drug list include the following:

- **Florida model** - Florida created a preferred drug list for its Medicaid program based on evidence of effectiveness. Manufacturers of drugs that agree to offer the state a supplemental rebate are guaranteed to have their drugs considered for the list. Drugs that are not on the list require prior authorization.
- **Michigan model** - Michigan created an evidence-based list of preferred drugs that applies to its Medicaid program as well as to all other pharmacy programs funded through its Department of Community Health. Manufacturers whose drugs are not selected for the list can have their drugs included if they offer the state a supplemental rebate. Drugs that are not on the list require prior authorization.
- **Oregon model** - Oregon uses an evidence-based review process to develop a statewide plan drug list regarding preferred drugs. The final decision of what is on the list is made by the department. The state focuses on educating providers about the list and changing prescribing behavior so that it is consistent with the evidence reviewed. The plan drug list is voluntary to the provider.

OTHER PHARMACY BENEFIT MANAGEMENT CONCEPTS

Attached as Appendix B is a list of pharmacy assistance programs offered in other states. According to reports from the National Conference of State Legislatures, other various types of pharmacy assistance programs designed to help residents pay for prescription drugs include the following:

- **Direct benefit programs** - Twenty-four states have programs in which the **state subsidizes all or part of the prescription costs** for qualifying individuals (enrollees) without requiring insurance premiums. Direct benefit programs are primarily targeted toward Medicare-eligible individuals aged 65 and older who have low or moderate incomes. Most programs cover drugs that are paid for by state Medicaid programs and require some form of cost-sharing or copayment for each prescription. In addition, direct benefit programs may have a deductible, or an amount that the enrollee must pay before becoming eligible for benefits. States may also limit the maximum benefits that can be received or have programs that limits the enrollees' out-of-pocket costs, with the limit varying according to the enrollee's household income.

Examples of direct benefit programs include the **Minnesota prescription drug program** and **Wyoming's prescription drug assistance program**. The Minnesota program is available to

individuals aged 65 and older or disabled of any age with income levels at or below 120 percent of the federal poverty level. Minnesota excludes single people with financial assets exceeding \$10,000 and couples with financial assets exceeding \$18,000. The Wyoming program does not have any age requirements and is available to individuals with income levels at or below 100 percent of the federal poverty level. Wyoming excludes individuals with more than \$1,000 in resources, excluding a home and one car.

- **Insurance programs** - Three states have programs that help pay the premiums for certain residents to purchase private or public insurance policies that cover prescription drugs. These plans require payment of a premium, may require copayments and deductibles, and often include subsidies for lower income individuals.

An example of an insurance program is the **Nevada senior Rx plan**. The Nevada senior Rx plan is a state-subsidized private insurance program to provide prescription drug coverage to low-income seniors. For seniors who qualify for the enhanced plan, the state pays the monthly premium and the \$100 annual deductible. Covered seniors are responsible for paying \$10 copayments. Maximum annual benefits are \$5,000.

- **Price reduction programs** - Sixteen states have programs that are designed solely to set legal limits on prescription drug prices that can be charged to certain segments of the population. These programs require little if any revenues from the state government, since they require price reductions from pharmacies, drug manufacturers, or both. Some of these programs are designed only to reduce retail prices, while others strive to reduce both retail pharmacy charges and the prices that drug manufacturers charge to pharmacies and drug wholesalers.

An example of a price reduction program is **California's discount prescription medication program**, which is a discounted prescription drug program for **Medicare** beneficiaries. In California, retail pharmacies may not charge Medicare beneficiaries a price that exceeds the Medi-Cal (the state Medicaid program) reimbursement rate and an amount to cover electronic transmission charges. Medicare beneficiaries are not allowed to use the Medi-Cal reimbursement rate for over-the-counter medications. Another example of a price reduction program is the Maine Rx program (see **court challenges** section below).

The 2003 South Dakota Legislative Assembly approved Senate Bill No. 216, creating the **South Dakota senior citizen prescription drug benefit program**. The purpose of the program is to negotiate the purchase of prescription drugs

to be offered at a reduced cost to the eligible participants. The program will be open to any resident aged 65 and older and any person meeting the eligibility criteria for a disability. It will be run by the Bureau of Personnel, which may enter into agreements and cooperate with other local, state, or federal agencies to implement the purposes of the program. The program will sunset on July 1, 2005, unless continued by the South Dakota Legislative Assembly.

- **Tax credits** - A tax credit program has the net effect of reducing prescription drug costs through a state income tax credit for residents with high prescription drug costs. No states currently offer a prescription drug credit. However, Michigan and Missouri recently offered such credits until they were replaced with more comprehensive pharmaceutical assistance programs. The **Michigan prescription drug program**, which ended December 31, 2001, provided qualifying low-income seniors a refundable credit of up to \$600 per year for expenses incurred on prescription drugs in excess of 5 percent of household income. The **Missouri tax credit program**, which ended December 31, 2001, provided qualifying low-income seniors could receive a refundable credit of up to \$200 to offset the cost of prescription drug purchases.
- **Section 1115 waiver programs** - Section 1115 of the Social Security Act was enacted by Congress in 1962 to allow the Department of Human Services to waive certain requirements and authorize demonstration projects for Medicaid. The waivers allow the six named states to receive federal matching funds for projects that would not otherwise qualify for federal participation or would qualify at a lower federal matching rate. A Section 1115 waiver program may allow a state to expand Medicaid services or eligibility levels, including providing prescription drug benefit coverage for residents who would otherwise be ineligible for Medicaid benefits.

Examples of Section 1115 waiver programs include the **Illinois senior care program** and the **healthy Maine prescription program**. The Illinois senior care program pays up to \$1,750 per year for most prescription drugs and many over-the-counter drugs if prescribed by a physician. The program is available to low-income Illinois seniors aged 65 years or older. The healthy Maine prescription program provides that Maine residents with incomes too high to qualify for Medicaid (up to 300 percent of poverty) and who lack prescription drug coverage may purchase prescription drugs at Medicaid prices, estimated to result in savings of up to 25 percent.

COURT CHALLENGES TO PHARMACY ASSISTANCE PROGRAMS

Preferred drug lists have been challenged by various groups, including pharmaceutical companies, from a number of perspectives. Some of these issues have been taken to court by individual pharmaceutical companies and by the trade association that represents them--the Pharmaceutical Research and Manufacturers of America.

The Pharmaceutical Research and Manufacturers of America argues that states such as Florida and Michigan are unfair to Medicaid beneficiaries because they limit consumer choice and may adversely affect patients who need special medicines not on the preferred list. They also object to the supplemental rebate agreements demanded by some states, claiming that such rebates were not authorized by federal statute.

To date, the states have won these arguments in federal and state appeals courts in both Florida (relating to its prior authorization program) and Michigan (relating to supplemental rebate policies).

On May 19, 2003, the United States Supreme Court approved for operation the state of Maine's pharmaceutical price reduction program for the uninsured. The **Maine Rx program** allows the state to negotiate price discounts and rebates with drug manufacturers, similar to price discounts and rebates provided through the state Medicaid program. The discounted prices would be made available to qualifying residents who lack insurance coverage for prescription drugs. If a company refuses to pay the rebate, Maine will require doctors to get prior approval from the state before prescribing that company's drug for Medicaid recipients.

MEDICAL ASSISTANCE APPEALS AND GRIEVANCE PROCESS

North Dakota Administrative Code Chapter 75-01-03, as authorized in North Dakota Century Code (NDCC) Chapter 28-32, provides for the medical assistance program appeals process. An applicant or enrollee has the right to appeal to the Department of Human Services regarding a reduction, termination, or denial of benefits. The appeal hearing process is an administrative procedure in which the Department of Human Services reviews a previous decision by considering evidence and arguments from claimants and a representative of the department that made the decision under appeal. A hearing officer, primarily an administrative law judge, oversees the hearing process and issues a recommendation to the Department of Human Services. The Department of Human Services may either adopt or deny the decision of the administrative law judge. Unfavorable decisions or decisions not adopted by the department may be further appealed by the applicant or enrollee through the district court system.

A grievance is a process for appealing a decision not related to coverage of health services or payment of benefits. Grievances are primarily filed by drug companies or manufacturers for matters such as not including a drug on a preferred list or requiring prior authorization

for a particular drug. Unlike the appeals process, which are decided by hearing officers, a grievance is decided internally within the Department of Human Services.

House Bill No. 1430 (2003), approved by the 2003 Legislative Assembly with an emergency clause, provides for the Department of Human Services to establish a separate drug use review board consisting of physicians, pharmacists, representatives of the pharmaceutical industry, and representatives of the Department of Human Services. Attached as Appendix C is the newly created Department of Human Services Drug Use Review Board. The board is to establish a prior authorization program, which would require approval or verification with the Department of Human Services prior to prescribing certain drugs to medical assistance program recipients. The department would determine whether the proposed medical use of a particular drug meets predetermined criteria for coverage by the medical assistance program. In addition, Section 6 of the bill provides for the Department of Human Services to adopt rules, pursuant to NDCC Chapter 28-32, for a grievance procedure through June 30, 2005, for interested persons to appeal a decision to place a drug on prior authorization. The fiscal note for House Bill No. 1430 indicated a reduction of expenditures of \$2,995,561, \$772,570 of which is from the general fund and a corresponding federal funds reduction of \$2,222,991.

RELATED PRESCRIPTION DRUG LEGISLATION

House Bill No. 1399 (2003) - This bill requires the Insurance Commissioner to create and implement a program to assist low-income individuals to gain access to prescription drug assistance programs offered by pharmaceutical manufacturers. The Legislative Assembly appropriated \$100,000 from the general fund to the Insurance Commissioner for the purpose of implementing and promoting the program.

Senate Bill No. 2088 (2003) - This bill, which failed to pass, would have required the Department of Human Services to establish a pharmacy best practices and cost-control program designed to reduce the medical assistance program's prescription drug costs. The program would have provided for the creation of a preferred drug list, including a prior authorization review process, and other cost-containment activity. The department would have been permitted to use the services of an outside consultant to implement this program.

Healthy SeniorsRx - The executive budget recommendation proposed the creation of a prescription drug assistance program entitled "Healthy SeniorsRx" for senior citizens with gross incomes of up to 210 percent of the federal poverty level. This recommendation was not approved by the 2003 Legislative Assembly. Eligibility would have been determined by the counties, and assets would not have been considered when determining eligibility. The recommendation included \$10.3 million total funding for the 2003-05 biennium, of which \$3.4 million was from the general fund. The program

was to have served an estimated 15,850 senior citizens by the end of the 2003-05 biennium.

House Bill No. 1116 (2001) - This bill, which failed to pass, would have authorized the Department of Human Services to require prior authorization for medical assistance coverage of outpatient drugs determined by the department's Drug Utilization Review Board to be subject to clinical abuse or inappropriate use.

Medicare prescription drug legislation - Congress is considering legislation creating a prescription drug benefit program for Medicare beneficiaries. Medicare Part A (hospital insurance) pays for prescription drugs during hospital stays; Part B (supplementary medical insurance) does not pay for drug costs. The United States Senate Finance Committee proposal would provide universal coverage under the current Medicare fee-for-service program. The proposed plan provides for a still undetermined monthly premium, a deductible, and a varying copayment based on an individual's annual prescription drug expenses. Individuals with incomes below 150 percent of the federal poverty level would receive additional benefits based on a sliding scale. The prescription drug program would take effect in 2006, with an estimated cost of \$400 billion over a 10-year period. Differences between the House and Senate version include the following:

- The Senate bill includes a \$275 deductible. After that, Medicare would pay 50 percent of costs up to \$4,500. Coverage would then stop until a senior reached \$3,700 in out-of-pocket expenses. After that, seniors would pay 10 percent of costs.
- The House version has a \$250 deductible. After that, seniors would pay 20 percent of drug costs up to \$2,000. There would be no coverage thereafter until out-of-pocket costs reached \$3,500. At that point, drug costs would be covered in full. Seniors with incomes higher than \$60,000 would face higher limits on out-of-pocket expenses.

RECENT LEGISLATIVE COUNCIL STUDIES

During the 2001-02 interim the Budget Committee on Health Care studied the prices of prescription drugs and possible mechanisms to lower costs to consumers and the state, and whether the state should establish a program to assist in the purchase of prescription drugs based upon income. The committee reviewed cost-containment strategies and pharmaceutical assistance programs in other states. The committee received testimony from representatives of the Pharmaceutical Research and Manufacturers of America regarding costs of pharmaceutical drugs. In addition, the committee learned that the state is required by federal law to maintain a Drug Utilization Review Board. This is a separate committee from the newly established Drug Use Review Board. The board meets quarterly to provide recommendations to the Department of Human Services regarding Medicaid pharmacy services. The

committee made no recommendations as a result of its study of prescription drug prices.

PROPOSED STUDY PLAN

The following is a study plan the committee may want to consider in its study of medical assistance program use of benefit purchasing pools, preferred drug lists, and other pharmacy benefit management concepts, including the fiscal impact of the appeals and grievance process on existing programs:

1. Receive information from the Department of Human Services regarding the feasibility of creating a prescription drug benefit program for Medicaid recipients, the fiscal impact of the appeals and grievance process on existing programs, and information on current and projected Medicaid drug utilization and expenditures.
2. Receive testimony from other interested persons and organizations regarding prescription drug benefit programs.
3. Receive reports from the Department of Human Services regarding the establishment and

effectiveness of a Drug Use Review Board and prior authorization program.

4. Receive a report from the Insurance Commissioner regarding the status of implementation and effectiveness of a program to assist low-income individuals to gain access to prescription drug assistance programs offered by pharmaceutical manufacturers.
5. Monitor pharmacy assistance programs and cost-containment strategies in other states and proposed federal legislation.
6. Develop committee recommendations and any related bill drafts regarding various prescription drug benefit programs and/or the current appeals and grievance process for existing benefit programs.
7. Prepare a final report for submission to the Legislative Council.

ATTACH:3