

STRETCHING STATE HEALTH CARE DOLLARS: POOLED AND EVIDENCE-BASED PHARMACEUTICAL PURCHASING

One of a Series of Reports Identifying Innovative State Efforts to Enhance Access, Coverage, and Efficiency in Health Care Spending

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INTRODUCTION

In recent years, pharmaceutical costs have contributed in a major way to the growth of overall health care costs generally and of Medicaid expenditures in particular, with states estimating an average increase of some 14 to 15 percent per year in Medicaid prescription-drug spending from 2001 through 2004. These expenses have been rising because of a number of factors: greater utilization of prescription drugs, introduction of new and more costly medications, price inflation for existing pharmaceuticals, and increases in capitation rates for managed care organizations.²

Thus many states have been addressing rising drug costs, not only for Medicaid but also for state employee health plans and other state programs, with purchasing strategies designed to stretch their limited dollars. Some are also attempting to make pharmaceuticals more affordable to vulnerable populations. In this section we examine such programs, especially those recent drug cost-containment mechanisms that do not merely pass state costs on to consumers in the form of higher copayments and deductibles but rather put into place innovative approaches that reduce state costs so as to expand or maintain access.

The matrix, state profiles, and snapshots that follow present examples of state initiatives in pharmaceutical purchasing. Some new and promising strategies involve pooling across states, or across groups within states, to achieve better negotiating clout with pharmaceutical manufacturers. Some are "pharmaceutical assistance programs" that extend state-negotiated discounts to uninsured and low-income populations who are not eligible for Medicaid. Others involve incorporating clinical evidence into purchasing decisions and Preferred Drug Lists (PDLs) in order to obtain supplemental rebates and promote cost-effective use of pharmaceuticals.

Implementing these strategies has not always been smooth sailing, however. The major association representing the pharmaceutical industry, Pharmaceutical Research and Manufacturers of America (PhRMA), filed lawsuits against Michigan and Florida that challenged the legality of these states' PDLs. PhRMA also challenged Maine's use of Medicaid discounts for non-Medicaid populations. While most of these challenges were unsuccessful, they resulted in delays to full implementation or discouraged participation (by states and manufacturers), which reduced the programs' savings. At present, the pharmaceutical industry is challenging Minnesota's plans to reimport pharmaceuticals from Canada, and the federal government has been considering legal action as well. The state

has expressed plans to follow through with its approach, however, and others may follow suit.

In addition to the pharmaceutical industry, provider groups and patient advocates have voiced opposition to some state pharmaceutical initiatives, such as PDLs and generic substitutions that limit coverage for certain medications or require prior authorization from a provider. They argue that such restrictions hamper access to drugs that may be most appropriate for certain individuals, and they suggest that patients not responding well to the PDL or generic drugs may need more expensive care down the road, resulting in higher costs for those patients. Also, providers generally oppose new rules (e.g., obtaining prior authorization) that add to their administrative burdens.

Despite the challenges, many of the initiatives described here have produced significant savings for the states and have enhanced access, particularly when savings allowed states to expand eligibility or scope of benefits. Michigan, for example, reported some \$68 million in savings in just over a year as a result of shifting people to less expensive drugs and obtaining supplemental rebates associated with its PDL and multistate purchasing pool. And Vermont claims that its participation in that pool is helping the state "preserve essential pharmaceutical coverage for [its] most vulnerable residents." Other initiatives are just beginning, and their impact on costs, access, and health outcomes should be carefully monitored and evaluated.

In the meantime, the new federal Medicare prescription-drug benefit law will also affect states' drug coverage for certain populations. State legislators and administrators must assess how the law will affect their existing programs that provide drug assistance to low-income elderly and disabled populations. In any case, states will continue to purchase pharmaceuticals for millions of individuals, and we can expect that the types of strategies described here will be replicated and expanded in coming years.

The kinds of pharmaceutical-purchasing strategies reviewed in the following profiles and snapshots include:

- Multistate purchasing and collaboration
- Intrastate purchasing
- State-negotiated discounts and drug-only benefits
- Evidence-based PDLs and supplemental rebates

Multistate Purchasing and Collaboration

A strategy that is receiving more and more attention is the multistate purchasing of pharmaceuticals. Through aggregation, states are able to enhance their bargaining clout—generally through a common pharmacy-benefits manager (PBM)—when negotiating drug purchases with manufacturers. Because prices and rebates are tied to volume, potential savings to states rise as participation in a purchasing pool expands. States may pool purchasing for Medicaid beneficiaries, or for state employees, State Children's Health Insurance Program (SCHIP) enrollees, and other groups in whose behalf states buy pharmaceuticals. Savings are enhanced when a pooling arrangement is combined with a preferred drug list, prior authorization requirements, and other mechanisms that shift individuals toward less expensive prescription drugs.

Michigan and Vermont began a multistate purchasing pool—the National Medicaid Pooling Initiative—for their Medicaid programs in 2002 (see profile below). In April 2004, the U.S. Department of Health and Human Services (HHS) approved that arrangement for these states, as well as for Alaska, Nevada, and New Hampshire, and additional states have expressed interest in joining. Multistate pools are particularly promising for smaller states that do not represent a large volume of covered lives on their own but together can muster the purchasing power of larger states. Further, multistate pools may counter one negative consequence of the new Medicare drug benefit: The elimination of Medicaid pharmacy coverage for people dually eligible for Medicaid and Medicare in 2006 will reduce the volume and purchasing power of state Medicaid programs, even in large states.

States can also collaborate to realize price and administrative efficiencies when purchasing pharmaceuticals for state employees and other groups. West Virginia, Missouri, New Mexico, and Delaware (the "Rx Issuing States," or RXIS) hired a common PBM that negotiates and purchases drugs for their state employees (West Virginia's group also includes its SCHIP enrollees). The states benefit by capturing rebates from the manufacturers and reducing per-unit administrative expenses. West Virginia, for example, estimates that it saved \$7 million in its first year.

A few initiatives, though not pooled purchasing per se, involve collaboration among states to achieve economies of scale and enhance efficiencies. Oregon's Drug Effectiveness Review Project involves the establishment of mutual standards, using evidence-based clinical research, for drug-effectiveness comparisons that participating states may then use for establishing PDLs and purchasing pharmaceuticals. Similarly, the Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP) includes 41 states and

achieves administrative efficiencies through lower inventory levels; it also incurs lower costs associated with the ordering process and with individual state pharmaceutical contracts.⁶

Intrastate Purchasing

Another form of bulk pharmaceutical purchasing involves pooling within a state—across agencies. Like multistate purchasing, intrastate pooling allows states to stretch their dollars by enhancing their purchasing power through administrative streamlining. Georgia, for example, selected one PBM to implement an intrastate drug-purchasing program for the its Medicaid, SCHIP, employees of higher-education institutions, and state employees. The plan uses a single PDL and covers almost two million residents.

State-Negotiated Discounts and Drug-Only Benefits

Some states are using their purchasing clout to extend discounts to individuals who are not eligible for Medicaid and who may not have any drug coverage. Often taking the form of "pharmacy assistance programs" that are generally geared toward the elderly and people with disabilities, a few states are extending such assistance to additional groups facing escalating drug costs. Under Maine Rx Plus, for example, the state serves as pharmaceutical-benefit manager for residents without prescription-drug insurance who have incomes up to 350 percent of the federal poverty level. The state negotiates discounts in the form of manufacturer rebates, which are distributed to participating pharmacies that pass on the savings to Maine Rx Plus cardholders.

A related strategy that not only extends Medicaid discounts to additional populations but also taps federal matching funds involves an actual expansion of Medicaid with a drug-only benefit. The result is a "Pharmacy Plus" waiver that allows states to implement a Medicaid drug-only benefit to low-income elderly populations. The requirement for budget neutrality may be met based on the expected savings in institutional long-term care costs that result from improved access to outpatient medications. Vermont spearheaded this approach in 1995 when it implemented drug-only coverage for elderly persons with income up to 125 percent of the federal poverty level under an 1115 waiver (which involves experimental, pilot, or demonstration projects).⁷

Substitutions, Evidence-Based Preferred Drug Lists, and Supplemental Rebates

Nearly all states encourage generic or therapeutic substitutions of pharmaceuticals to reduce prescription drug costs. Generic substitution saves money through lower-priced versions of brand-name drugs. Some states require generic substitution in state pharmacy programs, while others simply encourage it by providing information about generic

alternatives.⁸ Therapeutic substitution does not involve chemically equivalent compounds but rather "therapeutic equivalents" of the brand-name counterpart. The U.S. Food and Drug Administration determines therapeutic equivalencies, which then assist physicians and pharmacists in making substitutions. But some providers and patient advocates oppose such substitutions, arguing that they raise questions about effectiveness and safety.

As of April 2004, 33 states operated, were implementing, or had enacted legislation authorizing PDLs for Medicaid beneficiaries. States may select "preferred drugs" from different classes of pharmaceuticals, based on a committee's findings of the drugs' therapeutic action, safety, clinical outcome, and cost. Drugs not on the list are not covered, or they require that the prescribing physician obtain prior authorization. Most states using a PDL also obtain supplemental rebates from manufacturers that want their products to be included on the PDL and available without prior authorization. Michigan has greatly enhanced its savings from the National Medicaid Pooling Initiative by incorporating its PDL into the arrangement (each participating state maintains its own PDL).

Reimportation of Pharmaceuticals

Though outside the scope of this study, we briefly mention an emerging strategy whereby states reimport—or encourage individuals to purchase—pharmaceuticals from other countries where prices are lower than in the United States. Minnesota has taken the lead by establishing a Web site that offers step-by-step instructions for ordering certain types of medications from participating Canadian pharmacies that meet the state's quality-control criteria. Further, state employees are given incentives to reimport medications. The program is expected to save the state \$1.4 million, and could save state employees nearly \$1 million, by the end of 2004.

Reimportation has been the object of much opposition from the pharmaceutical industry, which claims that the practice reduces incentives for companies to invest in new medications; does not ensure quality control (e.g., allows counterfeit treatments to enter the United States); and raises liability issues. Oregon is requesting HHS approval for a reimportation program that addresses quality concerns by having the state's Board of Pharmacy inspect Canadian drug wholesalers to ensure that U.S. safety and quality standards are met. The Board could then license them to sell approved medications.¹¹

An HHS task force recently held a series of public meetings on the safety of reimportation and its likely impact on drug development, prompting the Secretary of HHS to acknowledge that the passage of legislation to allow the reimportation of pharmaceuticals is "inevitable." ¹²

* * * * *

As noted above, many of the pharmaceutical-purchasing strategies described here have been controversial. Skeptics argue that mechanisms such as PDLs, prior authorization requirements, and generic and therapeutic substitutions curtail full choice of medications, thereby restricting access to drugs that may not be the most appropriate for certain individuals. Proponents counter that these strategies are based on careful clinical evidence and therapeutic review; and that some limitations on choice are necessary, under current budget pressures, to help avoid more severe cutbacks in benefits or eligibility. So far, these strategies have survived legal challenges, though their long-term effects on health outcomes and costs remain unknown.

Additional Resources

Kimberley Fox, Thomas Trail, Susan Reinhard, and Stephen Crystal, *Managing Program Costs in State Pharmacy Assistance Programs* (New York: The Commonwealth Fund, February 2004).

http://www.cmwf.org/publications/publications_show.htm?doc_id=221461

Pharmaceutical Bulk Purchasing: Multi-state and Inter-agency Plans, 2004, Denver: National Conference of State Legislatures, Updated April 27, 2004).

http://www.ncsl.org/programs/health/bulkrx.htm

State Actions to Control Health Care Costs, issue brief (Washington, D.C.: National Governors Association Center for Best Practices, November 2003).

State Health Care Policy: First Quarter of 2004, state health policy brief, vol. 5, no. 1 (Denver: National Conference of State Legislatures, April 2004).

Matrix: State Activity—Multistate and Evidence-Based Pharmaceutical Purchasing

State	Program Name	Name Type of Strategy & Implementation Date					
Current Examples							
West Virginia, Missouri, New Mexico, Delaware, Ohio	RXIS (Rx Issuing States) Multistate Pharmaceutical Purchasing Pool	Multistate purchasing • Pooled purchasing of pharmaceuticals for state employees, SCHIP enrollees, other groups	July 2002 (first contract with PBM)	Five states, nearly 700,000 lives as of July 2004			
Oregon, Washington, Idaho, California, Wisconsin, Missouri, others	Drug Effectiveness Review Project	Multistate clinical reviews • Pooled effort to establish standards for drug effectiveness comparisons	Nov 2003 (first review began)	Eleven states and two nonprofit organizations as of July 2004			
Michigan, Vermont, New Hampshire, Nevada, Alaska	Preferred Drug List and National Medicaid Pooling Initiative	Multistate purchasing and formulary	April 2002 (Approval by the Centers for Medicare and Medicaid Services, April 2004)	Two states as of May 2004			
		Preferred drug list with less expensive and clinically preferred drugs	February 2002	1.3 million Medicaid beneficiaries in Michigan			
Georgia	Department of Community Health	Intrastate bulk pharmaceutical purchasing	2002	Two million residents			
<u>Maine</u>	Maine Rx Plus	State-negotiated discounts for uninsured low- to moderate-income residents	2004	Approx. 100,000 members as of July 2004			
Illinois	Rx Buying Club	State-negotiated discounts for elderly and disabled residents	2004	Over 62,000 members as of April 2004			

STATE PROFILES

WEST VIRGINIA: RXIS MULTISTATE PHARMACEUTICAL PURCHASING POOL

Purpose/Goal

The primary purpose of the "Rx Issuing States" (RXIS) initiative is to address the dramatic increase in prescription-drug costs by consolidating states' negotiating power, achieving efficiencies, and capturing rebates through a multistate purchasing collective. The goal is to contain spending—thereby stretching limited dollars—on pharmaceuticals for public employees and State Children's Health Insurance Program (SCHIP) enrollees. This profile focuses primarily on West Virginia, which has the longest experience with the initiative.

Key Participants

West Virginia, Missouri, New Mexico, Delaware, and Ohio contract with a single pharmacy-benefits management (PBM) firm—Express Scripts, Inc.—to negotiate and purchase pharmaceuticals for certain groups and agencies within the states. These participants include West Virginia's Public Employees Insurance Agency (WV–PEIA) and the state's SCHIP; Missouri's Consolidated health care plan (public employees); New Mexico's Risk Management Division (public employees), Retiree Health Care Authority, Public School Insurance Authority, and Albuquerque public schools; Delaware's public employee group; and Ohio's Department of Administrative Services (public employees).

Program Description

RXIS aggregates nearly 700,000 lives: about 210,000 in West Virginia and 490,000 in the other four participating states. The group serves as a bargaining unit to negotiate with the drug manufacturers, through a PBM, based on total market share. Members pay the PBM an administrative fee and the states receive 100 percent of the rebates provided by the pharmaceutical manufacturers.¹³

When its Public Employees Insurance Agency contracted with the PBM, West Virginia became the first state to participate. PEIA arranges health insurance for about 187,000 state-agency employees, county board-of-education employees, higher-education institutions, and employees of some local and county governments. It also covers dependents and retirees associated with these groups. The state's SCHIP program, administered by a small staff in a stand-alone agency (i.e., it is not connected with the state's Medicaid program), essentially piggybacks onto PEIA for purchasing pharmaceuticals and is therefore included in the RXIS arrangement. The SCHIP covers

approximately 22,700 children with family income between 100 and 200 percent of the federal poverty level.

This pooled purchasing arrangement grew out of the Pharmacy Workgroup, in which officials representing state employees, Medicaid programs, and senior programs from nearly 20 states participated. The Workgroup was formed in 2001 to foster cooperation among states in addressing the double-digit increases in prescription-drug costs that had occurred over preceding years. Those states interested in forming a multistate pool issued a request for proposal (RFP) and selected a PBM for an Administrative Services Only (ASO)-type contract. Administrative Services on harnessing the enhanced bargaining power and reduced unit costs for services, that may be gained when relatively small states merge their populations into more sizable numbers.

Time Frame

Each participating state enters into a separate RXIS contract with Express Scripts. West Virginia was the first to join, commencing a three-year contract in July 2002. It has the option for two one-year extensions after that contract expires in June 2005.

Required Legislation/Authority

West Virginia's state legislature passed a bill (SB 127) providing clear authority, through its Public Employees Insurance Agency, to enter into prescription-drug purchasing agreements and pharmacy-benefit management contracts, including those involving other states and jurisdictions. SCHIP administrators did not need special governmental approvals to participate in RXIS.

Financing Mechanisms

After extensive research (conducted by the Pharmacy Workgroup) and discussions with consultants and pharmaceutical manufacturers, the RXIS states sought to change their drug-purchasing arrangement of paying PBMs small administrative fees with the PBMs retaining the bulk of the rebates from drug manufacturers. The states issued an RFP stipulating that they benefit from the full rebate and other cost-cutting features (see Efficiencies, below). They then selected a PBM that agreed to an ASO-type arrangement whereby the states would pay higher administrative fees but receive all of the manufacturers' rebates. In West Virginia, both the administrative fees for the PBM and the state's costs of drugs for PEIA and SCHIP members come from a mixture of state revenues (SCHIP also receives a federal match).

Efficiencies

RXIS savings derive from the following:

- States receive 100 percent of manufacturer rebates, which are greater than the increase in administrative fees. This is West Virginia's main source of savings from the RXIS arrangement; the state's PEIA is now receiving rebates worth about 10 percent of total prescription-drug spending.
- Securing this type of rebate arrangement with the PBM is attributed in part to the collective power of the states that issued the RFP.
- The rebates will grow along with drug-cost escalation.
- Administrative fees are based on a sliding scale tied to volume, so pooling individuals in multiple states means lower per-unit administrative costs.
- It is expected that as the pool grows, bulk purchasing should enable the PBM to negotiate lower drug prices as well as higher rebates.
- It is less expensive to conduct periodic audits of the PBM when all participating states share the cost.

West Virginia realized \$7 million in net savings (after accounting for higher administrative fees paid to the PBM) for its initial year (July 2002–June 2003). ¹⁶ It expects some \$25 million in net savings over the three-year contract period.

West Virginia's SCHIP receives very little in rebates, as nearly all of its enrollees choose generic drugs (given the higher copayments for brand-name drugs), for which there are no manufacturers' rebates. The SCHIP has benefited, however, from the other efficiencies related to the multistate purchasing pool. According to its administrator, SCHIP drug costs in FY 2003 (after the RXIS contract began) were slightly lower than in FY 2002, despite higher enrollment.

The other participating states are experiencing or anticipating savings as well. Missouri expects savings of \$1.4 million, or 2 percent of the plan cost, in its first year. New Mexico expects \$2.0 million in savings, and Delaware reports \$1.9 million in rebates. To Ohio, which just joined RXIS on July 1, 2004, anticipates that the program will save the state \$15 million over the next three years.

Challenges

Looking ahead, the major challenge for RXIS is to expand the pool in order to lower costs further and increase rebates. In developing the program, the RXIS group has had to grapple with multiple state regulations, garner political will (to change the status quo and take a chance with a project whose outcome was unknown), and make significant time commitments for planning and implementing the new PBM arrangement.

Future Plans

Each state will be monitoring its costs and savings during the contract period. After West Virginia's three-year RXIS contract has expired, it may continue the arrangement through one-year extensions. The participating states are considering the development of a joint drug formulary; as of early 2004, they were using standard formularies developed by the PBM.

For More Information

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OREGON: DRUG EFFECTIVENESS REVIEW PROJECT/ OREGON CENTER FOR EVIDENCE-BASED POLICY

Purpose/Goal

The aim of the Drug Effectiveness Review Project (DERP), led by the Center for Evidence-Based Policy ("the Center"), is to provide states and other purchasers with information on the relative effectiveness of similar pharmaceuticals in 25 drug classes and consultation in applying that evidence to purchasing and management decisions.¹⁹ The project's participants and funders believe that purchasing in accordance with such evidence-based information will generate long-term efficiencies, more appropriate pharmaceutical utilization, and improved health outcomes.

Another mission of the Center is to help establish "the international standards for effectiveness comparisons between drugs in the same class." While others have evaluated specific pharmaceuticals, ²⁰ this initiative is the first to conduct comparative systematic reviews of all drugs within their respective therapeutic classes. DERP's planners hope that the results of their research will ultimately be made available to insurance companies, health plans, and self-insured employers, as well as to state Medicaid purchasers.

Key Participants

All governance, oversight, administrative, and communications activities for DERP are being conducted by the Center, which is housed in the Department of Public Health and Preventive Medicine at Oregon Health and Science University (OHSU). The drug evaluations will be conducted by the Evidence-Based Practice Center (EPC) located at OHSU. It is possible that OHSU will also look to other EPCs—such as the Research Triangle Institute-University of North Carolina EPC and the Southern California-RAND EPC—for methodological and analytical support during the course of the research.²¹

The Center is negotiating with a number of entities, including state governments and nonprofit organizations, to participate in the project. As of July 2004, it has signed contracts with 11 states.²² The project required at least 10 participants to begin its review process for the 13 drug classes, which then got under way in November 2003.

Program Description

Key Features

The DERP project is reviewing outcome data for 13 classes of drugs, as well as conducting follow-up reviews on the 12 classes of drugs originally studied by the Oregon EPC under an Agency for Healthcare Research and Quality (AHRQ) initiative. Thus the

OHSU-EPC/DERP will conduct a total of 25 drug-class reviews. In pursuit of that goal, the project's researchers are collecting and reviewing relevant published literature available on MBase, Medline, and the Cochran Registry of Systematic Reviews. They are also exploiting additional resources, including nonproprietary and unbiased studies conducted by pharmaceutical companies.

Outcomes are examined not according to intermediate measures (e.g., cholesterol level reductions following the use of a statin-class drug) but in terms of "final outcome" measures (e.g., decreased morbidity and mortality rates from heart disease and stroke for high-cholesterol patients on that drug). By focusing on clinical outcomes, the Center hopes to develop a body of evidence based primarily on patients' actual health experiences.

Toward this end, DERP is comparing effectiveness, comparing side-effect profiles, and examining evidence of differential responses among various subpopulations (according to age, gender, race, etc.) for each drug within each therapeutic class.

Role of Subscribing States and Organizations

Each participating entity gets an orientation to the project, which includes receipt of data on the 12 drug classes that have already been reviewed by the Oregon EPC.

By signing on to the DERP, participants are charged with helping to determine the following aspects of the review process:

- What drug classes to review
- Review methodology
- Questions to be answered by the research
- Dissemination format of the findings.

Participants work closely with the EPC. In fact, a key motivation to join the project (given that the findings may ultimately be made available to the public at no cost) is that participating organizations can play pivotal roles in the review effort.

Time Frame

As noted above, the reviews began in November 2003, once the obligatory 10 participating organizations had subscribed. Each month for 13 months, one new drug class

is chosen for review and the EPCs begin working on it. The Center estimates that the evaluation for each class will take approximately nine months. Reviews will then be updated at six-month intervals. The Oregon EPC will also continue to review and update at six-month intervals the original set of 12 drug classes.

Required Legislation/Authority

The Oregon state legislature passed a bill, during the final session of Governor John Kitzhaber's last term in office, that overturned a ban on the use of preferred-drug lists for the purposes of state pharmaceutical purchasing. The bill required that the list be based first on a given drug's effectiveness, and second on its cost. Within this context, the state embarked on a review process that would be marked by openness and a systematic nature. The Oregon EPC was asked to conduct the review, and thus it began its initial 12-drug-class evaluation. While no specific state legislation was required for the DERP to begin its work, it obviously built upon the administrative and legislative foundation underlying the Oregon EPC.

Financing Mechanisms

Initial planning and start-up funding for the project came from the Milbank Memorial Fund. Operational funding is provided by the participating organizations, each paying a subscription fee of approximately \$96,000 per year for three years. The Center then oversees the collaborative process, commissions the research, and communicates its results to the participants.

Efficiencies

As described above, the objective of the project is to create an information base that allows pharmaceutical purchasers to make decisions based on quality and value. It is believed that this purchasing strategy will yield cost savings as well as improved health outcomes and utilization patterns.

Challenges

The Center's major challenge is to manage the logistics of this collaborative effort involving many participants. Toward that end, it is coordinating a massive communications endeavor involving face-to-face meetings, newsletter and fax alerts, and teleconferences. Other challenges include the development of consensus on important issues, such as how to disseminate the findings so that they are most useful to consumers and whether or not the results should be made available free of charge. Also, because

participants make joint decisions, states report that the initial work progresses more slowly than it would if each worked separately.

Future Plans

The Center will continue to publicize the project in order to recruit additional organizations and to inform the field on the importance of quality-based purchasing. In addition, the Commonwealth Fund is supporting researchers at the National Academy for State Health Policy (NASHP) and Georgetown University who will evaluate the impact of DERP on states and patients. Finally, dissemination of findings will occur on a rolling basis as the review of each class is completed.

For More Information

Web sites: www.ohsu.edu/epc and www.ahrq.gov/clinic/epc/ohsuepc.htm

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MICHIGAN: PREFERRED DRUG LIST AND NATIONAL MEDICAID POOLING INITIATIVE

Purpose/Goal

The purpose of Michigan's Preferred Drug List (PDL) is to stretch state Medicaid dollars while preserving the quality of patient care. The cost-saving component operates in two ways: by shifting beneficiary utilization from higher-cost to lower-cost pharmaceuticals; and by obtaining "supplemental" rebates (beyond the standard rebates dictated by the federal government under OBRA '90)²³ from pharmaceutical manufacturers whose drugs are included on the PDL.

The purpose of the National Medicaid Pooling Initiative (NMPI) is to allow participating states to combine their populations of Medicaid recipients. In that way, they may acquire greater leverage for negotiating supplemental rebates from pharmaceutical manufacturers. Michigan and Vermont have been participating in the pool since October 2003, and several other states have recently joined or plan to join. Because the supplemental rebates are tied to volume, it is expected that as additional states enter the pool all participants will enjoy greater savings.

Key Participants

Michigan's Department of Community Health administers the Medicaid program and the NMPI. The Michigan Pharmacy and Therapeutics Committee, made up of physicians and pharmacists, plays a key role in reviewing and recommending drugs for the PDL.

The multistate purchasing pool includes Michigan, Vermont, New Hampshire, Nevada, and Alaska (as of June 2004). The states use First Health Services as their pharmacy-benefits manager (PBM) to negotiate with pharmaceutical manufacturers. Hawaii, Maryland, Minnesota, and Tennessee have expressed interest in joining NMPI.

Program Description

Preferred Drug List (PDL)

Michigan, like many other states,²⁴ has created a PDL with an expanded prior authorization list, based on clinical and therapeutic review as well as on cost.²⁵ Physicians and pharmacists serving on the Michigan Pharmacy and Therapeutics (P&T) Committee identified the most effective drugs from the 40 therapeutic classes that account for the majority of drug spending in the Medicaid program. On a continuing basis, they review scientific and clinical information in order to recommend additional drugs for inclusion in the list. There is a full review of the PDL each summer, and priority new-drug entities are

reviewed at each P&T meeting, which occur quarterly. The state includes on the PDL: 1) the least expensive, clinically effective medications in each drug class; 2) those that bring supplemental rebates to the state; and 3) those that are "clinically preferred" even if they are not the least expensive. Pharmaceutical companies can have their drugs added to the list if they lower their prices through supplemental rebate offers.

PDL drugs are automatically covered under Medicaid, although some are subject to age or other program restrictions. If a medication is not on the PDL, it requires prior authorization: a pharmacy-benefits technician asks the prescribing physician's office a set of questions, and if the responses meet established criteria, authorization is granted immediately. Otherwise, the request may be elevated to a pharmacist-level review or, finally, to the Department of Community Health's physicians for determination of the drug's medical necessity for that case.

Multistate Purchasing Pool

The savings from PDLs are magnified when states combine their purchasing power. Michigan and Vermont in particular were the first states to combine their Medicaid populations for the purposes of negotiating deeper discounts from pharmaceutical manufacturers. The U.S. Centers for Medicare & Medicaid Services (CMS) recently gave official approval of this multistate purchasing arrangement for pharmaceuticals, and numerous states and drug manufacturers have now expressed interest in participating. Though Michigan and Vermont were enjoying the benefits of the pooling arrangement before CMS's action, such broadened involvement is expected to enhance savings considerably.

Time Frame

Michigan implemented its PDL in February 2002, and in April 2002 it started collecting rebates based on negotiations between the manufacturers and Michigan's PBM. Although Michigan and Vermont initially hoped to collect multistate rebates from manufacturers beginning in April 2003, a CMS ruling pushed back the "official" start date to October 1, 2003. With CMS approval announced in April 2004, some of the states that had expressed interest have now joined, or are expected to join the pool later in 2004 (as noted above).

Required Legislation/Authority

Section 1927 of the Social Security Act allows states to negotiate additional rebates from manufacturers. In order to participate in a multistate Medicaid purchasing pool, states must obtain CMS approval and adhere to CMS standards of procurement.

Financing Mechanisms

Michigan's Department of Community Health spends over \$1 billion annually to provide pharmaceuticals to 1.4 million Medicaid and other low-income-program beneficiaries.²⁶ Its PBM, First Health Services, is reimbursed through annual flat fees and per-claim payments.

Efficiencies

The PDL represents about 70 percent of drugs used in Michigan's Medicaid outpatient pharmacy benefit. State officials estimate that the PDL saved as much as \$60.5 million in its initial year (Feb 2002 to March 2003), thereby helping to stretch health care dollars and avoid cutting Medicaid eligibility.

The state estimates that it realized savings of \$7.2 million during the first 12 months of supplemental rebate collection (April 2002 to March 2003). Though this figure represents only about 1 percent of pharmaceutical costs, the state expects an increase in savings as additional states join the pool.

Challenges

The pharmaceutical-industry trade association PhRMA challenged the PDL in court when it was first implemented, but the state was able to proceed while under litigation. The program was ruled legal in December 2002 by the Michigan Court of Appeals, and a federal court dismissed PhRMA's lawsuit in March 2003 on the grounds that Congress has given states the freedom to begin "prior-authorization prescription-drug programs" and that PhRMA "failed to show" Michigan was acting illegally. The ruling was then appealed to the U.S. Court of Appeals, but the legality of the program was again confirmed in early 2004.²⁷

Objections to the PDL were also raised by Medicaid providers and beneficiaries, who were unaccustomed to the new limitations and rules. Also, critics suggested that the PDL limits physicians' abilities to try different medications within a therapeutic class and that the list may hamper patients' access to drugs that best fit their individual needs. These challenges have been addressed in a number of ways, beginning with Michigan's education campaign focused on physicians who prescribe medications to Medicaid beneficiaries. For example, the state used Medicaid bulletins, communication with provider associations, and health-plan trade groups to familiarize prescribers with the new rules and procedures. Also, the state now gives longer notice when changes are planned for the PDL. And the Pharmacy and Therapeutics Committee's reviews ensure that the PDL is not based on

price alone. In June 2003, for instance, the committee recommended, and the Governor approved, the greater availability of mental-health drugs without the need for prior authorization.

Michigan faced additional barriers in gaining approval from CMS for its multistate purchasing pool. One state (South Carolina) joined the pool early on but withdrew, reportedly because of its concerns that the arrangement would not ultimately be approved. The stated reason why CMS initially halted the pool was that the contract between First Health and the pool members did not abide by federal procurement guidelines for the purchase of drugs. This was addressed by pointing out that the pool does not actually purchase drugs and store them in advance but that it simply negotiates a lower price. A second concern with the pool contract was that it was a single agreement between First Health and all involved states, which might create a monopoly situation. In response, the pool was modified so that each state establishes its own separate contract with the PBM. Though CMS officially approved the arrangement in April 2004, state officials contend that during the period when the agency was questioning the arrangement and approval was uncertain, some manufacturers' wariness to participate limited the savings achieved.

Future Plans

As noted above, with CMS approval of the multi-state arrangement announced in April 2004, some of the states that had expressed interest have now joined, or are expected to join the pool later in 2004. Many expect additional states to pursue this model in order to augment their purchasing power for pharmaceuticals.

For More Information

Web site: PDL found on http://www.michigan.gov/documents/ MPPL-20031001_75210_7.pdf.

Contact: Brad Sprecher, Departmental Analyst, Pharmacy Section, Michigan Department of Community Health. E-mail: sprecherB@michigan.gov.

SNAPSHOTS OF ADDITIONAL PHARMACEUTICAL PURCHASING INITIATIVES

GEORGIA: INTRASTATE CONSOLIDATED DRUG MANAGEMENT

Implemented 2000

In 1999, Georgia created the Department of Community Health, consolidating the state's public health insurance purchasing into one agency. The Department solicited bids from pharmaceutical benefits managers (PBMs) to implement, in 2000, a single contract for pharmaceutical management services for the state's Medicaid, PeachCare for Kids, Board of Regents for higher education health insurance benefits, and State Health Benefit Plan for state employees programs. The plans cover almost two million residents. Express Scripts was selected as the PBM, which handles prior authorization, claims adjudication, and other administrative services for all of the above populations (actual negotiation and purchasing for Medicaid and PeachCare are performed by a different vendor under contract with the Department of Community Health). The state's Drug Utilization Review Board established a single preferred drug list (PDL) to be used across the programs. In addition, the state designed a three-tiered formulary for state employees and the Board of Regents (similar to one used in Medicaid), and expanded its Maximum Allowable Cost (MAC) list, which sets price ceilings on generic drugs and encourages their use when appropriate. Together, these changes have helped reduce the pharmaceutical cost growth trend line from 26% in FY 2001 to 16% in FY 2002 (the most recent estimate available). The state is exploring, nevertheless, additional mechanisms to address the double-digit cost growth faced by Georgia and most states.²⁸ In 2004, for example, the state began using a different PDL for Medicaid/PeachCare, in part to enable the state to solicit supplemental rebates from pharmaceutical manufacturers under these programs.

For More Information: Julie Kerlin, Georgia Department of Community Health. E-mail: jkerlin@dch.state.ga.us.

MAINE: RX PLUS

Implemented 2004

Under Maine Rx Plus, the state serves as pharmacy-benefits manager for residents who lack prescription-drug insurance and who have incomes up to 350 percent of the federal poverty level. The state uses its purchasing power (based on negotiating Medicaid prices with pharmaceutical companies) to obtain discounts for the uninsured; the state negotiates discounts in the form of manufacturer rebates, which are distributed to participating pharmacies that then pass on the savings to Maine Rx Plus card holders. Enrollees are

expected to save 15 percent on brand-name drugs and up to 60 percent on generic drugs on the state's Medicaid Preferred Drug List (PDL).²⁹ Implementation is now proceeding in steps, with ultimate enrollment expected to reach up to 270,000 members; as of July 2004, there were approximately 100,000 members.³⁰ Maine Rx Plus survived legal challenges by the pharmaceutical industry, and began operating in January 2004.³¹ Hawaii has developed a similar program called Hawaii Rx Plus.

For More Information: http://www.maine.gov/dhs/mainerx/.

ILLINOIS: RX BUYING CLUB

Implemented 2004

In January 2004, Illinois created a "prescription drug buying club." Pooling the purchasing power of state employees, enrollees of various state-supported programs, and up to two million senior citizens and people with disabilities, the club negotiates discounts with drug manufacturers and pharmacies. In April 2004, for example, the state launched a partnership with Walgreen's, the nation's largest retail pharmacy chain, to promote and expand Illinois' new Rx Buying Club; and through direct negotiations the state implemented a new rebate agreement with the pharmaceutical manufacturer Merck. The rebates get passed on to enrollees in the form of discounts. Members pay an annual administrative fee of \$25 and receive a discount card they can use for buying medication through a mail-order program or at more than 50,000 participating pharmacies both within and outside the state.³² The club enrolled 62,450 individuals during its first three months (January to March 2004) and achieved average savings of 21 percent.

For More Information: http://www.illinoisrxbuyingclub.com/.

NOTES

- ¹ Based on 38 responses, the average estimated annual increase in prescription-drug costs was 14.7 percent in FY 2001 and FY 2002, 14.0 percent in FY 2003, and 13.8 percent projected for FY 2004 (Crowley et. al., *Medicaid Outpatient Prescription Drug Benefits: Findings from a National Survey, 2003* [Washington, D.C.: Kaiser Commission on Medicaid and the Uninsured, December 2003]).
- ² State Actions to Control Health Care Costs, issue brief (Washington, D.C.: National Governors Association Center for Best Practices, November 2003).
- ³ State-sponsored pharmacy-assistance programs utilize a variety of mechanisms to provide prescription drug coverage for low-income, older, and disabled persons who are not eligible for Medicaid and who may have no other drug coverage (Fox et al., <u>Managing Program Costs in State Pharmacy Assistance Programs</u> [New York: The Commonwealth Fund, February 2004]).
- ⁴ Governor Jim Douglas of Vermont, press release: "Governor Douglas Praises Hawaii Governor for Joining Rx Purchasing Pool—Hawaii's Participation Will Help Lower Costs for Vermonters," April 18, 2004.
- ⁵ For more information on multistate and intrastate purchasing, see *Pharmaceutical Bulk Purchasing: Multi-state and Inter-agency Plans, 2004* (Denver: National Conference of State Legislatures, updated April 27, 2004), http://www.ncsl.org/programs/health/bulkrx.htm.
- ⁶ Pharmaceutical Bulk Purchasing: Multi-state and Inter-agency Plans, 2004 (Denver: National Conference of State Legislatures, updated April 27, 2004), http://www.ncsl.org/programs/health/bulkrx.htm.
 - ⁷ Fox et al., Managing Program Costs, 2004.
- ⁸ State Health Care Policy: First Quarter of 2004, state health policy brief, vol. 5, no. 1 (Denver: National Conference of State Legislatures, April 2004).
 - ⁹ Ibid.
- 10 State employees' \$15 copayments for prescription drugs are waived for drugs obtained from Canada.
- ¹¹ "Oregon Governor Proposes Reimporting Drugs From Canada," Kaiser Daily Digest, May 19, 2004.
- ¹² Secretary Tommy Thompson, news conference, May 5, 2004 (*Kaiser Daily Digest*, May 5, 2004).
- ¹³ It is common practice for pharmaceutical manufacturers to offer large purchasers rebates on brand-name drugs. Typically, however, PBMs that negotiate on behalf of purchasers retain much of the rebates "in exchange" for charging relatively low administrative fees.
- ¹⁴ Several states participated in the RFP but did not join the pool because they negotiated favorable arrangements with their own PBMs.
- ¹⁵ The states discovered that what they had been receiving in rebates from manufacturers amounted to only about 3 to 5 percent of their total drug spending.
- ¹⁶ In its first plan year, PEIA spent almost \$128 million before rebates and collected approximately \$14 million in rebates.
- ¹⁷ Source: Presentation by Tom Susman, Director of West Virginia's Public Employees Insurance Agency, at The Council of State Governments Annual Meeting, October 23–26, 2003.

- ¹⁸ Ohio Department of Administrative Services, "Benefits Fax Bulletin 2004-09," March 1, 2004, http://das.ohio.gov/hrd/benefax/benefax0409.html.
- ¹⁹ Drug classes are used for grouping drugs considered similar according to the disease that they treat or the to effects they have on the body. Subclasses further categorize these drugs into smaller groupings (www.phpni.com/form_faq.htm#Anchor-Wha-1941). The 25 classes include the 12 that were originally reviewed by the Oregon Center for Evidence-Based Policy under an AHRQ (Agency for Healthcare Research and Quality) grant, and the 13 new classes being reviewed by DERP.
- ²⁰ The Drug Effectiveness Review Project builds upon work already begun in Oregon, which has been systematically reviewing evidence on 12 drug classes. Unlike most state-based reviews, DERP is funded by subscriptions from states and other organizations that will share in the research activities.
- ²¹ The AHRQ has established 13 EPCs in the U.S. and Canada to rigorously review, analyze, and synthesize all relevant scientific literature, and then produce reports and technology assessments.
- ²² Contracted entities include Oregon, Washington, Idaho, California Health Care Foundation/CalPERS, Wisconsin, Missouri, and the Canadian Coordinating Office for Health Technology Assessment. Most participating states are represented by their respective Medicaid agencies.
- ²³ The Medicaid Drug Rebate Program, created by the Omnibus Reconciliation Act of 1990 (OBRA '90) that added Section 1927 to the Social Security Act (the Act), requires that manufacturers enter into an agreement with the U.S. Centers for Medicare & Medicaid Services to provide rebates for their drug products paid for by Medicaid. As of 1996, the rebate for "innovator" drugs was the larger of the following two measures: 15.1 percent of Average Manufacturer Price (AMP) per unit or the difference between AMP and best price per unit, with a CPI-U adjustment. The rebate amount for non-innovator drugs is 11 percent of AMP per unit. (http://www.cms.hhs.gov/medicaid/drugs/mrphistory.asp)
 - ²⁴ About 25 states have or are developing PDLs for their Medicaid programs.
 - ²⁵ Unlike a typical formulary, nonpreferred products may be covered with prior authorization.
- ²⁶ Includes the state's Children's Special Health Care Services (CSHCS), or Title V program, Dual Title XIX/Title V beneficiaries.
- ²⁷ California Healthline, http://www.californiahealthline.org/index.cfm?Action=dspItem&itemID=101664.
- ²⁸ Based on discussions with Julie Kerlin, Georgia Department of Community Health July 2004 and August 2004; and National Conference of State Legislatures, *State Health Lawmakers' Digest: Prescription Drug Pricing* 2 (Spring 2002).
- ²⁹ Also, individuals enrolled in the state's Low Cost Drugs for the Elderly and Disabled (DEL) program receive savings through Maine Rx Plus as well as under DEL.
- ³⁰ At the outset, the state sent Maine Rx Plus cards to the approximately 73,000 residents who participated in the phased-out Healthy Maine program—a similar pharmacy-assistance program that offered discounts on prescription drugs but was suspended because of legal challenges by PhRMA.

³¹ In 2000, PhRMA was granted a U.S. District Court (Maine) injunction to block an earlier version of the program, Maine Rx, which was charged to be in violation of constitutional interstate commerce laws and an illegal expansion of the federal Medicaid Act. This injunction was overturned in 2001, and in 2003 the U.S. Supreme Court ruled the program was not unconstitutional. A slightly revised version, Maine Rx Plus, began in early 2004.

³² The program also uses a national preferred-provider network of pharmacies arranged by Sav-Rx, a pharmacy-benefits management company.

RELATED PUBLICATIONS

Publications listed below can be found on The Commonwealth Fund's website at www.cmwf.org.

<u>Stretching State Health Care Dollars During Difficult Economic Times: Overview</u> (October 2004). Sharon Silow-Carroll and Tanya Alteras, Economic and Social Research Institute. This overview report summarizes a series of four reports identifying innovative state efforts to enhance access to care, coverage, and efficiency in health care spending. topics include: building on employer-based coverage; pooled and evidence-based pharmaceutical purchasing; targeted care management; and innovative use of uncompensated care funds.

<u>Stretching State Health Care Dollars: Building on Employer-Based Coverage</u> (October 2004). Sharon Silow-Carroll and Tanya Alteras, Economic and Social Research Institute. Whether subsidizing an existing employer plan or creating a new and more affordable program for uninsured workers, states are using their dollars, regulatory/legislative powers, and purchasing clout to leverage employer and employee contributions in order to cover more people. This is one of a series of four reports identifying innovative state efforts to enhance access to care, coverage, and efficiency in health care spending.

Stretching State Health Care Dollars: Care Management to Enhance Cost-Effectiveness (October 2004). Sharon Silow-Carroll and Tanya Alteras, Economic and Social Research Institute. With more than three-quarters of current Medicaid spending devoted to people with chronic conditions, states are pursuing efficiencies through various types of "care management" strategies for high-cost individuals. These services can be provided directly or contracted out to specialized vendors. This is one of a series of four reports identifying innovative state efforts to enhance access to care, coverage, and efficiency in health care spending.

Stretching State Health Care Dollars: Innovative Use of Uncompensated Care Funds (October 2004). Sharon Silow-Carroll and Tanya Alteras, Economic and Social Research Institute. Experts warn that providing uncompensated care could become more difficult for hospitals in the years ahead as a result of their rising costs and lower operating margins, limited state revenues, cuts in Medicaid DSH, and a growing uninsured population. These trends have spurred strategies in several states aimed at reducing the need for expensive uncompensated services over the long term. This is one of a series of four reports identifying innovative state efforts to enhance access to care, coverage, and efficiency in health care spending.

Dirigo Health Reform Act: Addressing Health Care Costs, Quality, and Access in Maine (June 2004). Jill Rosenthal and Cynthia Pernice. Jointly supported by The Commonwealth Fund and The Robert Wood Johnson Foundation, this report by the National Academy for State Health Policy comments on the status of Maine's Dirigo Health Reform Act, which aims to provide affordable coverage for all of the state's uninsured—approximately 140,000—by 2009.

Expanding Health Insurance Coverage: Creative State Solutions for Challenging Times (January 2003). Sharon Silow-Carroll, Emily K. Waldman, Heather Sacks, and Jack A. Meyer, Economic and Social Research Institute. The authors summarize lessons from 10 states that have innovative strategies in place for health insurance expansion or have a history of successful coverage expansion. The report concludes with recommendations for federal action that could help states

maintain any gains in coverage made and possibly extend coverage to currently uninsured populations.

<u>Small But Significant Steps to Help the Uninsured</u> (January 2003). Jeanne M. Lambrew and Arthur Garson, Jr. A number of low-cost policies could ensure health coverage for at least some Americans who currently lack access to affordable insurance, this report finds. Included among the dozen proposals outlined is one that would make COBRA continuation coverage available to all workers who lose their job, including employees of small businesses that are not currently eligible under federal rules.

Medicaid Coverage for the Working Uninsured: The Role of State Policy (November/December 2002). Randall R. Bovbjerg, Jack Hadley, Mary Beth Pohl, and Marc Rockmore. Health Affairs, vol. 21, no. 6 (In the Literature summary). The authors conclude that insurance coverage rates for low-income workers would increase if state governments chose to do more for their uninsured workers. But states decline to tackle this issue for several reasons. Federal law requires them to cover many low-income nonworkers before they insure workers. As well, poorer states cannot afford much coverage for their low-income workers.