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## Issue Brief

# Using Clinical Evidence to Manage Pharmacy Benefits: Experiences of Six States

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**ABSTRACT:** Medicaid agencies report that pharmacy costs are a major driver of overall program spending growth. Many states believe that clinical evidence can be used to curtail pharmacy costs while ensuring beneficiary access to needed prescription drugs. In 2004, researchers from the National Academy for State Health Policy and Georgetown University conducted site visits to examine how state Medicaid agencies in California, Florida, Kansas, Michigan, Missouri, and Washington manage their pharmacy benefits. This brief focuses on states' use of clinical evidence and preferred drug lists. It summarizes the states' experiences in four areas of pharmacy benefit management: the role of pharmaceutical and therapeutics committees in developing preferred drug lists; use of prior approval processes to enforce preferred drug lists; the role played by the Drug Effectiveness Review Project in helping states manage drug utilization; and the management of behavioral health pharmaceuticals.

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### BACKGROUND

State Medicaid agencies report that pharmacy costs are a major driver of overall program spending growth.<sup>1</sup> In 2004, Medicaid programs spent \$36.6 billion on prescriptions—roughly 19 percent of national prescription drug spending.<sup>2</sup> Many states believe that clinical evidence about the effectiveness of specific drugs or classes of drugs can curtail pharmacy costs, while at the same time ensuring beneficiary access to needed prescription drugs.

In 2004, researchers from the National Academy for State Health Policy and Georgetown University conducted site visits to examine how six state Medicaid agencies manage their pharmacy benefit. The researchers selected the states—California, Florida, Kansas, Michigan, Missouri, and Washington—after soliciting input from an advisory group of state officials

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and other experts. Researchers met with Medicaid agency staff and other stakeholders, including pharmacy vendors, pharmacists, physicians, drug utilization review and pharmaceutical and therapeutics committee members, and consumers or their advocates.

This brief summarizes the states' experiences in the following areas of pharmacy benefit management:

1. The role of pharmaceutical and therapeutics committees convened by Medicaid agencies in developing preferred drug lists.
2. The use of prior approval processes in managing the pharmacy benefits and enforcing preferred drug lists.
3. The Drug Effectiveness Review Project, a subscription service that provides comparative reviews of drug effectiveness to states.
4. Management of behavioral health pharmaceuticals.

## **PHARMACEUTICAL AND THERAPEUTICS COMMITTEES**

Many state Medicaid agencies use preferred drug lists (PDLs) to ensure access to needed medications, restrict inappropriate use of prescription drugs, and contain pharmacy costs. To develop the PDLs, states rely on pharmaceutical and therapeutics (P&T) committees to produce actionable, evidence-based recommendations. P&T committees use clinical evidence to evaluate the merits of drugs on a class-by-class basis. States vary in how they accomplish this. In some states, drugs that are judged to be superior to others in their therapeutic class are placed on the preferred list. If drugs are deemed therapeutically equivalent, then the preferred drugs are selected based on cost, among other factors. In other states, clinical and cost factors are reviewed simultaneously.

Most Medicaid agencies create incentives for beneficiaries and providers to use preferred drugs by requiring them to obtain permission before prescriptions for non-preferred drugs can be filled. Because of beneficiaries' low incomes, federal law

restricts cost-sharing for Medicaid services to a "nominal" standard; nonetheless, some agencies employ copayments to encourage use of preferred drugs.<sup>3</sup> Educating physicians, pharmacists, and beneficiaries about the PDL, its purpose, and evidence base is also important for promoting compliance, especially in states that do not require prior approval or use copayments. States also use PDLs to negotiate supplemental rebates from pharmaceutical manufacturers.<sup>4</sup>

### **Forming Effective P&T Committees**

P&T committees consist largely of clinical professionals, mainly physicians and pharmacists, who make recommendations during formal meetings. However, there is some variation. For example, California's committee is an informal advisory group composed mainly of academic researchers who do not convene for in-person meetings. Washington's committee includes a nurse and physician assistant, while Florida's committee has a consumer representative and requires that at least one member represents pharmaceutical manufacturers.

Stakeholders in all six states and Medicaid agency staff members in all states except Michigan emphasized the importance of having practicing clinicians, ideally from a range of professional disciplines, on P&T committees. Practicing clinicians can offer insights about patients' adherence to medication regimens and pharmaceutical side effects. Many respondents also felt that committee members should have experience caring for Medicaid beneficiaries.

### **P&T Committee Inputs**

States provide P&T committee members with information about the available scientific evidence on the prescription drugs to be classified, usually in both summary and detailed forms. At the time of the site visits, four of the states (Kansas, Michigan, Missouri, and Washington) obtained summaries from the Drug Effectiveness Review Project, a subscription service based at Oregon Health & Science University that provides comparative reviews of

drug effectiveness to states (see discussion below). These four states also use clinical evidence from other sources. Florida employs a private company, Provider Synergies, to review and summarize clinical evidence, while California relies on a variety of sources, including unpublished information supplied by drug manufacturers (Table 1).

Among the six states, only Florida provides information about the cost of drugs to their P&T committee members and asks them to develop recommendations that reflect relative cost and clinical effectiveness. State officials and the state’s contractor believe that practitioners are best equipped to assess the tradeoffs between cost and clinical outcomes. In the five other states, Medicaid officials consider drug costs after the P&T review is complete.

Five of the six states hold public meetings at which consumers, providers, and drug manufacturers can provide committee members with their input and evidence not included in the research summaries. California’s advisory group does not meet and there is no formal mechanism for group members to hear from consumers and providers. However, consumers and providers can contact advisory group members or state staff to offer their input. California state staff reported that advisory group members sometimes consult with colleagues.

**Developing Recommendations**

The P&T committees in the six states do not dictate which drugs should be listed as preferred products on the PDLs. In four of the states, the

committees make recommendations to state officials, while in Florida and Missouri the committees produce provisional PDLs, which are then reviewed and ratified by other committees. In five of the six states, the P&T committees make decisions about clinical equivalency of the drugs in a particular therapeutic class by member vote. In California, each committee member provides their recommendations to state Medicaid staff, who then compile the recommendations and their analysis of cost considerations to produce a PDL.

As discussed above, Florida’s P&T committee members use both clinical and cost data to create their recommended PDL. In the five other states, Medicaid officials or their contracted staff members integrate the P&T committee recommendations with data on cost:

- In Kansas, Michigan, and Washington, P&T committees designate each drug as clinically essential, clinically inferior, or clinically equivalent to the best alternative in the same class. Those judged to be essential are included on the PDL and those judged to be inferior are excluded. State officials use price considerations to select drugs for the PDL from among those judged to be therapeutically equivalent.
- In California, Medicaid agency staff review feedback from the P&T advisory group, scientific evidence, and cost information in the form of bids by drug manufacturers. Staff

**Table 1. Overview of Pharmaceutical and Therapeutic (P&T) Committee Functions**

	California	Florida	Kansas	Michigan	Missouri	Washington
What does the P&T committee review?	Other	Other	DERP* and other	DERP and other	DERP and other	DERP
Does the P&T committee consider cost?	No	Yes	No	No	No	No
What does the P&T committee produce?	PDL** framework	Provisional PDL	PDL framework	PDL framework	Provisional PDL	PDL framework

\* DERP = Drug Effectiveness Review Project.

\*\* PDL = preferred drug list.

members then designate preferred drugs within a therapeutic class and produce a series of “clinical edits,” or descriptions of the specific clinical conditions under which a prescription should be filled.

- In Missouri, state staff members present the clinical evidence and a proposed PDL developed by the Medicaid agency based on the evidence, cost, and utilization. The committee then produces a series of clinical edits and a provisional PDL. The provisional PDL is then presented to the Drug Utilization Board for final approval. The Board retains the authority to make changes.

**PRIOR APPROVAL**

Many states use a prior approval process in conjunction with a preferred drug list.<sup>5</sup> A well-designed prior approval process can encourage prescribers to comply with the PDL while ensuring that beneficiaries are able to access non-preferred drugs under clinically appropriate circumstances. At the same time, it should minimize administrative burdens on providers and the financial costs of administration for the state.

To obtain approval to prescribe drugs not on the PDL, providers must submit a formal request to the state Medicaid agency. These requests are granted when a Medicaid agency determines that the drug in

question is medically necessary. When a state determines that there is insufficient clinical justification provided or that a drug is not medically necessary, prior approval requests are denied. If a request is denied, beneficiaries or their physicians have the right to appeal under the fair hearing process.

In practice, most prior approval requests are approved. Some argue that this high approval rate obviates the need for prior approval. However, requiring approval for non-preferred drugs appears to produce a significant sentinel effect. The site visit states say that the prior approval process aligns physician prescribing patterns with the PDL and report compliance rates of 85 to 95 percent. Florida began its pharmacy management efforts with a voluntary PDL but found that physicians did not comply with it.<sup>6</sup>

**Submitting Prior Approval Requests**

States require a high level of coordination between prescribing physicians and dispensing pharmacists in submitting prior approval requests (Table 2):

- In California, pharmacists have prior approval submission authority. Pharmacists must contact physicians to obtain notes of medical necessity before submitting the requests.
- In Florida, Michigan, and Missouri, only prescribing physicians can submit prior approval requests. However, pharmacists

**Table 2. Prior Approval Processes by State**

	California	Florida	Kansas	Michigan	Missouri	Washington
Submitting professional*	Pharmacists	Physicians	Pharmacists Physicians	Physicians	Physicians	Pharmacists
Submission conduit	E-mail Fax Internet	Fax Telephone Wireless	Fax Internet	Internet Telephone	Internet Telephone	Fax Telephone
Professional status of initial reviewer	Pharmacist	Pharmacist	Registered Nurse	Pharmacy Technician	Registered Nurse	Pharmacy Technician
Experience with “dispense as written” instructions	No	Yes	Yes	No	No	Yes

\* States that allow pharmacists to submit the request require them to coordinate with the prescribing physician.

report calling physicians to suggest preferred drugs or asking them to submit requests for non-preferred drugs.

- Kansas allows both pharmacists and physicians to submit prior approval requests, but all requests must bear the prescribing physician's signature.
- In Washington, physicians can choose to participate in the Therapeutic Interchange Program, a global authorization that permits pharmacists to substitute a preferred drug when a physician prescribes a non-preferred drug. In addition, pharmacists are allowed to submit prior approval requests after coordinating with the prescribing physicians.

### Review Processes

In most cases, states establish clinical criteria to determine whether a specific prior approval request meets the definition of medical necessity. For example, if there is evidence demonstrating that patients with a history of heart disease are more likely to suffer certain side effects from a preferred drug than from a non-preferred drug, then a state might establish criteria granting prior approval requests for the non-preferred drug for beneficiaries with a history of heart disease.

Site visit states report that their prior approval review processes balance the need to ensure that patients can obtain the specific drugs they need with the need to enforce the PDL. These states have established procedures enabling beneficiaries with prescriptions used to treat certain conditions to receive those drugs, even when they are not preferred. In Missouri, once a prior approval for a specific drug is granted for an individual, the system will automatically accept any subsequent prescriptions for that drug without requiring a new prior approval. In California, prior approvals last one year.

In cases where clear evidence does not exist, decisions are made by Medicaid agency reviewers. Four of the six states employ professionals who are

less costly than pharmacists to conduct the initial reviews of prior approval requests: Michigan and Washington use pharmacy technicians, Kansas and Missouri use registered nurses, while California and Florida employ pharmacists for the initial review.<sup>7</sup>

### Exceptions to the Prior Approval Process

There are two common ways to bypass the prior approval process: emergency provisions and “dispense as written” (DAW) instructions.

Emergency provisions are intended to ensure that prior approval system interruptions do not stand in the way of dispensing necessary drugs. Federal law requires that any state drug authorization process enables beneficiaries to receive at least a 72-hour supply of covered outpatient drugs in emergency situations.<sup>8</sup> Site visit states report that these provisions are rarely used. For example, Missouri reported that pharmacists provided an emergency prescription only three times from January 2002 through the end of 2004.

However, advocates and pharmacists in site visit states also report that the emergency provisions do not always work as intended. Advocates report that pharmacists on occasion do not dispense needed medications, while pharmacists report that they are reluctant to dispense emergency medications out of concerns that they will not be reimbursed and that they would be liable should anything happen to the beneficiary.

In Florida, pharmacists expressed concerns about the potential for abuse. They note that Medicaid beneficiaries, after having received an emergency provision, might not return to pick up remaining medications from an approved prior approval request. In this case, the pharmacist could re-stock the medication while submitting an invoice for payment on the filled prescription.

“Dispense as written” is a privilege granted to physicians by states. Of the six states, Florida, Kansas, and Washington have experience with DAW. Kansas eliminated the privilege after finding that physicians used it to override the PDL 70 percent of the time. Florida also reported problems.

In Washington, physicians were given the DAW privilege after they agreed not to oppose the creation of a PDL during legislative debate. However, DAW is available only to physicians participating in the Therapeutic Interchange Program (TIP), which permits pharmacists to substitute a preferred drug when a physician prescribes a non-preferred drug (without also writing DAW). This agreement is relatively new. Although the state is concerned that the DAW privilege might be used to circumvent the prior approval process and the TIP, early evidence suggests that the DAW provision is being used modestly.

Linking the DAW privilege to participation in TIP might be a key to success of such programs. However, therapeutic exchange by pharmacists might not be an option in all states because of state-to-state variation in licensing requirements.

### **THE DRUG EFFECTIVENESS REVIEW PROJECT**

The Drug Effectiveness Review Project (DERP) is a collaborative partnership between states and other government and non-profit entities that conducts systematic, evidence-based reviews of pharmaceuticals. DERP currently has 19 members, the majority of which are state Medicaid programs. It is the largest effort to apply evidence-based analysis to pharmacy management issues.

DERP is based at the Oregon Health & Science University in Portland, Oregon. The DERP model was pioneered by the administration of John Kitzhaber, past governor of Oregon, beginning in 1999. The project was formally transferred from the state to the Center for Evidence-Based Policy at the university in January 2004. Since its inception, DERP has developed 12 drug class reviews commissioned by Oregon, Washington, and Idaho, as well as 13 drug class reviews commissioned by the larger DERP collaborative. Each of these reviews is updated based on new evidence every six months. Together, these drug classes account for more than half of all drug utilization.

### **The DERP Model**

DERP develops information on drug effectiveness, drawing on financial support and intellectual input from multiple organizations, while members make their own decisions about how to use this information to develop pharmaceutical management tools.<sup>9</sup>

The Center for Evidence-Based Policy supports DERP by executing the agreements and contracts required to operate the collaborative and by staffing the governance process that directs it. The Center contracts with several evidence-based practice centers to conduct drug class reviews, with coordination and oversight provided by the Oregon Evidence-Based Practice Center. In addition, the Center for Evidence-Based Policy supports communication among the states, other participating organizations, the evidence-based practice centers, and pharmaceutical companies and provides technical assistance to participating organizations. The Center does not participate in the evaluation of evidence.

DERP operates as a self-governing project with member organizations setting priorities, determining which drug class reviews to conduct, and developing key questions and inclusion criteria for each review.

### **Evidence-Based Practice Centers**

Drug class reviews conducted for DERP draw on a tradition of evidence-based research promoted by the federal Agency for Healthcare Research and Quality in establishing evidence-based practice centers.<sup>10</sup> The reviews involve a comprehensive search of the literature for all relevant articles, including citations received as a result of soliciting input from pharmaceutical companies. All articles are selected according to inclusion criteria (based on such factors as the patient populations, treatments, and outcomes studied). Articles are then rated for their methodological quality by at least two independent reviewers. The data from the included studies are also abstracted by two reviewers, allowing the research team to synthesize the results in various ways.

Voting by participating organizations determines which classes of drugs will be reviewed. Participating organizations agree to consider the following when selecting drug classes for review:

- drug classes that account for a significant amount of the pharmaceutical budget;
- drug classes with multiple drugs;
- drugs that are being used for off-label purposes;
- drug classes with recent additions of similar drugs (including extended release formulations);
- the addition of a significantly expensive drug to a class; and
- consideration only of drugs approved for use in the jurisdictions of participating organizations.

**Impact of DERP on State Medicaid Decision-Making**

The DERP drug class reviews provide a tangible product that states can use to inform their Medicaid pharmaceutical policy decisions. Among the site visit states, two made DERP their sole source of evidence to support decisions, two had at least one alternate source, and two did not participate in DERP (Table 3).

Stakeholders reported several benefits of participating in DERP apart from use of the publicly available reports. Both state pharmacy staff and Center for Evidence-Based Policy staff reported that the collaboration offered valuable

opportunities to discuss pharmacy management issues with peers. Further, state participants receive information that is not available to the public as well as technical support.<sup>11</sup> Participating organizations also value the ability to participate in the decision-making process, helping to determine which drug class reviews will be conducted and identify the specific research questions investigated.

**Views of Evidence-Based Analysis**

Several states indicated that some stakeholders (including physicians and pharmacists) questioned whether PDLs and prior approval policies would really be evidence-driven. Participation in DERP has helped to convince some skeptics that pharmacy management decisions are based in clinical evidence. Other stakeholders needed to be reassured that, while DERP reports and other products inform states’ decision-making processes, they do not take final decision-making out of the hands of officials in their own state.

DERP officials and some state respondents reported that pharmaceutical companies’ views of DERP reviews have shifted over time. Although many companies continue to oppose any use of PDLs, others have shown some willingness to accept the DERP process as an appropriate way to bring evidence into decisions about the PDLs. For example, companies regularly take advantage of the opportunity to submit literature for consideration, and increasingly debate state decisions on the basis of their scientific merits.

**Table 3. Participation in the Drug Effectiveness Review Project (DERP) Among Site Visit States**

	Uses DERP as sole source	Uses DERP and other sources	Non-participant in DERP
California*			X
Florida			X
Kansas	X		
Michigan		X	
Missouri		X	
Washington	X		

\* California was not a member of DERP when this site visit was conducted; it became a member in May 2005.

However, drug manufacturers and others fault the DERP model for focusing on comparative evidence from randomized controlled trials to the exclusion of other information, including observational studies. Staff at the Center for Evidence-Based Policy respond that, while the evidence from trials is the gold standard for evidence and thus is what the DERP collaboration is intended to develop, they are beginning to incorporate other types of evidence, including observational studies, especially as the nature of the questions addressed in the reviews has evolved.

For example, the most straightforward reviews examine whether differences exist among competing products. Yet in some drug classes, the array of competing products is more complicated. For example, some believe that one class of diabetes drugs (glitazones, or TZDs) might be helpful in treating pre-diabetes, a condition characterized by blood glucose levels that are elevated, but not high enough for a diagnosis of diabetes. DERP might seek to investigate this and draw comparisons between these diabetes drugs and other classes of diabetes drugs. Because few clinical trials have addressed these questions, such a review creates challenges for the researchers.

To date, most DERP reviews have focused on whether there are differences among a set of competing products in classes such as statins for managing cholesterol, proton-pump inhibitors (PPIs) for gastrointestinal disorders, or angiotensin-converting enzyme (ACE) inhibitors for lowering blood pressure. To the extent that reviews show few if any significant differences among the competing products, states can negotiate with manufacturers. Where there is evidence that certain drugs result in better outcomes, states can help to ensure that these products are available to beneficiaries. Future DERP reviews might evaluate the effectiveness of combination drugs (such as a new drug that combines a cholesterol medication with a treatment for hypertension) or the effectiveness of different dosage forms.

## BEHAVIORAL HEALTH PHARMACEUTICALS

In recent years, states have begun to consider ways to manage behavioral health pharmaceuticals because of increases in cost as well as shifts in utilization. Medicaid agencies in the site visit states reported that pharmaceuticals that treat mental illnesses command a greater proportion of their pharmaceutical expenditures than drugs for any other disease category. For example, Florida reported that, of the \$2.6 billion spent on pharmaceuticals in Medicaid fee-for-service plans in 2003, behavioral health pharmaceuticals cost more than \$500 million—just below 20 percent of the total. And while behavioral health pharmaceuticals include many drug classes, states report that anti-psychotics and antidepressants—and in particular atypical antipsychotics, or AAPs (e.g., Risperdal and Zyprexa) and second-generation antidepressants (e.g., Paxil, Prozac, and Zoloft)—are of greatest concern.

AAPs and second-generation antidepressants are among the most expensive and widely used drugs. Most of these drugs came on the market in the last 15 years, and nearly all are still protected by intellectual property rights that limit the availability of generic alternatives to high-cost, brand-name drugs (although patent expirations for some products might allow more generics onto the market in the next few years). AAPs comprise more than 90 percent of the national market for antipsychotics—a class that cost Medicaid programs more than \$3 billion in 2004.<sup>12</sup>

However, site visit states report that they view psychotropic medications, particularly AAPs and second-generation antidepressants, as efficacious and cost-effective. As a general rule, AAPs are believed to treat serious conditions such as schizophrenia with fewer side effects—particularly the irreversible tardive dyskinesia—than older antipsychotic medications.<sup>13</sup> Similarly, second-generation antidepressants, including Prozac and other selective serotonin reuptake inhibitors, are considered at least as effective as older-generation antidepressants and often have fewer side effects.<sup>14</sup>

However, these newer medications do not work for all beneficiaries. In some cases, older AAPs and antidepressants are more appropriate—part of the reason why states have been reluctant to engage in access management strategies for such drugs.

States say that prescribing for psychotropic drugs must take into account individual response and tolerance for side effects. As a result, site visit states were concerned that managing access through PDLs or other means could inadvertently lead to psychiatric destabilization and more costly acute or inpatient care. These more intensive forms of care can be significantly more expensive for states, since federal Medicaid funds cannot be used to pay for services provided to beneficiaries between the ages of 22 and 65 in institutions for mental disease.<sup>15</sup>

In addition, every site visit state reported that strong advocacy coalitions for behavioral health issues make it politically difficult to manage access. Missouri, for example, encountered stiff resistance to a seemingly minor change that

required consumers to switch from brand-name Clozaril to its generic equivalent.

However, the new Medicare prescription drug benefit might cause states to reconsider strategies to manage use of behavioral health pharmaceuticals. As of January 1, 2006, Medicaid agencies no longer manage the pharmacy benefit for dual eligibles, or beneficiaries of both Medicaid and Medicare. Many state staff interviewed during the site visits anticipated that behavioral health drugs will represent a large share of their remaining market. As a result, states might consider implementing strategies to manage the remaining high-cost therapeutic classes, including those drugs used to treat behavioral health conditions.

**Managing Access and Improving Prescribing**

Among the six states, four strategies to control access to behavioral health drugs were in use, though none widely (Table 4). Two of the strategies—PDLs and caps on the number of prescriptions a

**Table 4. Strategies to Manage Behavioral Health Pharmaceuticals**

	California	Florida	Kansas	Michigan	Missouri	Washington*
Exemption of psychotropics from a PDL or other access management strategies	Established by the Medicaid agency for some drugs)	No	No	None, established by the Medicaid agency, then by the legislature	Established by the legislature	N/A
Grandfather clause <sup>§</sup>	No	Yes	No	Yes	No	N/A
Submission conduit	6	4 (Mental health drugs exempted from the limit)	No	No	No	No
TMAP <sup>†</sup> / Fail First <sup>**</sup> strategy	TMAP	None	None	None	None	None
Drug utilization review process for mental health drug issues	Yes	No	Yes	Yes	Yes	No

\* At the time of our visit, Washington had not reviewed AAPs and was considering implementing a fail first policy for second-generation antidepressants.

§ Grandfather clause: Beneficiaries using a non-preferred drug before becoming subject to the PDL can continue to use that drug.

† TMAP, or the Texas Medication Algorithm Project, is a treatment and medication protocol specifically designed for schizophrenia, major depressive disorder, and bipolar disorder.

\*\* Fail first: Beneficiaries may only access a non-preferred drug after they have tried the preferred drug and it has not worked for them.

beneficiary can have filled each month—are not specific to behavioral health pharmaceuticals.

Four states reviewed physician prescribing patterns for behavioral health pharmaceuticals. Kansas, Missouri, Michigan, and California use their federally mandated drug utilization review programs to manage behavioral health pharmaceuticals.<sup>16</sup> In particular, these states seek to change the practices of physicians who have a history of suboptimal behavioral health pharmaceutical prescribing patterns. Both Missouri and California focus on polypharmacy—prescriptions for more than one drug in the same class—for AAPs. But Missouri has the most aggressive process for identifying suboptimal prescribing patterns and changing physician practice.

### **Missouri Mental Health Medicaid Pharmacy Partnership Program**

In 2003, Missouri's Department of Mental Health and the state Medicaid agency developed the Missouri Mental Health Medicaid Pharmacy Partnership Program in conjunction with Comprehensive NeuroScience, a health care consulting company based in White Plains, New York. The pharmaceutical company, Eli Lilly, supported the partnership in its first two years and the state began fully funding the program in mid-2005.

The Missouri program uses health care encounter data, as well as beneficiary and prescription data, to compare Medicaid physician prescribing practices against nationally recognized guidelines. Physicians who deviate from the guidelines are notified that their prescribing practice does not conform to the standard of practice and sent appropriate educational materials. The program also identifies beneficiaries who receive the same or similar prescriptions from multiple providers and works to eliminate unnecessary prescriptions.

Physicians who deviate from the guidelines are targeted for three levels of educational interventions:

1. Initially, the Medicaid director of the Missouri Department of Mental Health sends the physician a letter, detail sheets for all relevant beneficiaries (including information specifying the drugs, dates, dosages, etc.), and educational materials on the standard of practice.
2. After five to six months, if the physician has not improved, a letter is sent that identifies the physician's rank among worst offenders in the state in the relevant area of prescribing practice. Missouri state staff report that this step is effective in most cases.
3. If the suboptimal prescribing practice continues, the Department of Mental Health calls the physician and offers to establish a call or in-person meeting with a well-respected physician in Missouri to review the specific case.

Physicians do not face consequences if they continue to deviate from the standards of practice. Nonetheless, Missouri reports that these efforts are usually successful.

This approach is an efficient use of resources because it enables the state to concentrate on a limited number of providers. State data show that 5 percent of prescribing physicians account for more than 50 percent of the cost associated with deviations from standard guidelines. Missouri reports that these efforts have reduced anticipated 2004 Medicaid costs by \$7.7 million. The program has also led to:

- a 98 percent reduction in beneficiaries receiving the same prescription from multiple providers;
- a 64 percent reduction in beneficiaries taking multiple drugs within the same class;
- a 43 percent reduction of children on three or more behavioral health drugs; and

- a 40 percent reduction in the number of beneficiaries receiving medication doses that exceed guideline recommendations.<sup>17</sup>

Stakeholders—including pharmaceutical manufacturers and consumer advocates—report that they are satisfied with the work of the Missouri program and view it more favorably than access restrictions.

## CONCLUSION

States face critical issues in designing and implementing strategies to manage the Medicaid pharmacy benefit. The site visit states recognize that prescription drugs—even expensive ones—can be cost effective and improve quality of life. At the same time, they believe that clinical evidence can be used to curtail pharmacy costs while ensuring beneficiary access to needed prescription drugs. Based on the experience of the site visit states, it is important that states seeking to apply clinical evidence to coverage decisions:

- base coverage decisions on comprehensive, high-quality clinical evidence;
- involve practicing clinicians and local opinion leaders in the process of applying the evidence to coverage decisions;
- offer those affected by the policies an opportunity to provide input; and
- ensure that beneficiaries who need access to non-preferred drugs are able to access those drugs when medically necessary.

## NOTES

<sup>1</sup> V. Smith et al., *The Continuing Medicaid Budget Challenge: State Medicaid Spending Growth and Cost Containment in Fiscal Years 2004 and 2005: Results from a 50-State Survey* (Washington, D.C.: Henry J. Kaiser Family Foundation, Oct. 2004). Available at <http://www.kff.org/medicaid/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=48004>.

<sup>2</sup> Center for Medicare and Medicaid Services, Office of the Actuary, *National Health Expenditures by Type of Service and Source of Funds: Calendar Years 2004–1960* (Washington, D.C.: U.S. Government Printing Office). Available at [http://www.cms.hhs.gov/NationalHealthExpendData/02\\_NationalHealthAccountsHistorical.asp#TopOfPage](http://www.cms.hhs.gov/NationalHealthExpendData/02_NationalHealthAccountsHistorical.asp#TopOfPage).

<sup>3</sup> N. Kaye, *Affording Prescription Drugs: State Initiatives to Contain Cost and Improve Access* (Portland, Maine: National Academy for State Health Policy, July 2002). Available at [http://www.nashp.org/docdisp\\_page.cfm?LID=666CB5DC-7948-11D6-BD1700A0CC76FF4C](http://www.nashp.org/docdisp_page.cfm?LID=666CB5DC-7948-11D6-BD1700A0CC76FF4C).

<sup>4</sup> Supplemental rebates are cash payments, in excess of those obtained through federal legislation, that states receive from pharmaceutical manufacturers in exchange for including drugs on the PDL or not restricting access to their products through the use of prior approval. Some states obtain non-cash considerations, such as assistance with disease management programs, from manufacturers in exchange for placement of drugs on the PDL.

<sup>5</sup> Prior approval can be used for drugs that are subject to abuse (e.g., Oxycontin), unusually high cost, subject to overuse (e.g., triptans for migraines), or used for different indications (including off-label uses). Prior approval may even be used to manage access to non-drug services. This brief focuses on the role of prior approval concerning PDLs.

<sup>6</sup> In 2002, Florida established a non-binding PDL that did not require physicians to seek prior approval for non-preferred drugs. Through this voluntary effort, the state failed to get physicians to prescribe preferred medications.

<sup>7</sup> Washington's prior approval process as described here concerns only non-preferred drugs in classes that are included on the PDL. For a relatively small group of drugs that are expensive, or that have a narrow indication, safety concerns, or strong potential for abuse, prior approval requests are reviewed by the Drug Utilization Review Board.

<sup>8</sup> §1927(d)(5)(B) of the Social Security Act.

<sup>9</sup> See DERP's Web site for more information, <http://www.ohsu.edu/drugeffectiveness/index.htm>.

<sup>10</sup> For further discussion of evidence-based research, see E. P. Steinberg and B. R. Luce, "Evidence Based? Caveat Emptor," *Health Affairs* Jan./Feb. 2005

24(1):80–92; D. M. Fox, “Evidence of Evidence-Based Health Policy: The Politics of Systematic Reviews in Coverage Decisions,” *Health Affairs* Jan./Feb. 2005 24(1):114–22; M. Helfand, “Using Evidence Reports: Progress and Challenges in Evidence-Based Decision Making,” *Health Affairs* Jan./Feb. 2005 24(1):123–27.

<sup>11</sup> <http://www.ohsu.edu/drugeffectiveness/reports/index.htm>.

<sup>12</sup> “Little Difference Found in Schizophrenia Drugs,” *New York Times*, Sept. 20, 2005: A1.

<sup>13</sup> “Drug Class Review on Atypical Antipsychotic Drugs,” DERP, Jan. 2005.

<sup>14</sup> “Drug Class Review on Second Generation Antidepressants,” DERP, July 2005.

<sup>15</sup> §435.1008 (a)(2) of Title 42.

<sup>16</sup> §1927(g) of the Social Security Act specifies the requirements for drug utilization review programs.

<sup>17</sup> “Missouri Sees \$7.7 Million in Mental Health Services Savings,” Missouri Department of Mental Health News Release, December 9, 2004. Available at <http://www.dmh.mo.gov/newsreleasesevents.htm>.

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This issue brief is an overview of four briefs that go into greater depth on individual topics. These briefs are available on the National Academy for State Health Policy Web site at [http://www.nashp.org/docdisp\\_page.cfm?LID=341D7DA7-A140-4A10-A9AB4F82C47F8850](http://www.nashp.org/docdisp_page.cfm?LID=341D7DA7-A140-4A10-A9AB4F82C47F8850).

*State Experience in Creating Effective P&T Committees*

*State Design and Use of Prior Authorization Processes*

*Understanding Key Features of the Drug Effectiveness Review Project (DERP) and Lessons for State Policy Makers*

*State Efforts to Manage the Behavioral Health Pharmaceutical Benefit*

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