



Medicaid Preferred Drug Lists

A Review of Three States

CHH policy brief

Colorado Health Institute

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Colorado Health Institute

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Three things to know . . .

- Evidence-based preferred drug lists (PDLs) are a relatively new policy option for states, and no two PDL programs are exactly alike. Committee structures, administrative procedures and authorizing regulations vary greatly.
- Efficient, rapid and automated procedures for prior authorization are key to a PDL's success. Unnecessary or burdensome delays frustrate doctors and have the potential to harm Medicaid clients.
- Exemptions and other safeguards to protect the treatment regimens of special populations who require exceptions to a PDL are warranted to maintain patients' health and safety.

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The Colorado Health Institute (CHI) was established in 2002 as a nonprofit corporation to serve as an independent source of objective, non-partisan health information for Colorado decision-makers in the public and private sectors. CHI was established and funded through a memorandum of understanding between The Colorado Trust, Caring for Colorado, and Rose Community Foundation.

Like other states, Colorado continues to seek relief from rising Medicaid costs. One strategy that states have used to increase efficiency, value, and quality in the Medicaid program is the implementation of an evidence-based Preferred Drug List (PDL). An evidence-based PDL is generally defined as a formal published list of preferred drugs selected for their efficacy, safety, and cost-effectiveness, based on documented scientific evidence. The list contains pharmaceuticals for which a Medicaid agency will provide reimbursement to an authorized pharmacist or other dispensing agent. To receive reimbursement for a “non-preferred” drug, physicians generally must obtain prior authorization (PA) from the state agency administering the pharmacy benefit program.

Evidence-based PDLs are a relatively new policy option for states; most have been implemented between 2001 and 2004. No two PDL programs are exactly alike; committee structures, administrative procedures, and authorizing regulations vary greatly. Proponents argue that an evidence-based PDL can provide physicians and their patients a safer, more appropriate list of drugs based on known efficacy, while also controlling costs. Opponents argue preferred drug lists can limit access to important medications, require extra work for physicians, and put certain Medicaid recipients’ health at risk.

This brief presents information about Colorado’s current Medicaid prescription drug reimbursement policies and examines evidence-based Medicaid PDL programs in three states—Florida, Missouri and Washington. These states were chosen based on their geographic diversity; the methods by which they evaluate the evidence basis of drug classes; unique characteristics of the PDL review process; and the availability of documented process and program outcomes information. The three

specific aspects of the states’ PDL programs the Colorado Health Institute examined were:

(1) Committee Structure and Review Process

– Each state has a designated committee that evaluates the evidence-based research on specified classes of drugs and makes recommendations to state administrators about which drugs should be included on the Medicaid PDL. While they have similar goals, the committees have unique structures and processes through which they reach their recommendations. It is important to note that the company or organization with whom a state contracts to conduct the evidence-based reviews does not make recommendations to the state’s committee, but rather provides the results of their evidence-based reviews. The committee makes recommendations after reviewing the results of the research studies.

(2) Prior Authorization Procedures

– The three states reviewed have PA procedures for the prescription drugs not included on their PDLs. Each state recognizes that efficient, rapid, and automated procedures for PA make the difference in physician acceptance of the preferred drug list policy, how well the policy works overall, and the extent to which they successfully negotiate supplemental rebates with drug manufacturers for brand name products.

Therefore, the three states reviewed have efficient operational infrastructures in place to conduct their PA process. A cumbersome or time consuming PA process leads to frustrated physicians and patients who often have a legitimate claim for a drug requiring a PA. Unnecessary or burdensome delays have the potential to cause harm to patients. In some cases, exemptions from the PA process are

warranted to assure certain classes of patients' health and safety.

(3) Costs and Policies Related to Special Populations – To increase efficiency, quality, and value in their Medicaid programs, all three states reviewed focus on more than just reducing net costs in their pharmaceutical budgets. In particular, the states track the internal costs and those incurred outside their respective pharmaceutical budgets. They also have instituted safeguards to protect the treatment regimens of special populations and individuals who require exceptions to the PDL.

Colorado's Current Medicaid Pharmacy Benefit

While certain policies and exemptions apply to some of the restricted drug classes discussed below, this summary provides a broad description of Colorado's current reimbursement policies for the Medicaid out-patient prescription drug benefit. This brief does not evaluate the current Colorado system. The Office of the Colorado State Auditor conducted a performance audit of the Medicaid prescription drug program in 2004. The full report can be found online at www.leg.state.co.us/OSA/coauditor1.nsf/Home?openform.

The Colorado Department of Health Care Policy and Financing (HCPF) administers an

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open formulary prescription drug benefit for the state's Medicaid Medical Assistance Program with some restrictions. Federal law requires drug manufacturers to sign a national rebate agreement with the federal Centers for Medicare and Medicaid Services (CMS) in order to participate in state Medicaid programs. Currently, the Colorado Medical Assistance Program covers any drug produced by a pharmaceutical company that has signed a rebate agreement with CMS. While the formulary is classified as "open," it does place restrictions on over 40 drug classes and excludes (in part) five specific categories—diet pills, fertility drugs, drugs used for cosmetic purposes only, smoking cessation drugs and "DESI" drugs (those that the Food and Drug Administration has declared "less than effective.") Smoking cessation products are partially covered as a one-time, lifetime benefit for 90 days and require a PA to prescribe.

If a physician wants to prescribe a restricted drug or restricted dosage, s/he must apply for a PA exception. Colorado's PA program is not a preferred drug list as defined by this brief. Although the restricted drugs are publicly listed on the HCPF website, the list only shows the drugs that HCPF restricts, it does not list the preferred drugs available on the open formulary.

HCPF delegates the PA process to its fiscal agent, Affiliated Computer Services (ACS). ACS operates a PA Call Center; the front-line staff is comprised of pharmacists and technicians who are supervised by a nurse and a clinical pharmacist. By federal law, all PA calls must be answered within 24 hours, and the state must allow pharmacists to dispense a 72-hour supply when the PA decision is not forthcoming. If a Medicaid enrollee is denied a PA, the enrollee and his/her physician must be notified and may appeal the decision.

HCPF decides which drugs will require PA based on the recommendation of several groups including the Drug Utilization Review

Board. The final decision takes the following criteria into account:

- Possible impacts on the health of Colorado's Medicaid population and costs to the Medical Assistance Program;
- Results from on-going monitoring of prescribing protocols that deal with the long-term efficacy of a drug;
- Potential for, or a history of, illegal use of a drug;
- Inconsistencies in prescribing practices between Medicaid patients and those covered by private insurance;
- Availability of more cost-effective and comparable alternatives within a drug class;
- Documentation in the medical literature of inappropriate uses of certain drugs; and
- Results from program audits that review drug utilization on an on-going basis.

Beyond the specified classes of restricted drugs, HCPF requires PA for: brand name products whose price is in excess of the state maximum allowable cost or the federal upper payment limit; some over-the-counter drugs; some home intravenous (IV) solutions; certain nutritional therapies; and other brand named drugs deemed medically necessary by a physician. Further, in 2003, Colorado passed legislation requiring PA for most brand-name drugs that have a generic equivalent.

State Case Studies

At least two-thirds of the states administer a Medicaid evidence-based PDL. This brief reviews the PDL programs in Florida, Missouri, and Washington, and highlights similarities and differences among them. In all three states, the PDL is used as one tool in a broader prescription drug cost containment effort.

Florida

Prior to developing a PDL, Florida implemented a four brand name drug limit program that restricts the number of brand name drugs a physician may prescribe to an individual Medicaid patient. Currently, physicians must seek PA for a fifth brand name drug, unless the other four are on the state's PDL. The "four brand cap" program was established in 2000 and paved the way for future prescription drug cost containment strategies, notably the PDL program implemented in 2001.

Florida was one of the first states to establish a PDL through legislation. In addition to administering the PDL and its PA process, the Florida Medicaid program has the authority to negotiate supplemental rebates with pharmaceutical manufacturers that want their drugs included on the state's PDL. In the first three years of the program, companies that did not want to pursue the rebate option could negotiate a contract with Florida Medicaid to conduct "value added programs" in lieu of cash rebates. For example, Pfizer operated a statewide disease management program that included other public health efforts "in lieu of" a supplemental rebate agreement. The value added programs were discontinued in 2004 and now Florida only offers manufacturers the opportunity to negotiate supplemental rebates.

Committee Structure and Review Process

Florida's Pharmacy and Therapeutics Committee (P & T Committee) makes recommendations to the director of the Medicaid Office of Pharmacy Services located in the Agency for Health Care and Administration. The governor appoints Committee members and is required to include five physicians, five pharmacists and one consumer. One member represents the interests of pharmaceutical manufacturers and the consumer does not need to represent a certain demographic group. The Committee meets quarterly and members do not receive compensation, although the

state does cover Committee members' meeting-related expenses.

Florida contracts with Provider Synergies in Ohio to conduct clinical research and reviews of the drug classes under consideration for Florida's PDL, and to negotiate supplemental rebates with drug manufacturers. Provider Synergies only provides the results of the evidence-based reviews it conducts on certain drug classes under consideration for Florida's PDL. It does not make any type of recommendation to the Committee.

The P & T Committee makes its recommendations based on three criteria: proven, scientific efficacy; documentation of adverse events; and comparative costs relative to other drugs in the therapeutic class. During the first hour of each P & T Committee meeting, consumers and manufacturers may testify in support of or in opposition to a drug being considered for the PDL. At the end of each meeting, the Committee announces the therapeutic drug classes that will be considered at the next meeting, which provides three months notice to consumers and manufacturers. If manufacturers want to submit scientific studies for inclusion in a drug class' evidence-based clinical review, the manufacturer must submit the study directly to Providers Synergies in Ohio.

All information regarding the Committee's activities is posted on the Committee's website and is available to the public for review.

Approximately 80 percent of PA requests are approved with the first call made by a doctor or pharmacist.

Prior Authorization Procedures

If a physician wishes to prescribe a FDA – approved drug not found on Florida's PDL,

s/he must request a PA by calling the Therapeutics Consultation Program. Because of the supplemental rebates with drug manufacturers, the Florida PDL has become much broader than when it was first implemented. It currently includes 60 therapeutic drug classes. All antipsychotics, antidepressants, anticonvulsants, HIV-related antiretroviral agents and insulin products are statutorily exempted from the PA process. Contraceptives and immunosuppressive transplant drugs are also exempted by administrative rule.

When Florida implemented its PDL, the Office of Medicaid Pharmacy Services conducted extensive outreach to physicians, in an effort to educate them about and gain support for the PDL. In addition, the agency committed a significant number of staff to the PA call center. This decreased the amount of time a doctor or pharmacist needs to spend on the phone. Approximately 80 percent of PA requests are approved with the first call made by a doctor or pharmacist. The call center's front-line staff is pharmacy technicians. If the PA cannot be determined by the pharmacy technician, based on available criteria, the call is forwarded to a physician or pharmacist. If a physician seeks PA to use a drug for a clinical diagnosis other than that approved by the FDA, the PA is automatically denied.

Costs and Consideration of Special Populations

Over the past three years, Florida has implemented three programs to curtail the growth in drug expenditures in the Medicaid program: the four-brand limit; PA; and the PDL. In combination, these programs have saved nearly \$500 million. The Office of Medicaid Pharmacy Services began monitoring health care expenditures in other areas of the Medicaid budget including emergency room visits, physician visits, and hospitalizations, when the agency first implemented the four-brand limit policy. To date, the office has not documented any cost-shifting due to the implementation of its pharmacy initiatives. For individuals who require special consideration due to complex

diagnoses or extraordinary pharmaceutical needs, the Office of Medicaid Pharmacy Services provides case managers who help beneficiaries navigate the pharmaceutical programs to ensure access to needed care and services. Medicaid enrollees can appeal any decisions they feel are clinically inappropriate.

As one of the pioneers in PDL development, Florida has not escaped controversy. In 2001, the Pharmaceutical Research and Manufacturers of America sued Florida claiming the PDL preempted federal law by restricting access to drugs from manufacturers that already participate in the federal drug rebate program. Florida won the case and set a legal precedent for other states to develop PDL programs.

In 2002, another legal challenge, *Hernandez vs. Meadows*, challenged the level of transparency of the state's PA system. Florida Legal Services, Legal Aid of Palm Beach County, and the National Health Law Program filed a case against the Florida Agency for Health Care Administration for failure to provide written notice and fair hearings to Medicaid beneficiaries when PA requests were denied. The parties settled the case with the following provisions:

- Patients shall receive written notice of the denial at the point of contact, i.e., the pharmacy.
- The Agency will provide an ombudsman to help beneficiaries mediate resolution of a denial or complaint, and will assist with fair hearing requests.
- Patients will receive a notice of their rights to a fair hearing at the time they receive a denial.
- Pharmacists may provide a 72-hour temporary medication supply in the event a claim is denied until final resolution of the case.
- All Medicaid health maintenance organizations (HMOs) must comply with the provisions of the settlement.

Missouri

Unlike Florida and Washington, the 2002 legislation that created Missouri's evidence-based PDL was a small part of the annual appropriations bill. Therefore, much of the implementation detail was left to the Department of Social Services' Division of Medical Services to establish by administrative rule. The Medicaid Pharmacy Administration Program oversees the outpatient pharmacy benefit program.

Committee Structure and Review Process

Missouri's Drug Prior Authorization Committee includes three practicing physicians, three practicing pharmacists, one of whom must be a PharmD, and one nurse who practices in a long-term care setting. The committee members are appointed by the director of the Department of Social Services and serve a four-year term. Committee members do not receive compensation, but are reimbursed for expenses.

Unlike Florida and Washington, the Committee uses a range of resources for its evidence-based review process. First, Missouri contracts with the Oregon Center for Evidence-Based Policy at the Oregon Health Sciences University. Second, the administrative rule governing the PA process requires the Committee to use Missouri-specific data. As a result, the Committee uses regional and local information from the University of Missouri-Kansas City Drug Information Center. Lastly, the Committee calls upon two private sector companies, Heritage Information Systems and First Health Services Corporation, for further clinical and economic analysis respectively. First Health also negotiates Missouri's supplemental rebate agreements with pharmaceutical manufacturers. These resources provide information, but do not make recommendations. The Committee makes its recommendations to the director of the Medicaid Pharmacy Administration Program,

first based on medical efficacy and second on costs. Drug manufacturers and consumers receive three months notice about which drug classes will be reviewed at the next meeting, and they may testify at the beginning of each meeting.

Prior Authorization Process

Missouri also contracts with First Health Services Corporation to operate the PDL PA program. Missouri has worked to make the PA process as transparent as possible including implementing a new program in 2003 that streamlines the PA process through a system of electronic interfaces. Doctors, pharmacists and staff at the PA hotline all have access to a Medicaid patient's pharmaceutical history through an online, real-time, point of sale management information system.

When a PA request is made, the pharmacist enters the Medicaid patient's information into the on-line system. The request is evaluated according to the patient's other PA requests, pharmaceutical history, and clinical diagnoses. Seventy-five percent of the PA requests made online meet approval criteria and do not

Missouri has worked to make the PA process as transparent as possible including implementing a new program in 2003 that streamlines the PA process through a system of electronic interfaces.

require a phone call from the doctor or pharmacist. If a PA request is rejected online, a pharmacist or physician must make a call to the Pharmacy Administrative Program's PA hotline.

In 97 percent of calls, the PA is handled within the first two and a half minutes on the first call to the hotline. Pharmacy technicians staff the hotline. If they cannot determine whether a PA request meets approval, the call needs a "clinical override" by a pharmacist or physician, which can be done on the first phone call. Missouri has a "Fail First" policy that requires a Medicaid patient to try three of the therapeutically equivalent drugs on the PDL before an override is granted. The Division of Medical Services employs a full-time physician consultant to provide expertise within the Pharmacy Administration Program, and two nurse coordinators help manage complex calls on the hotline. In addition, the Pharmacy Administration Program staff includes several pharmacists. All anti-psychotic, cancer, and HIV drugs are exempt from the PA process.

Costs and Special Populations

Missouri estimated \$66 million in savings in FY04 - \$22 million from the negotiated manufacturer supplemental rebates, and the remaining \$42 million from implementing the PDL. The supplemental rebates have "leveled the playing field" in terms of pharmaceutical prices and allow Missouri to offer a broader choice of pharmaceutical products than when the PDL was first implemented.

Like Florida, the Pharmacy Administration Program monitors the claims and costs outside the pharmacy budget, in response to many advocates concerns that cost shifting would occur. To date, no cost shifting has been documented in emergency room use, physician visits, or hospitalizations. For those who require special consideration due to complex diagnoses or extraordinary pharmaceutical needs, the Pharmacy Administration Program provides case managers who help beneficiaries navigate the pharmaceutical programs to ensure access to needed care and services. Medicaid enrollees may appeal any decisions they feel are clinically inappropriate.

Washington

Prior to establishing a PDL, the Washington Medicaid program experimented with a variety of pharmaceutical cost containment strategies, including a long history of PA. Like Florida, Washington implemented a four brand name drug limit program in 2002 that restricts the number of brand name drugs a physician may prescribe to an individual Medicaid client.

In 2003, Washington passed Senate Bill 6088, a comprehensive piece of legislation that created the Prescription Drug Program (PDP). The program was developed to: control state prescription drug costs without reducing quality; provide affordable prescription drugs to those in need; and educate the public about the safe and cost-conscious use of prescription drugs.

This new program is a joint effort by the Washington Health Care Authority (HCA), the Department of Social & Health Services (DSHS), and the Department of Labor and Industries (L&I). The PDP includes the following five components: the Medicaid Prescription Drug Assistance Program; a Senior Prescription Drug Discount Card; a “Pharmacy Connections” program; the Senior Drug Education Program; and an Evidence-Based Medicaid Preferred Drug List (PDL)/ Therapeutic Interchange Program (TIP). The PDL is a coordinated effort by HCA’s Uniform Medical Plan, the DSHS Medical Assistance Administration’s fee-for-service program, and the L&I Workers Compensation Program. In January 2004, the agencies implemented one statewide PDL.

In January 2005, the three agencies submitted a comprehensive progress report on all five components of the Prescription Drug Program to the Washington Legislature. The full report is available online at www.rx.wa.gov, a comprehensive website for all Washington consumers, providers and other interested

parties. This brief only discusses Washington’s Evidence-Based PDL Program.

Committee Structure and Review Process

Washington’s Pharmaceutical and Therapeutics (P&T) Committee consists of four physicians, four pharmacists and two ancillary healthcare providers. The directors of all three agencies involved in the program appoint the Committee members for three-year terms. The Committee meets quarterly and each member receives an honorarium and all expenses paid. The P&T Committee also serves as the Drug Utilization Council, but the activities of the Council are separate from the evidence-based PDL review process. Because the Committee serves both purposes, the members meet more stringent criteria set out by the federal Centers for Medicare and Medicaid Services, compared to other states.

Washington only uses the evidence-based reviews conducted at the Oregon Center for Evidence-Based Policy for the Committee’s evaluation of various therapeutic drug classes. If manufacturers want to submit scientific studies for inclusion in a drug class’ evidence-based clinical review, the manufacturer must submit the study directly to the Oregon Center research staff. The Committee is advisory only and makes recommendations to the three agencies. The Committee reviews new drugs or new data for existing drugs at least annually after they have been reviewed by the Oregon Center.

Unlike Florida and Missouri, Washington’s P&T Committee only considers drug efficacy and safety, not cost-effectiveness, when deciding which drugs to recommend for inclusion on the PDL. Cost is not considered until after the Committee makes its recommendation to the three agencies, and they make their final decision based on efficacy and net costs for each drug. The PDL currently includes 12 therapeutic drug classes. By 2007, the Committee plans to have 27 drug classes on the PDL.

Prior Authorization Process

Washington administers PA programs in each of the three agencies that are similar to other states, but also offers a unique program to physicians and others who choose to support the PDL and want to formally become an “endorsing practitioner.” Washington’s Therapeutics Interchange Program (TIP) permits physicians and other authorized prescribers who endorse the PDL to allow pharmacists to therapeutically interchange a preferred drug for a non-preferred drug when the “endorsing” practitioner writes a prescription.

For example, if a patient of an “endorsing” physician presents a pharmacist with a prescription for a non-preferred drug, the pharmacist can replace the drug with a therapeutically equivalent drug on the PDL without threat of liability. In addition, if an “endorsing” physician writes the prescription for a non-preferred drug and indicates the pharmacist should “dispense as written (DAW),” the pharmacist can fill the prescription with the specified non-preferred drug without a PA. If a non-endorsing physician wants to prescribe a non-preferred drug, the physician must go through the specific agency’s PA procedures.

Washington’s Therapeutics Interchange Program was a major selling point to stakeholders and consumers who did not want to become burdened with a difficult PA process.

The Therapeutics Interchange Program was implemented in May, 2004 and provides an incentive for practitioners to endorse the PDL

and avoid PA when a non-preferred drug is medically appropriate.

When the agencies implemented TIP, they undertook extensive outreach efforts to publicize the program. As of January 2005, more than 5000 practitioners formally endorse Washington’s PDL. The program was a major selling point to stakeholders and consumers who did not want to become burdened with a difficult PA process.

Costs and Special Populations

Although Washington agencies do not have cost data available, the HCA believes the evidence-based review process with the Oregon Center has improved the quality, safety and efficacy of the drugs on Washington’s PDL. The credibility of the review process has served to engage the physician community to become “endorsing physicians.”

Washington has enacted quality assurance mechanisms to address the needs of Medicaid clients that have a mental illness. Currently, the Committee has a Mental Health Public Workgroup to assess the proper approach to evaluating drug classes for psychiatric diagnoses. In addition, Washington has implemented a “refill exemption” for persons on antipsychotic, antidepressant, chemotherapy, antiretroviral, or immunosuppressive drugs. Individuals using these classes of drugs receive automatic refills unless the patient is new to the system or is initiating a new therapeutic regime. In the new regime cases, the DAW exemption for endorsing physicians applies.

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