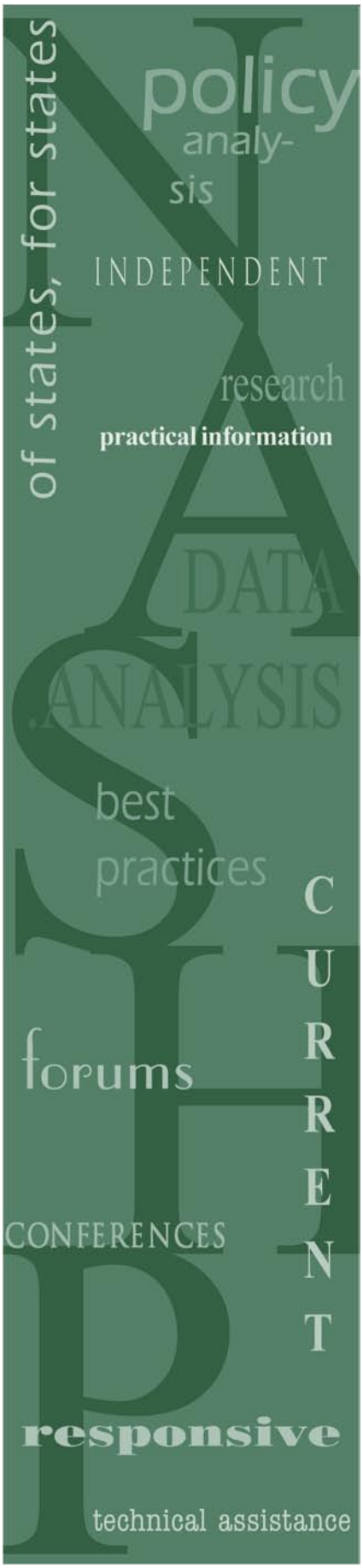

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State Design and Use of Prior Authorization Processes

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Prior Authorization

Prior authorization (PA) is a critical component of state efforts to manage access to different kinds of medical interventions and equipment, including prescription drugs.[2] Many states use PA in conjunction with a preferred drug list (PDL) to encourage prescribers to comply with the PDL while ensuring that beneficiaries can access non-preferred dugs under clinically appropriate circumstances. PA is a formal process that includes an official request, review, and a decision (approval or denial) for those drug classes subject to a PDL. A well-designed PA process is one that promotes both compliance and access to appropriate care. At the same time, it must minimize the administrative burden on providers and the financial costs of administration for the state.

The following illustrates the scope of PDL-related prior authorization activity. Michigan uses a PDL to manage about 70 percent of drugs in its Medicaid outpatient pharmacy benefit. In 2003, the state received about 128,200 prior authorization requests for non-preferred drugs. Of these, seventy percent were approved, 27 percent were changed by prescribers to a preferred drug and three percent were denied. Michigan also reported that they denied about 6,000 prior authorization requests for drugs in 2003 (this is all requests—not just those related to the PDL). Only 111 of these 6,000 denials were appealed—and of those 111 appeals, none has been reversed (although 15 were still pending as of August 2004).[3]

Most PA requests are, in fact, approved. For example, in California the PA approval rate is as high as 85 percent. As a result, some beneficiaries and other stakeholders argue that the high approval rate for PA requests obviates the need for PA. According to this logic, access to non-PDL drugs should be unfettered since approval requests are so commonly granted. However, requiring PA for nonpreferred drugs appears to produce a substantial sentinel effect; all site visit states report that the PA process itself is sufficient to align physician prescribing patterns with the PDL, and report PDL compliance rates in the range of 85-95 percent. Furthermore, Florida began their pharmacy management efforts with voluntary PDL,[4] but found that physicians did not comply with it.

No site visit state included every drug class in its PDL, leaving many drugs available without PA. For example, 17 percent of the drugs dispensed to Kansas Medicaid beneficiaries (representing about 19.7 percent of total pharmacy costs) were subject to the PDL. Of the 17 percent, 14 percent were preferred products and three percent were nonpreferred products.

PA requests are granted when the state determines the requested drug is medically necessary; they are denied when insufficient clinical justification is provided or the drug is determined to be not medically necessary. If a PA request is denied, beneficiaries or their physicians may appeal or request a preferred drug. The site visit states reported that few denials were reversed on appeal.

This brief summarizes site visit state experience in implementing and operating PA processes that support a PDL. The PA process can be divided into three major components: Submission, Review, and Appeal. This brief examines state policy choices and experience in each of these areas. It will also examine two common means these states established for bypassing the PA process. Emergency supplies and the Dispense as Written (DAW) provision.

Table 1: Prior authorization processes by state

	California	Florida	Kansas	Michigan	Missouri	Washington
Submitting Professional[5]	Pharmacists	Physicians	Pharmacists, Physicians	Physicians	Physicians	Pharmacists
Submission Conduit	Email, 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 DAW	No	Yes	Yes	No	No	Yes

Submission

Site visit states reported that their submission processes required coordination between the prescribing physician and the dispensing pharmacist. The requests themselves could then be submitted by several methods.

PA Requests Must Be Submitted by a Prescribing Physician or Dispensing Pharmacist

All site visit states require physician involvement in submitting PA requests. Three states—Florida, Michigan, and Missouri—permit only physicians to submit the request, while California, Kansas and Washington[6] permit pharmacists to submit requests after coordinating with the prescribing physicians.

Florida, Michigan, and Missouri, states that allow only physicians to submit PA requests, reported that physicians have more comprehensive knowledge about a particular beneficiary and greater medical knowledge. For example, some PA requests are granted only when a beneficiary has tried and failed another drug, a fact the pharmacist would be less likely than the physician to know.

California, Kansas, and Washington, which permit pharmacists to submit PA requests, reported that pharmacists have the financial incentive to complete the PA process and fill prescriptions quickly. In many states, pharmacists sought involvement in the PA process in order to protect their revenue stream. In California, pharmacists were successful in obtaining the authority to submit requests. These states also report that, unlike physicians, pharmacists spend most of their time filling prescriptions and may be more aware of PDL requirements.

While physicians and pharmacists in site visit states generally report "signing off" on PA requests, in most cases office staff submit the requests. Even where this occurs, authority and responsibility still rests with the licensed professional.

When deciding whether a physician or pharmacist (or both) should have the authority to submit a request, it may be helpful to consider policies that commercial health plans have in place. For example, in Florida, Medicaid allows only physicians to submit PA requests to Medicaid, while many commercial health plans allow both pharmacists and physicians to submit them. Pharmacists and physicians in Florida reported that they found this difference cumbersome because they had to comply with different practices depending on the beneficiary's coverage.

Site visit states reported that pharmacists and physicians play different roles in dispensing prescription drugs. Most site visit states require a high level of coordination between the two because of the important role each plays in the delivery of care. For example:

- In California, pharmacists have the authority to submit PA requests. Pharmacists contact the physicians, attach notes on medical necessity they obtain from the physician, and make the requests.
- Pharmacists in Florida, Michigan and Missouri report initiating PA requests, even if they do not have formal authority. They do so by calling physicians to suggest a preferred drug, or ask that he request PA for a nonpreferred drug.
- Kansas allows both pharmacists and physicians to submit PA requests, but all requests must bear the prescribing physician's signature.
- In Washington, physicians can participate in a program, known as the Therapeutic Interchange Program (TIP). Pharmacists may substitute a preferred drug for a prescribed nonpreferred drug without specific permission from physicians who choose to participate in this program.

Providers need more than one way to submit a request

States can use a number of methods for providers to submit a PA request, including phone, fax, internet, and email. All site visit states reported using at least two methods of submitting a PA request. Site visit states tend to use a primary submission method that is supported by secondary methods. States generally reported that multiple submission methods allow physicians and pharmacists—with different technological expertise—to choose the most suitable method.

Stakeholders in site visit states were generally comfortable with available request conduits, with the exception of phone-based request lines. Stakeholders found them inconvenient, as they frequently require a series of back and forth calls before both the provider and reviewer are on the line.
At the time of the site visit, Florida was experimenting with a PA request process based on a wireless personal digital assistant (PDA). This project was largely financed by a specific technology vendor to test the product. The limited roll-out of the PDAs among high-volume prescribers was successful enough that

Florida increased the number of physicians using them. Florida reported that physicians were very pleased with the PDAs, and hoped to make them available state-wide. However, they expressed some concern that older physicians might be less comfortable with this kind of technology.

Review

After a pharmacist or a physician submits a PA request, it is reviewed by the state or its agent. Only requests determined to be medically necessary are approved. While states differ in how criteria are established and who conducts the review, there is a much greater agreement on what constitutes medical necessity.

PA decisions are based on medical necessity

Site visit states approve PA requests when medically necessary. While the specific definition of "medical necessity" varies from state to state, its use is very similar across states. Furthermore, medical necessity is germane to all manner of health care interventions, not just pharmaceutical benefit management. For example, Kansas' definition of medical necessity states that "medical necessity refers to a health intervention that meets the following guidelines:

1. it is recommended by the treating physician or other appropriate licensed medical professional.
2. it has the purpose of treating a medical condition.
3. it provides the most appropriate supply or level of services, considering potential harms and benefits to the patient.
4. it is known to be effective in improving health outcomes.
5. it is cost-effective for the condition being treated when compared to alternative interventions."[7]

When reviewing PA requests, states decide whether each individual request meets the state's definition of "medical necessity." In most cases, states establish clinical criteria to determine whether a specific request meets the medical necessity definition. For example, if there is evidence demonstrating that people with a history of heart disease are more likely to suffer certain side-effects from a preferred drug than from a nonpreferred drug, then the state might establish criteria that approve PA requests for the nonpreferred drug for beneficiaries with a history of heart disease. For this situation, this criterion operationalizes the "most appropriate supply or level of services, considering potential, harms and benefits to the patient." In other cases clear evidence that can be used to establish review criteria may not exist. In these cases, the decision must be based on clinical judgment, so, as will be discussed in more detail later in this brief, all site visit states include staff with clinical qualifications in the review process.

Site visit states report that the design of their PA processes is intended to balance the need for continuity of care for those with chronic conditions against the need to enforce the PDL. These states have all established review criteria and procedures that enable beneficiaries who have prescriptions for drugs used to treat chronic conditions, such as statins for high cholesterol, to receive those drugs on an ongoing basis—even when they are not preferred. For example, in Missouri, once a PA for a specific drug is approved for an individual, the system will automatically approve any subsequent prescriptions for that drug without requiring a new PA. In California, meanwhile, PA approvals are good for a year, at which point PA is again required.

Clinical Professionals Review PA Requests

Site visit states generally have defined the professional background of those permitted to adjudicate requests. States are primarily concerned that the reviewers have adequate clinical expertise to determine medical necessity, but they are also concerned about cost. Therefore, four of the site visit states use a professional who is less costly than a pharmacist to conduct the initial review of a request.

- Michigan and Washington,[8] through a third-party vendor, use pharmacy technicians for the initial review;
- Kansas and Missouri use registered nurses to review initial PA requests.

The two states that employ pharmacists for the initial review (California and Florida) cited their extensive pharmaceutical training. Others report that nurses and pharmacy technicians are both adequately trained to make an initial determination and are less expensive than pharmacists. Those states that do not use a pharmacist for the initial review include either a pharmacist or a physician in the appeal process (described in more detail below.)

Michigan's review process seeks to balance cost and expertise by having lower-level clinical staff complete the initial review, while using the most highly trained staff to review final decisions on denials. Specifically, PA requests are initially reviewed by a pharmacy technician at the PBM. The technician has the authority to approve, but not deny, the request. If the technician decides the request should be denied, it is then passed to a clinical pharmacist for further review. The pharmacist also has the authority to approve, but not deny, the request. If the pharmacist agrees with the technician, then the PBM contacts the staff physician for the Michigan Department of Community Health (MDCH). This ensures that a physician reviews each denial in the system before it reaches the appeal level.

Appeals Process

If a PA request is denied, beneficiaries in all states have the right to appeal the decision. All denials of service (including pharmacy denials) are subject to the fair hearing, a process that is required by Medicaid but is not specific to denials for pharmaceuticals. States inform beneficiaries of the right to a fair hearing, which entitles them to both a review before an impartial decision-maker and the continuation of benefits until the hearing.[9]

The only site visit state to establish an appeals process that is specific to prescription drugs is California. When a denial is appealed in California, it is first reviewed by another pharmacist. If the pharmacist finds medical necessity, the appeal is granted and the prescription is filled. If the pharmacist instead continues to finds no medical necessity, the case is reviewed by a physician on the PBM staff who makes the final decision on the appeal.

Exceptions to the PA process

Site visit states use two common means for bypassing the formal PA process: Emergency provisions and dispense as written (DAW) instructions. With the former, states acknowledge that PA system interruptions may occur and should not stand in the way of dispensing necessary drugs immediately. The latter, meanwhile, is a privilege granted to physicians and so is more closely linked with a state's overall PA strategy. Both permit nonpreferred drugs to be administered without PA under specific circumstances.

Federal Law Requires Dispensing of an Emergency Supply

Federal law requires that any state drug authorization process must allow beneficiaries to receive at least a 72-hour supply of covered outpatient drugs in emergency situations.[10] Site visit states have implemented these provisions in different ways. For example,

- Michigan allows pharmacists to phone the PBM call center when the prescriber (who in Michigan is the only individual who can request PA) is not available to request PA.
- Kansas and Missouri allows pharmacists to dispense a 72-hour supply in emergency situations that occur outside of normal office hours.
- Florida permits pharmacists to dispense enough of any prescribed medication for 72 hours.
- California permits pharmacists to dispense an emergency supply of medication lasting 30 days, but only for a new prescription.

Site visit states report that these provisions are rarely used. For example, Missouri reported that pharmacists provided an emergency prescription only three times between January 2002 and 2004.

Advocates and pharmacists in site visit states reported that the emergency provisions program does not work as intended. Advocates report that, occasionally, pharmacists do not dispense needed medications, jeopardizing the health of beneficiaries. Pharmacists report that they are reluctant to dispense emergency medications for two reasons. They are concerned that they will not be reimbursed, or that they will be held liable if the new medication harms the beneficiary.

Pharmacists in Florida also reported concerns about the potential for fraud and abuse. They note that Medicaid beneficiaries, having received the emergency provision, may not return to pick-up remaining medications from an approved PA request. The pharmacist could then easily re-stock the medication and submit for payment on the filled prescription.

States Report Mixed Experience with "Dispense as Written"

Dispense as written, or DAW, is a notation a physician may write on a prescription which instructs the pharmacist to dispense only the brand name drug written in the dosage indicated. By writing DAW, physicians bypass the PA process and ensure that the listed drug is dispensed without state review. As a result, DAW privileges offer physicians a great deal of control over which drugs are used and when. Of the three site visit states with DAW experience, only Washington—while reporting that DAW is too young for a full evaluation—reports that DAW was not problematic. Of the other states with a DAW privilege—Florida and Kansas—Kansas has already eliminated the privilege because they discovered that physicians used the DAW to override the PDL 70 percent of the time.

Washington experience with the DAW privilege is instructive. Available for any drug in any class covered by the PDL, physicians negotiated for DAW in exchange for not opposing the creation of a PDL during the legislative debate. However, DAW is only available to those physicians participating in the Therapeutic Interchange Program (TIP), a global authorization that permits pharmacists to substitute a preferred drug when a physician prescribes a nonpreferred drug but does not specify DAW. Although the state was—and remains—concerned that the DAW privilege will be used to circumvent the PA process and the TIP, early evidence suggests that DAW is only being used modestly. Linking the DAW privilege to participation in TIP may be a key to success. However, therapeutic exchange by a pharmacist may not be an option in all states because of variation in state licensing requirements for pharmacists.

Conclusion

PA processes are intended to serve two functions: to encourage prescribers to comply with the PDL, and ensure that beneficiaries can access nonpreferred drugs when medically necessary. A well-designed PA process is one that promotes both compliance and access to appropriate care. At the same time, it must minimize the administrative burden on providers and the financial costs of administration for the state. To these ends, the site visit states report that their systems feature:

Multiple means of submitting requests (phone, fax, internet);

- PA request submissions that require coordination between the prescribing physician and the dispensing pharmacist;
- Review criteria that define the conditions that demonstrate medical necessity;
- Review of PA requests by professionals with clinical expertise;
- An adjudication process that requires physician or pharmacist review before denying the request; and
- Decisions that are based on scientific evidence and clinical judgment.

Several of the states have also focused on ways to make the process less burdensome for providers. For example, Florida is piloting a program that uses PDAs to decrease the burden by allowing providers to submit requests wirelessly from most places in the state. Washington has established a program that reduces the administrative burden by creating a program that enables physicians to give pharmacists broad authority to substitute preferred for nonpreferred drugs—unless the physician specifically indicates that the drug should be dispensed as written.

Notes

[1] Vernon 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*. Henry J. Kaiser Family Foundation. October 2004. http://www.kff.org/medicaid/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=48004 (downloaded May 8, 2005).

[2] PA can be used for drugs that are subject to abuse (e.g., Oxycontin), drugs that are unusually high cost, drugs that are subject to overuse (e.g., triptans for migraines), drugs that may be used for different indications (including off-label uses) and even to manage access to non-drug services. However, this brief is focused on the role of PA in conjunction with PDLs.

[3] Michigan Department of Community Health, *Pharmaceutical Best Practices Initiative Report*, August 2004

[4] In 2002, Florida established a non-binding PDL that did not require physicians to seek PA for nonpreferred drugs. Through this voluntary effort, the state failed to get physicians to prescribe preferred medications.

[5] Those states that allow pharmacists to submit the request require them to coordinate with the prescribing physician.

[6] Washington's PA process is only incumbent on physicians not participating in its Therapeutic Interchange Program, which permits pharmacists to automatically substitute a preferred drug where a physician had prescribed a nonpreferred drug and did not write dispense as written.

[7] The Kansas Economic and Employment Support Manual (KEESM) 07-01-05, Appendix P-1. (Accessed 7/21/2005).

[8] Washington's PA process as described here concerns only nonpreferred 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 protential for abuse, Prior Approval requests are reviewed by the Drug Utilization Review (DUR) Board.

[9] *The Medicaid Resource Book,* Kaiser Commission on Medicaid and the Uninsured, July 2002.

[10] §1927(d)(5)(B) of the Social Security Act

About the Series

Medicaid agencies report that pharmacy costs are a major driver of overall spending growth in Medicaid programs.[1] Many states believe clinical evidence can help curtail pharmacy costs while ensuring beneficiary access to needed prescription drugs, since medications—even expensive ones—can be cost-effective and improve quality of life.

In 2004, the Commonwealth Fund funded the National Academy for State Health Policy and Georgetown University to conduct a series of site visits to examine state efforts to manage the pharmacy benefit in Medicaid programs. With input from an advisory group of state officials and other experts, a site visit team selected six states (California, Florida, Kansas, Michigan, Missouri, and Washington) where they met with multiple stakeholders including agency staff, pharmacy vendors, pharmacists, physicians, DUR and P&T committee members, and consumers/advocates.

This brief, the second of four, summarizes state experience with prior authorization, the process used to manage beneficiary access to specified services. The first brief describes the structure and function of Pharmacy and Therapeutics (P&T) committees. The two remaining briefs will examine state efforts concerning the behavioral health pharmacy benefit, and the role of the Drug Effectiveness Review Project in providing comprehensive reviews of the clinical evidence to states. Our observations indicate that states face critical issues in designing and implementing their efforts.

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