

PRIOR AUTHORIZATION FOR MEDICAID
PRESCRIPTION DRUGS IN FIVE STATES:
LESSONS FOR POLICY MAKERS

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The Kaiser Commission on Medicaid and the Uninsured serves as a policy institute and forum for analyzing health care coverage and access for the low-income population and assessing options for reform. The Commission, begun in 1991, strives to bring increased public awareness and expanded analytic effort to the policy debate over health coverage and access, with a special focus on Medicaid and the uninsured. The Commission is a major initiative of The Henry J. Kaiser Family Foundation and is based at the Foundation's Washington, D.C. office.

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Report Highlights

Medicaid prescription drug costs have grown rapidly in recent years, motivating states to use the various cost and utilization controls available to them. One strategy used by at least 30 states is prior authorization—requiring prescribers to obtain approval from the state Medicaid agency (or its contractor) before a particular drug can be dispensed. States directly oversee or conduct prior authorization for their fee-for-service drug expenditures, and many Medicaid managed care plans also use some form of prior authorization for their Medicaid enrollees. While prior authorization can produce cost savings for states, little is known about its effects on beneficiaries, pharmacists, and physicians.

This report used an exploratory, case study approach to elicit the views of state officials and other key stakeholders about prior authorization in five states – California, Georgia, Oklahoma, Oregon, and Washington – all with well-established procedures. These states’ experiences and perspectives may be useful for states considering implementation or expansion of prior authorization in their Medicaid programs.

In this study, key stakeholders indicate that prior authorization processes cause some beneficiaries and providers access and bureaucratic problems. Beneficiary groups’ main concerns about prior authorization include possible changes to their established drug regimens and the potential for multiple trips to pharmacies and practitioners to get the medications they need. Providers report communication problems with pharmaceutical benefit management firms under contract to the state, and they also cite the complexity of the multiple formularies or preferred drug lists they must use and the prior authorization processes they must navigate.

There appears to be limited monitoring of the effects of prior authorization on beneficiaries and providers at the state level. Thus, although some basic information is available about issues such as waiting times for decisions, in most states virtually nothing is known about the effect of prior authorization on individual beneficiaries’ access to appropriate, medically necessary medications. An exception in this study is Oklahoma, which appears to be making an effort to determine how beneficiaries are affected by prior authorization. Most providers’ experiences are also unknown, other than information such as the average amount of time practitioners must spend on the phone with pharmaceutical benefit managers (PBMs).

Regulation and monitoring of managed care plans’ formularies and prior authorization processes appears to be minimal in some of the case study states. This is a particular concern in states where a large proportion of aged and disabled beneficiaries – the most frequent users of medications – are enrolled in managed care plans.

States with the least controversial prior authorization processes also appeared to be those with the procedures regarded as most credible by stakeholders. In California and Oklahoma, pharmacists have a major role in authorizing requests and in providing information to the Medicaid program to aid in formulary decisions. Oregon has initiated a consensus decision-making process that most stakeholders strongly support. In Oklahoma and Oregon, most agree that decision-making is based on clinical evidence of the efficacy of evaluated products. Some stakeholders in Georgia believe that extending prior authorization beyond the Medicaid program to state employees and others lends credibility to that state's process.

In short, creating credible prior authorization processes that are streamlined and minimize the burden on beneficiaries and providers is desirable from the perspective of most of the respondents. In addition, the need for more data regarding the effects of prior authorization on those who regularly interface with the systems, namely beneficiaries and providers, is undisputed and could inform future policy decisions. However, it is important to note that prior authorization is only one of a range of prescription drug management tools that states have at their disposal, and most states use a variety of approaches. Further research is needed to better understand how these mechanisms work individually and together to impact drug utilization and access.

Introduction

Medicaid expenditures for fee-for-service, outpatient prescription drugs have grown rapidly in the last several years, rising by an average 19.6 percent per year between fiscal years 1998 and 2001.¹ These expenditures increased faster than other major categories of Medicaid spending such as inpatient hospital and nursing facility costs, which rose at an average annual rate of 6.3 percent and 7.9 percent respectively during the same period.²

This prescription drug expenditure growth has been accompanied, in more recent years, by declining growth in state revenues or revenue decreases due to the economic recession. State policymakers have been forced to consider how to contain their budgets, including Medicaid, which accounted for an average 15% of state general fund expenditures in FY 1999. Prescription drug spending, because of its rapid escalation and the fact that it represents about 10 percent of total Medicaid expenditures,³ is a major cost containment target.

States have a number of options for controlling Medicaid prescription drug costs. One strategy used by many states is prior authorization—requiring prescribers to obtain approval from the state Medicaid agency (or its contractor) before a particular drug can be dispensed. In most states, prior authorization is a key element in other increasingly popular utilization management tools, including formularies or preferred drug lists. A preferred drug list comprises medications that states encourage practitioners to prescribe for Medicaid beneficiaries. When practitioners prescribe non-preferred drugs, states often require prior authorization before the drugs may be dispensed, and/or they may require provider education about alternatives to the prescribed drugs. Some states, including Michigan and Florida, go further by encouraging pharmaceutical manufacturers to provide supplemental state rebates in order to have their products added to the list.

Other principal cost containment methods states can use include:

1. Setting limits on prescription drug coverage, such as restricting the number of prescriptions that can be filled in a month or the quantity of medications dispensed;
2. Reducing payments, such as dispensing fees and reimbursement for ingredient costs, to pharmacists;
3. Obtaining pharmaceutical manufacturer rebates, where manufacturers return a portion of Medicaid spending for their drugs to the federal and state governments; and
4. Including drug costs in capitated payments to managed care plans.⁴

Most states use some mixture of these methods and more than 30 incorporate some type of prior authorization into their cost containment strategies.⁵ When they administer drug benefits, many Medicaid managed care plans also use some form of prior authorization. Since

little is known about prior authorization's effects on beneficiaries, pharmacists, and prescribers, this research project used an exploratory, case study approach to elicit the opinions of state officials and key stakeholders about prior authorization in five states with well-established procedures. Experiences in these states could inform the decisions of other states considering implementation or expansion of prior authorization in Medicaid.

Background

The Omnibus Budget Reconciliation Act (OBRA) of 1990, as amended in 1993, governs many of the options states have for containing expenditures on prescription drugs. The laws established the federal Medicaid prescription drug rebate program and dictate provisions of prior authorization programs and state formularies.⁶ The rebate program denies federal Medicaid matching payments for the medications of any manufacturer that does not agree to participate. In return for rebates, state Medicaid programs that include pharmaceutical benefits must cover the participating manufacturers' outpatient drugs, with the exception of medications in 10 categories such as weight management and smoking cessation products, barbiturates, and benzodiazepines.

A state may create a formulary or preferred list to restrict coverage for certain drug products if the formulary meets several requirements. In general, the formulary must include the outpatient prescribed drugs made by manufacturers participating in the rebate program. However, formularies can exclude drugs used to treat diseases for specific populations if these medications do not offer a "significant, clinically meaningful therapeutic advantage" over other drugs in the formulary. Any drug excluded from the formulary must still be available to beneficiaries pursuant to the state's prior authorization requirements. A committee of physicians, pharmacists, and other appropriate individuals appointed the governor must develop the formulary.

States may require prior authorization for any drug covered by Medicaid. Prior authorization processes for covered outpatient drugs must meet two federal requirements: 1) they must respond to requests for authorization within 24 hours; and, 2) a 72-hour supply of medications must be available in an emergency situation. Medicaid managed care plans' prior authorization procedures must meet the same criteria.

Little evidence of the cost effectiveness of prior authorization programs has been published, and even less exists about how these programs work from the perspectives of state officials and key stakeholders. Mackinnon and Kumar, in a 2001 review of six quantitative studies of prior authorization, concluded that such procedures appear to reduce drug-related

costs and may reduce other health care costs.⁷ They cautioned, however, that these studies had “severe methodological flaws” and did not measure “humanistic factors” such as consumer satisfaction or health-related quality of life, and most did not address clinical outcomes.

Research Methods

This paper addresses the dearth of information about state official and stakeholder views by examining their opinions about prior authorization in five states with long-standing procedures. The study was designed to address the following public policy research questions:

1. How have state prior authorization processes evolved over time and why?
2. What types of prior authorization procedures do states use?
3. What are state officials’ and stakeholders’ views of these procedures and their effects on providers and beneficiaries?
4. What is the role of managed care plans in prior authorization?
5. What recommendations do state officials and stakeholders have for other states considering prior authorization as a cost containment method?

Officials and stakeholders in five states were interviewed by telephone during the spring of 2002. The states were chosen to represent a variety of approaches to prior authorization and each had a procedure in place for at least two years. The five states that participated in the study were California, Georgia, Oklahoma, Oregon, and Washington.

In each of these states, the research began with interviews with key state officials to determine how the current prior authorization processes work, how they evolved over time, and the role of managed care plans in prior authorization. Interviews were conducted with at least one state official in each state for a total of 10 interviews. Next, at least four attempts (via telephone and e-mail) were made to secure interviews with representatives of key stakeholder groups in each state. Thirty-two interviews were conducted with respondents representing beneficiaries (7), pharmacists (5), retail pharmacies (4), physicians (9), and pharmaceutical manufacturers (7). Stakeholders were asked to describe and evaluate their state’s prior authorization process from the perspective of their constituents.

Telephone interviews were conducted using a standard set of open-ended questions to guide the discussions and lasted an average of one hour. The discussion guide that appears in Appendix 1 addresses the five research questions listed above. Interviewees were assured that they would not be quoted by name and that their individual responses would remain confidential. Most of the states provided little quantitative data about their prior authorization

processes. State officials reviewed the descriptions of their states' prior authorization procedures that are included in this report.

Overview of Current Prior Authorization Processes in the Five Case Study States

The broad nature of the federal rules governing prior authorization has led to a great deal of variation in state procedures. For example, the medications subject to prior authorization in the case study states range from about 20 categories to 3000 individual drugs. State staff or pharmaceutical benefit management companies may manage the process. States also vary in the degree to which managed care plans are involved in prior authorization. Some states keep some or all of their prescription drug benefits in the fee-for-service system, while other states include most prescription drugs in the capitated payments to Medicaid managed care plans. When such plans have responsibility for medications, they can create their own formularies and prior authorization programs. The five study states' basic approaches to prior authorization are described briefly below to provide the context for the officials and stakeholders' opinions of the procedures. Detailed descriptions of each state's system appear in Appendix 2 of this report.

California has used prior authorization in its Medicaid program for many years. In this state, pharmacists are largely responsible for obtaining prior authorization when a beneficiary attempts to fill more than 6 prescriptions in a month. Certain drugs are exempt from this requirement, including HIV/AIDS drugs, cancer drugs, contraceptives, and drugs for patients in long-term care and subacute facilities. California also requires prior authorization for most drugs that do not appear on its preferred drug list. Manufacturers' products generally appear on the list when they agree to give the state rebates above those required by the federal government (i.e., supplemental state rebates). State-employed pharmacists manage the prior authorization process. Medicaid managed care plans administer most drug benefits for their enrollees, with the exception of certain medications used to treat mental health conditions or HIV/AIDS.

Georgia requires prior authorization for 25 categories of drugs, including, most recently, proton pump inhibitors. Physicians and pharmacists have a role in the state's prior authorization process, with pharmacists generally handling the paperwork; physicians receive information about alternatives to the drugs they have prescribed and must document medical necessity when prior authorization is required. A unique feature of Georgia's prior authorization process is that it applies to state and state university employees and Childrens Health Insurance Program (CHIP) participants, as well as Medicaid beneficiaries. The state contracts with the PBM

Express Scripts to conduct prior authorization. Georgia does not have any capitated Medicaid managed care plans, so they do not play a role in prior authorization in this state.

Oklahoma requires prior authorization for some prescriptions exceeding certain quantity limits, for drugs in four therapeutic categories, and for “off label” use of medications; that is when drugs are prescribed for conditions or in ways that the Food and Drug Administration has not approved. The pharmacist consults with the physician to fill out the prior authorization form and sends it to the University of Oklahoma’s College of Pharmacy, which handles the process under contract to the state. Medicaid managed care plans administer most prescription drug benefits for their enrollees, particularly in urban areas of the state.

Among the mechanisms Oregon uses to control fee-for-service prescription drug costs are a prior authorization process and the Practitioner-Managed Prescription Drug Plan (PMPDP). The state contracts with First Health to administer its prior authorization process, which applies to drugs in 20 drug categories, including non-sedating antihistamines, acne medications and oral/nutritional supplements. The state also has quantity limits for certain medications that it says are designed to assure appropriate use. To create the PMPDP, Medicaid has set benchmark drugs within four therapeutic categories. These drugs and any other therapeutically equivalent drugs with prices near the benchmark are included in Medicaid’s preferred drug list. Rather than imposing additional prior authorization requirements, the PMPDP is designed to educate providers and encourage them to adopt cost-effective prescribing practices. Still, most Medicaid beneficiaries in Oregon enroll in managed care plans, including most of those who are aged and disabled. These plans can set up their own prior authorization processes and can use formularies to control drug costs.

Washington has one of the more complex approaches among the five study states. It combines prior authorization for several thousand drugs, an expedited review process for some, an additional process – the Therapeutic Consultation Service (TCS) – for beneficiaries who request more than four brand name prescriptions in a month, or a non-preferred drug in one of several therapeutic classes. TCS reviews the appropriateness of prescriptions and educates physicians about alternative, less costly prescriptions. State employees staff the first two processes, while the PBM ACS manages the new process. Managed care plans receive capitated payments that include most drug costs but plans largely serve families with children, Medicaid beneficiaries with the lowest average drug use.

Evolution of State Programs

Each of the case study states' prior authorization systems has evolved over time in response to the need to contain fee-for-service prescription drug costs and pressures from key stakeholders, which sometimes conflict. Pharmaceutical manufacturers, at times allied with "disease groups" such as those representing persons with mental health conditions, have opposed virtually all attempts to impose prior authorization processes. These alliances' efforts have resulted in exemptions from prior authorization for some drugs, such as those used to treat mental health conditions and HIV/AIDS, in most of the case study states.

Other than disease groups, consumer advocates have been largely absent from most discussions about prior authorization, with the exception of debates over recent legislation in Oregon and Washington. In these states, broad coalitions of stakeholders, galvanized by Medicaid pharmaceutical cost increases, united behind bills requiring the states to rely on clinical evidence to determine a preferred drug list. The bill in Washington, which would have allowed drugs to appear on the preferred drug list if their manufacturers agreed to price their products no higher than the reference drugs, was defeated. The legislation in Oregon passed with major modifications.

Pharmacists, pharmacies, and physicians have been split over prior authorization and have taken varying positions in the five study states. These providers have successfully advocated change when the prior authorization processes have been considered too onerous but have supported the processes in lieu of provider reimbursement cuts on other occasions.

In response to stakeholder pressure and cost increases, each state has a history of changes over time with some states' processes becoming simpler and others more complex. Georgia is an example of a state whose processes have become less complicated over time. Beginning in 1993, Georgia required beneficiaries wishing to fill more than five prescriptions in a month to obtain prior authorization. Some stakeholders said that this threshold created access problems for beneficiaries because pharmacists did not always fill prescriptions and then neglected to contact practitioners to explain why or to discuss the need for prior authorization. In 1999, certain consumer advocates, perhaps with financial backing from drug manufacturers, made an unsuccessful attempt to prohibit Georgia from using any type of prior authorization. Subsequently, the state relaxed the prior authorization requirement by allowing pharmacists to override it easily, saying that there was a high approval rate for prior authorization requests and the administrative costs of the process did not justify retaining it in its original form. In the late 1990s, the state exempted mental health drugs from prior authorization because of pressure from consumer advocates and a consultant's report that warned of future cost increases in such

services as hospitalization if beneficiaries did not have ready access to these medications. However, the state recently imposed a controversial prior authorization requirement on proton pump inhibitors.

Washington's processes have become more complex over time. The state first established prior authorization in 1993 to contain costs and ensure that prescription drugs were used appropriately. Since then, the state has changed its process several times in response to problems and complaints. Between 1993 and 1994, the state required prior authorization for manufacturers' products when the manufacturers did not agree to a supplemental state rebate. This requirement was removed when savings were less than what Washington had projected. In the mid-1990s, the state instituted an expedited review process for about 140 drugs in response to provider complaints about the burdensome nature of the prior authorization process and concerns about delays in beneficiaries' access to certain drugs. In the late 1990s, the state imposed prior authorization on all drugs carrying a black box warning for physicians, meaning that misuse of these drugs could seriously harm or kill patients; about 400 drugs require prior authorization for this reason. Currently about 3000 drugs require prior authorization, about 2000 of which are rarely prescribed according to state officials. In 2002, the executive branch set up the Therapeutic Consultation Service (TCS), which educates practitioners about alternatives when beneficiaries use more than four brand name drugs or when they receive a prescription for a medication that does not appear on the state's preferred drug list.

Decision-Making about Medications Requiring Prior Authorization or Practitioner Education

To determine which medications are subject to prior authorization, the case study states rely to varying degrees on their drug utilization review committees.⁸ While in most states these committees serve a minor advisory role, in Oklahoma the committee takes an active part in decision-making. Oregon has charted its own course by charging its Health Resources Commission with recommending therapeutically effective drugs under the PMPDP.

Oklahoma's Drug Utilization Review Board makes recommendations to Medicaid about prior authorization requirements. The recommendations are based on an analysis of one to two years of drug claims data, the cost to Medicaid of a day's treatment, the availability of drugs from multiple sources, lowest net cost of drug therapies, and clinical reviews of data regarding differences in outcomes. Most observers said that the Board has well qualified members and competent staff and usually engages in careful decision-making. Only one stakeholder group disagreed, saying that the board does not take sufficient account of clinical factors when making decisions.

Oregon's Health Resources Commission, which makes policy recommendations to the state on a wide range of health care issues, is making recommendations for a preferred drug list based on clinical evidence compiled by Oregon Health Sciences University (OHSU). In 2001, the Commission, which includes pharmacists, doctors, and consumers created subcommittees to deal with four therapeutic classes of drugs: non-steroidal anti-inflammatory drugs (NSAIDs), cholesterol drugs, anti-ulcer medications, and analgesics. The Commission focused on these classes first because there are many clinically effective alternatives within each therapeutic class and large price differentials among the medications. The subcommittees have found few clinical differences among drugs within the four therapeutic classes.⁹

Prior Authorization and Practitioner Education Processes

The five states' procedures are quite similar, although there are some variations. Generally, when a Medicaid beneficiary tries to fill a prescription, the pharmacist either already knows that the prescription requires prior authorization or finds out when processing the claim. For those prescriptions requiring prior authorization, pharmacists must file a form electronically or by fax; these forms often require contact with the prescriber. This may involve telling the doctor about alternatives to the prescribed drug or obtaining additional patient information to process the form. In some states, for example in Washington's TCS, the physician must get directly involved in the process.

The pharmacist typically sends the prior authorization form to the authorizing entity where a decision is made about whether to allow the prescription to be filled or to provide the prescriber with information about alternatives to the prescription. This entity is: 1) a private PBM in the cases of Georgia and Oregon, and one of Washington's processes; 2) the College of Pharmacy in Oklahoma; and, 3) state Medi-Cal or Medicaid employees in California and Washington. Authorizations usually have several possible levels of review, with clerks or interns often making initial, simple decisions while more complicated cases go to pharmacists or nurses. Decision-making can be almost instantaneous or can take more than a day; however, decisions that take more than a day are a violation of federal law and the effects of such time lags on beneficiaries are unclear. Providers and beneficiaries dissatisfied with the decision can appeal it to other medical professionals within Medicaid or to the program's administrative law judges. Oregon's PMPDP and Washington's TCS follow the same general process but the final decision about the prescription rests exclusively with the beneficiary's physician. By federal law, in all states, pharmacists are required to provide a 72-hour supply of a medication in emergency cases.

Views of these procedures varied by state and by type of stakeholder, although some states' procedures were not controversial. Beneficiary representatives most often took issue with delays in getting needed prescriptions, multiple trips to providers, and inadequate information about the procedures. Some providers complained about having to assume additional administrative burdens for which they are not compensated. Overall, manufacturers were opposed to prior authorization processes.

Beneficiary Issues

Beneficiary advocates raised a number of problems about the prior authorization processes in most of the case study states. Chief among beneficiary complaints was the need to make multiple trips to the doctor or to the pharmacy to get prescriptions written or filled, as many beneficiaries – especially those who are elderly or have disabilities – have difficulties arranging transportation. In addition, for those who are stable on an existing medication, if their drug is dropped from the preferred drug list, they may have to make multiple trips to practitioners for adjustments to drug regimens. Beneficiary groups also reported that when pharmacists tell patients that their drug is not on the preferred drug list, patients are often unaware of their right to appeal a denial. Thus, consumers may believe that their only options are to leave the pharmacy without the prescription or pay for it themselves out-of-pocket. Patients also generally are not informed about changes to the preferred drug list. Some beneficiaries reported difficulty getting either emergency supplies of medications or strong pain medications.

Provider Issues

The least controversial state processes for providers were those in California, Oklahoma, and Oregon. Most stakeholders in California agreed that pharmacists, the big retailers, and doctors have learned how to navigate the system, resulting in less resistance to the process over time. Oklahoma's process has a great deal of credibility among providers and is regarded as fair in large part because pharmacists staff it. Program staffing may be key to provider acceptance because pharmacists in California and Oklahoma are the key decision-makers and most stakeholder perspectives of their programs are good. And, in Oregon, where the PMPDP was implemented in the summer of 2002, almost all stakeholders were optimistic that it could contain Medicaid prescription drug costs without much controversy because of the credibility of the decision-making process and because physicians would not be forced to obtain prior authorization for their prescriptions.

In contrast, many provider groups expressed concerns about prior authorization in Georgia and Washington during their start-up periods. Most Georgia stakeholders had complaints about Express Scripts' administration of the process for proton pump inhibitors. Providers reported remaining on hold for several minutes at a time, not being able to discuss medical necessity with the company's staff, and not having easy access to a pharmacist or a nurse who could discuss the nuances of a patient's condition. There were also complaints that the manual detailing the process did not have explicit instructions regarding emergencies and that it was not clear who decides what constitutes an emergency. However, some stakeholders said that Medicaid beneficiaries had sufficient access to prescriptions during emergencies. Initially, Washington providers were frustrated with TCS because of their belief that the Department implemented it with very little discussion or education of providers. TCS' initial months of operation were problematic because many providers complained about not being able to get through to the PBM ACS, among other issues. However, some observers said that pharmacists are now finding TCS less burdensome than they had feared.

Some providers appear to avoid prior authorization whenever possible. There is the sense among some stakeholders in California and Washington that physicians prescribe only medications on the preferred drug list and do not exceed the prescription thresholds to avoid prior authorization. Since many physicians are unlikely to master the multiple, public and private prior authorization processes, formularies, and other constraints on their prescribing behavior they may face, they may find out that a drug requires prior authorization only when a prescription is denied, and they then change the prescription to avoid the process.

Education about and Monitoring of the Processes

Education about prior authorization processes focuses almost exclusively on providers and involves bulletins included with provider reimbursement paperwork, changes to providers' Medicaid manuals, and workshops or updates during periodic provider meetings. Oklahoma and Georgia also fax major changes to every provider in the state, and Georgia mailed out a provider-specific letter that listed the patients who would be affected a month before new proton pump inhibitor requirements were implemented. Education regarding Washington's TCS involves the PBM examining physicians' prescribing practices and identifying those operating outside the norm. Company pharmacists visit these physicians to provide information about generic alternatives and to provide comparisons of the physician's prescribing practices to state averages. None of the states appears to make much of an effort to educate beneficiaries about the prior authorization processes.

Monitoring of the prior authorization procedures' effects on beneficiaries and providers is minimal in most case study states and typically relies exclusively on receipt of complaints or analysis of prior authorization denial rates and reasons for denial. The exception is Oklahoma, which also has a monthly random call back of people who have been denied a prescription to determine if any negative outcomes resulted from the denial. According to the University of Oklahoma College of Pharmacy, these surveys of 100-150 people per month have not turned up any problems. The response rate to these surveys is about 25 to 30 percent.

Medicaid Managed Care Plans' Prior Authorization Procedures

Just as prior authorization procedures vary among the states, the role of managed care ranges from none in Georgia to significant involvement in Oregon where managed care plans enroll the majority of Medicaid beneficiaries, including most of those who are aged and disabled. In California and Washington, managed care plans serve largely younger beneficiaries with families, and most drug costs are included within plans' capitated payments. Oregon has no contractual requirements regarding availability of specific drugs so plans are free to have formularies, but plans' prior authorization procedures must follow federal requirements such as providing drugs in emergencies and making decisions within 24 hours. A recent review of five Oregon Medicaid managed care plans' formularies for eight classes of drugs found great variability in the drugs on the formularies and that some newer medications such as COX-2 inhibitors did not appear on any of the formularies.¹⁰

Oklahoma, with about one-third of its beneficiaries in capitated managed care plans, appears to have the strongest rules regarding plans' prescription drug benefits. Plans in this state must make all drugs that Medicaid covers available to beneficiaries and they cannot limit prescriptions. However, plans can impose prior authorization requirements, promote generics, and require physician documentation of the need for certain drugs. Prior authorization requirements can only be imposed when there are at least two medications available in a therapeutic class.

Most case study states perform rather perfunctory monitoring of managed care plans' formularies and prior authorization processes. California appeared to have the most thorough monitoring of managed care plans, although some stakeholders assert that it relies mostly on paper compliance measures. The state has independent auditors who audit plan formularies, assess the adequacy of their pharmacy networks, and review grievances and complaints, looking for indicators such as turnaround times for authorization requests and inappropriate

denials. The department also has a managed care ombudsman and each enrollee is given a toll-free number to call to register complaints.

Beneficiaries' primary concerns about plan formularies and prior authorization processes center around problems that can arise when formularies change. For example, beneficiaries may have to change medications if they switch plans or if their current plan makes changes to its formulary. In addition, stakeholders said that many plans' grievance and appeals procedures are complex enough that beneficiaries are likely to need representation to file and follow through on a complaint.

In Washington, there appears to be some difficulty coordinating Medicaid managed care plan enrollees' short-term use of mental health medications with the state's managed behavioral health contractor, which handles the long-term needs of persons with mental health conditions. Pharmacists are not always aware that the beneficiary is entitled to certain medications through the contractor, and the pharmacist may bill the managed care plan when the plan is not financially responsible for the prescription.

Conclusions and Stakeholder Recommendations

Given the rapid escalation in Medicaid expenditures for prescription drugs, state officials and others are considering various methods to control drug utilization and cost. Of the many strategies that states may use, prior authorization, if well designed and implemented, has the potential to do less harm to beneficiary access than other, more drastic actions such as benefit or enrollment cuts. Lessons from the five case study states' experiences with prior authorization – particularly those relating to unintended barriers that beneficiaries and providers face, the credibility and oversight of the processes, and provider education about procedures – could be instructive for states considering this option.

Stakeholders report that prior authorization can create access problems for some beneficiaries. Beneficiaries' key concerns about prior authorization and its related processes include the need for multiple trips to pharmacies and practitioners, and changes to their established drug regimens. In addition, in states that require medication reviews when beneficiaries' prescriptions exceed a monthly threshold, some of the sickest beneficiaries may face drug regimen changes only because providers want to avoid triggering reviews.

Respondents also pointed out that prior authorization could create unnecessary bureaucratic problems for providers. Providers cited communication problems with PBMs under contract to the state, and they also noted that Medicaid's formulary is only one of many formularies or preferred drug lists and prior authorization processes with which they must

comply, making timely, accurate information exchange critical. For example, if a prescription is not authorized, the reason why should be clearly noted. Claims may be rejected because the product requires prior authorization, or because the patient is not eligible for Medicaid or the program does not cover the product. Unless the reason has been made clear, pharmacists might have to make contact with various offices within Medicaid to determine why the prescription was denied.

Some of these issues could be addressed under current systems. For example, some observers recommended electronic systems with rapid decision-making so that if a beneficiary's prescription requires authorization, it can be approved while he or she waits, eliminating the need for a separate trip to get the prescription filled. One stakeholder from Oklahoma suggested making a patient's entire claims history available to prior authorization decision-makers and having a PBM handle all interactions with pharmacists to reduce the amount of time needed to determine why a claim has been rejected.

To streamline some of their administrative burden, some stakeholders would like to have as much standardization as possible across payers' formularies and prior authorization processes to reduce complications for beneficiaries and to minimize providers' administrative time and expenses. Georgia has taken a major step in this direction by applying its prior authorization requirements to Medicaid beneficiaries, state and state university employees and CHIP participants.

In this study, there was little evidence that the states monitor the effects of prior authorization on beneficiaries or providers. Thus, although some basic information is available (e.g., waiting times for decisions), in most states virtually nothing is known about how prior authorization affects individual beneficiaries' access to appropriate, medically necessary medications. One exception is Oklahoma, which appears to be the only state in this study currently making an effort to determine how beneficiaries are affected by prior authorization. Most providers' experiences are also unknown, except for indicators such as the average amount of time practitioners must spend on the phone with PBMs. Without more data about prior authorization's effects, it is difficult to determine what problems beneficiaries and providers might have or how to solve them. The potential advantages of prior authorization for these groups, such as reduction in medication errors or increases in appropriate prescribing, are also hard to determine.

Managed care plans' formularies and prior authorization processes appear to undergo little regulation and monitoring, for example, as described in Oregon and Washington. This is a particular concern in states where a large proportion of aged and disabled beneficiaries – the

most frequent users of medications – are enrolled in managed care plans. The effects of some medications can be quite idiosyncratic, making access to a wide range of drugs important to some patients, heavy users in particular. Increased state oversight of managed care plans' administration of the Medicaid drug benefit may improve access and care for enrollees.

An important indicator of the perceived success of prior authorization in some of the study states was how key stakeholders regarded the validity of the process. States with the least controversial prior authorization programs appeared to be those with the most credible procedures. In California and Oklahoma, pharmacists have a major role in prior authorization staffing and in providing information to the Medicaid program to aid in its decision-making. Oregon has initiated a consensus decision-making process regarding its PMPDP that most stakeholders strongly support. In Oklahoma and Oregon, most agree that decision-making is based on clinical evidence about the efficacy of the products that either require prior authorization or will be incorporated into a preferred drug list. Including *systems external to Medicaid in the prior authorization process may confer credibility; some Georgia stakeholders believe that extending prior authorization to state drug purchases outside of Medicaid shows that the state is treating all its beneficiaries equitably*

Some stakeholders recommended disease management and physician education as additions to or replacement of prior authorization processes. Although little evidence exists about the efficacy of such measures, Oregon's new PMPDP and other states' adoption of disease management offers new opportunities to test these approaches. Stakeholders recommended that any provider education include strong clinical evidence from trusted opinion leaders.

In short, most respondents described the importance of credible prior authorization processes that are streamlined and that minimize the burden on beneficiaries and providers. More data on the effects of prior authorization on key stakeholders would inform the national debate on prescription drug utilization management and cost control. However, it is important to note that prior authorization is only one of a range of prescription drug management tools that states have at their disposal. Understanding how these mechanisms work both independently and in concert to affect beneficiaries and providers is critical to effective public and private benefit design.

¹ Bruen, Brian K., "States Strive to Limit Medicaid Expenditures for Prescribed Drugs." Presentation to CMS/SAMHSA Conference on Medicaid and Mental Health Services, September 18, 2002. These increases do not include Medicaid managed care plans' expenditures on medications.

² Ibid..

³ Bruen, Brian K., States Strive to Limit Medicaid Expenditures for Prescribed Drugs, Kaiser Commission on Medicaid and the Uninsured, Washington, DC, February 2002.

⁴ Please see Schneider Andy and Linda Elam, Medicaid: Purchasing Prescription Drugs, Kaiser Commission on Medicaid and the Uninsured, Washington DC, January 2002, for a detailed description of measures states can use to control prescription drug costs.

⁵ Schwalberg Renee, Bellamy Hilary, Giffin Mary, Miller Chris, Schreiber Williams Susan, Elam Linda, Medicaid Outpatient Prescription Drug Benefits: Findings from a National Survey and Selected Case Study Highlights, Kaiser Commission on Medicaid and the Uninsured, Washington DC, October 2001.

⁶ 42 U.S.C. chapt. 7, subchapter 19, Sec.1396r-8.

⁷ Mackinnon Neil J and Kuman Ritu, "Prior Authorization Programs: A Critical Review of the Literature," Journal of Managed Care Pharmacy, vol.7, no.4, July/August 2001.

⁸ Medicaid rules require states to have drug utilization review programs to determine the appropriateness of beneficiaries' use of medication. To oversee this process, states must set up drug utilization review committees.

⁹ Bureau of National Affairs, First Medicaid Formulary Study Shows Little Difference in Drug Effectiveness, Health Care Policy Report, May 5, 2002.

¹⁰ Minutes from the Health Resources Commission Meeting on May 8, 2000 at the Clackamas Community Center. Accessed on June 17, 2002 from http://www.ohppr.state.or.us/hrc/pdf/Min_05-08-00.PDF

Appendix 1

California's Prior Authorization Process for Med-Cal Prescription Drugs

California's Medicaid program, known as Medi-Cal, has required prior authorization for certain prescriptions for about 30 years. The process requires prior authorization for medications that do not appear on the state's preferred drug list and limits the number of prescriptions that can be filled without prior authorization. The state's system has changed over time due to the need to contain Medi-Cal's prescription drug costs. Most stakeholders had few complaints about California's current prior authorization system, perhaps because it has been in existence for so long and the decision-makers are pharmacists employed by the state. However, beneficiaries appear to have some of the same difficulties in California that they have in other states, including the need to make multiple trips to pharmacies and prescribers' offices and problems with changes in their medications. Some providers complain about inconsistent decision-making and paperwork burdens. Managed care plans are free to set their own formularies but must have prior authorization processes available for medications that are not on the formulary; the state audits plans' compliance with these regulations.

Evolution of Prior Authorization in California

Prior authorization in California has two parts – a preferred drug list and a prescription threshold. In the 1970s, California began requiring prior authorization for Medi-Cal beneficiaries when they had prescriptions for medications that did not appear on the state's List of Contract Drugs (i.e., preferred drug list). Manufacturers' products generally go on the list after they pass a Medi-Cal review and manufacturers agree to provide Medi-Cal with a state supplemental rebate in addition to the standard federal rebate. Negotiations over the supplemental rebates are confidential and the state reports only aggregate data about rebate amounts.

In response to prescription drug cost increases, the state began requiring prior authorization for beneficiaries who had more than 10 prescriptions in a month in 1994; this threshold was reduced to six in 1995. Certain medications are exempt from the six-prescription threshold, including HIV/AIDS drugs, cancer drugs, contraceptives, and medications for patients in long-term care and subacute facilities. Compound drugs, all

of which require paper claims forms, are also exempt from the threshold to avoid excessive burdens on pharmacists.

Most California stakeholders contend that Medi-Cal's prior authorization requirements have been used primarily to contain costs. State officials assert that many of the provisions have been implemented to ensure beneficiaries' appropriate use of medications.

Some stakeholders remarked that manufacturers have periodically tried to eliminate the preferred drug list and the supplemental state rebates but they have not been successful due to implications for the Medi-Cal budget. For example, according to state officials, in the SFY 2003 budget, the standard federal rebate amounts to \$700 million on a \$3.8 billion program (expenditures before rebate) and the state supplemental rebate adds another \$270 million in savings; the federal and state governments share both rebates. One stakeholder observed that the state's supplemental rebate used to be considered the most onerous in the country, but now is viewed as more reasonable because manufacturers can decide whether to negotiate with the state about a supplemental rebate, rather than having the state set a reference price for medications.

Development of the Preferred Drug List

California's preferred drug list contains about 700 medications that do not require prior authorization. New HIV/AIDS and cancer drugs are automatically added to the list. In addition, all newer anti-psychotics and anti-depressants are on the list. Most stakeholders said that these exemptions were implemented under pressure from pharmacists, patient advocacy groups, and manufacturers.

The types of products that require prior authorization are generally sole source products where manufacturers do not offer rebates, although sometimes the state places these medications on the preferred drug list solely because of their clinical efficacy.

Medi-Cal is responsible for decisions regarding the medications that appear on the preferred drug list. The central office summarizes clinical evidence about the medications' effectiveness using manufacturers' submissions to the federal Food and Drug Administration, journal articles, and other research. Based on the information compiled, the state uses five criteria to determine whether to add or remove a medication from the list – its potential for misuse, safety, cost, and efficacy as well whether the drug meets an essential need. The state also reviews medications by

therapeutic category and may require prior authorization for off-label uses. Removals from the list can occur because of safety issues or significant misuse of a prescription drug and such actions occur only after the state holds public hearings on the issue.

The Department makes clinical information about medications available to its voluntary Medi-Cal Contract Advisory Committee, which is composed of three physicians, three pharmacists, and one beneficiary representative. The committee has a strictly advisory role regarding changes to the list and, though they meet about once a year, provide written input on medication and therapeutic category reviews.

Prior Authorization Process

About 2.5 to 3 million fee-for-service Medi-Cal beneficiaries, most of whom are aged, blind, or disabled, are subject to the prior authorization process in California. The process relies largely on pharmacists who submit about 96 percent of prior authorization requests. They take one of two actions when they know that a prescription requires prior authorization. If the pharmacist has enough information about the beneficiary's condition to determine that he or she should receive the product, the pharmacist enters the appropriate code and can process the claim. If the pharmacist does not have enough information, then he or she must contact the beneficiary's practitioner to see why the medication was prescribed and determine if alternatives on the preferred drug list were considered. Based on the information from the prescriber, the pharmacist fills out a treatment authorization request (TAR) form. The pharmacist faxes the form to one of the Department's field offices in Los Angeles or Stockton. Within one business day, the field office consultant faxes back a decision to the pharmacist.

In emergencies, pharmacists can use their own judgment and fill part of the prescription. After filling the prescription, the pharmacist must file a paper claim certifying that an emergency existed to receive payment or the pharmacist may submit the TAR form for retroactive approval.

About 87 percent of requests are approved on initial submission. Pharmacists often have to resubmit TARs with more complete information about the patient's condition. Only seven or eight percent of TARs are denied and then beneficiaries receive a denial letter with information about how they can appeal the decision before an administrative law judge.

Education about Prior Authorization

Education about prior authorization and the preferred drug list is handled through monthly bulletins sent to pharmacists and physicians. This information comes in the form of changes to the provider manual. The department also has the manual on its website. This type of education is problematic in the view of some stakeholders because pharmacists do not seem to know about changes when they occur, nor do some pharmacists know that beneficiaries can receive prior authorization for their prescriptions for up to 12 months.

Prior Authorization Process Monitoring

There is no formal monitoring of the prior authorization process. The legislative audit bureau used to issue semi-annual reports on the process, which largely focused on the number of claims and the time it took to process them. The 2000 report was reviewed for this paper.

This audit primarily raised issues about the timeliness of decision-making.¹ In 2000, California's contract with Electronic Data Systems, a company that provides data entry services for the state, allowed the company up to five working days to enter data for TARs, which "clearly exceeds the department's policy of processing a TAR within one working day." In addition, the Department's policy allows a processing time of 48 hours for TARs, while federal rules require 24 hours. The Auditor reviewed 2711 TARs from December 1999 through May 2000 and 77 percent were processed within one workday. The Department received 662,288 TAR requests during this time period. Eighty-one percent or 537,276 were approved, 61,871 (9 percent) were denied, 24,531 (4 percent) were modified, and 38,610 (6 percent) were returned for more information.

The audit also found very small numbers of appeals of decisions. Medi-Cal beneficiaries only submitted 103 fair hearing requests, 50 of which were withdrawn, 14 denied and 21 approved. Thirteen were dismissed and five were pending. During the prior six months there were 132 fair hearing requests.

Observers' Perspectives on Prior Authorization

California's prior authorization procedure is not controversial but beneficiaries and providers did raise some issues about its operations. One of the most pressing concerns is that beneficiaries might have to make multiple trips to the pharmacy to get their prescriptions filled, as transportation is a critical issue for some beneficiaries. In

addition, changes to the preferred drug list can affect a person who is stable on an existing medication. A respondent cited the example of a patient who went to refill her Zoloft prescription, which required prior authorization at the time. Her pharmacist told her that she had to switch her prescription to Paxil, which recently had been added to the state's preferred drug list. Unfortunately, the patient's doctor was on vacation for a week and the prior authorization request for Zoloft could not be completed in the physician's absence. The patient suffered a severe worsening of her depression and temporarily committed herself to a hospital. Stakeholders also reported that pharmacists sometimes say a patient's medication is not on the preferred drug list, rather than submitting the TAR. Patients do not realize that pharmacists can submit a TAR for a non-preferred medication. Patients also are not informed about changes to the preferred drug list. Some beneficiaries have difficulty getting emergency supplies of medications or strong pain relief drugs from pharmacists.

An issue for beneficiaries who are dually eligible for Medicare and Medi-Cal is that those who are enrolled in Medicare managed care plans must receive a rejection from their plan before a prescription can be filled under Medicaid. This is done to ensure that Medicaid remains the payer of last resort when plans provide prescription drug coverage. According to state officials, pharmacists now only have to put in a code saying that the plan has rejected a prescription, which they should know to do automatically for brand name prescriptions because most Medicare managed care plans in California restrict their coverage to generic drugs.

Most stakeholders agreed that pharmacists, the big retailers, and doctors have learned how to navigate Medi-Cal's system because it has been in existence for so long. For example, some large retailers will go ahead and fill a prescription and submit the TAR during slow times at night, under the assumption that they will absorb the medication's cost in the unlikely case of a denial. Despite the lack of controversy, providers do have some concerns about Medi-Cal's prior authorization procedure.

For pharmacists, issues arise around uniformity of decision-making and paperwork. Providers claim that state staff's decisions about TARs can vary under similar situations. In addition, pharmacists do not receive compensation for the time spent on TARs so they relegate completion of forms to the least costly staff. These employees sometimes do not fill out forms completely, which can lead to delays in decision-making. The state is moving toward a fully electronic system that should mitigate this burden somewhat.

Some providers appear to try to avoid the prior authorization process altogether. According to one stakeholder, pharmacists sometimes give a beneficiary one free medication (the least expensive) just to avoid triggering the six-drug threshold for prior authorization. Other pharmacies sometimes tell Medi-Cal beneficiaries to go to another pharmacy to get their prescriptions filled. Thus, consumers can be faced with a choice between leaving the pharmacy without the prescription and paying for it themselves. The result is that some beneficiaries pay out-of-pocket for their prescriptions, despite the fact that any pharmacy serving Medi-Cal beneficiaries must file a TAR that is rejected before they can accept payment from a beneficiary.

Like pharmacists, physicians and other prescribers do not receive compensation for the time they spend dealing with the prior authorization process. There is the sense among some stakeholders that practitioners prescribe medications on the preferred drug list and do not prescribe a seventh medication to avoid having to deal with the procedures. Also, practitioners and pharmacists must cope with multiple, differing formularies and prior authorization processes from Medicaid, managed care plans, and private insurers.

Medi-Cal's Managed Care Plans and their Prior Authorization Procedures

Managed care plans generally serve younger Medi-Cal beneficiaries in families, although 20 percent of plan enrollees are aged or disabled. Plans' capitated payments include all prescription drug costs except for certain medications used to treat mental health conditions (e.g., atypical anti-psychotics) or HIV/AIDS. Plans can create their own formularies as long as they include at least one medication in each therapeutic class. Plans are supposed to use five criteria when determining their formularies: safety, medical necessity, cost, abuse potential, and efficacy – criteria similar to those that Medi-Cal's fee-for-service system uses. Each plan must have its own pharmaceutical and therapeutics committee to determine the formulary or the plan can delegate this function to a pharmaceutical benefit manager.

Medications that are not on the formulary must be available, if medically necessary, through a plan's prior authorization process. These processes must meet the federal requirements regarding 24 hour or next business day decisions on requests and provision of emergency medication supplies sufficient to last until a decision is made.

The state has independent auditors who evaluate plan formularies and the adequacy of their pharmacy networks. Plans also make information on grievances and complaints available to auditors who examine inappropriate denials and the timing of prior authorization decisions. The department also has a managed care ombudsman and each enrollee receives a toll-free number they can call to register complaints. Some stakeholders view the state's monitoring of plan compliance to be a perfunctory paper review.

Beneficiary concerns about plan formularies and prior authorization processes relate to problems that can arise when formularies change. For example, beneficiaries may have to change medications if they switch to another plan or the plan they are in could make changes to the formulary. In addition, many plans' grievance and appeals procedures are complex enough that beneficiaries are likely to need representation to file and follow through on a complaint.

Observers' Recommendations

There is little sentiment among stakeholders that major changes are needed to California's system. Rather, stakeholders recommended devoting more resources to the system and moving quickly to electronic processing of paperwork to reduce the burden on providers. Stakeholders were generally supportive of the system's reliance on pharmacists for decision-making. However, some stakeholders said that the system's response time could be improved and that the effects of California's processes should be examined in the context of their effects on the entire health care system. For example, restrictions on access to medications might lead to increased costs due to increased doctor visits and unnecessary hospitalizations. Recommendations to other states were to examine the cost of starting a prior authorization system because it can be quite expensive.

Georgia's Prior Authorization Process for Medicaid Prescription Drugs

Georgia has two primary prior authorization mechanisms to control Medicaid beneficiaries' use of medications: 1) prior authorization for adult Medicaid beneficiaries wishing to fill more than five prescriptions in a month (six for children), which pharmacists can now easily override at the time of dispensing; and, 2) requiring prior authorization for about 25 categories of prescription drugs. Georgia's recent move to require prior authorization for proton pump inhibitors caused controversy among provider groups, with opinion about the process split. Georgia does not have any capitated Medicaid managed care plans so all prescription drug costs are in the fee-for-service system.

Evolution of Prior Authorization in Georgia

Beginning in 1993, Georgia required beneficiaries wishing to fill more than five prescriptions in a month to obtain prior authorization. Some stakeholders said that this threshold caused beneficiary access problems because pharmacists sometimes denied refills and neglected to contact practitioners about the need for prior authorization. In 1999, certain consumer advocates, who, according to some sources may have had financial backing from drug manufacturers, made an unsuccessful attempt to prohibit Georgia from using any type of prior authorization. Subsequently, the state eased the prior authorization requirement by allowing pharmacists to override it easily, if they check for such problems as drug interactions and duplicative therapies. The state did this because there was a high approval rate for prior authorization requests and the administrative costs of the process did not justify retaining it. In the late 1990s, the state exempted mental health drugs from prior authorization because of pressure from consumer advocates and a consultant's report that warned of future cost increases in such services as hospitalization if beneficiaries did not have ready access to this type of medication.

Although Georgia requires prior authorization for about 25 categories of medications, a recent battle over prior authorization related to proton pump inhibitors (PPIs). In response to the governor's order to cut Medicaid expenditures by five percent in 2001, the Department of Community Health began requiring prior authorization for this category of medications. The process, which was modified after consultation with the

state's Drug Utilization Review Board, requires beneficiaries with certain diagnoses to try and fail on less-expensive H2 antagonists before they can get be prescribed PPIs.

Opinion among stakeholders about the PPI requirement is split. Some believe that the requirement interferes with the relationship between patient and practitioner, while others believe that the requirement could help avoid inappropriate use of these expensive medications. These stakeholders say that PPIs are effective only for 90 days and H2 antagonists are an appropriate alternative for those with routine reflux disease.

A unique feature of Georgia's prior authorization procedures is that they apply to state and state university employees, Children's Health Insurance Program participants, as well as Medicaid beneficiaries. Some stakeholders believed that this adds to the credibility of the process.

Role of the Drug Utilization Review Board (DURB)

The DURB makes recommendations to the state about prior authorization requirements, in addition to a variety of clinical issues, but the state Department of Community Health retains final decision-making power. The DURB has 20 members – one consumer advocate, one nurse, one pharmacologist, 10 physicians, and seven pharmacists. Generally, the DURB meets quarterly.

The views about the operation of the DURB are split. According to one group, the DURB does not consider recent clinical evidence when it makes decisions but state officials counter that detailed clinical reports about the medications that will be reviewed are provided to members prior to meetings. The same stakeholder group stated that pharmacists usually side with the state when decisions are made. In contrast, another group of stakeholders said that Georgia's clinical approach has a great deal of credibility because the process is scientifically based, decision-making is by professionals, and the system is applied to state and state university employees in addition to Medicaid beneficiaries.

Prior Authorization Process

The prescriber and the pharmacist have major roles in Georgia's procedure. If the prescriber knows the prescription requires prior authorization, he or she can call the pharmaceutical benefit manager - Express Scripts - directly to get it. If Express Scripts staff deny the request over the telephone, the beneficiary's prescriber will receive a faxed letter explaining the denial. Then the practitioner can fax back a one-page sheet or

a letter with information documenting medical necessity. If the prescription receives another denial, the appeal goes directly to Medicaid, where the medical director makes the final decision.

When pharmacists find out that prior authorization is required, they can call Express Scripts directly if they know the patient's condition and can explain why the prescription is necessary. If the request is denied because the pharmacist has not provided sufficient evidence that the prescription meets the medical necessity criteria, the pharmacist and the practitioner receive notice of the denial and it is up to the prescriber to appeal the denial by documenting medical necessity for the patient's prescription. In all cases, there is an expectation that the prescriber will receive counseling from the pharmacist or Express Scripts about therapeutically equivalent alternatives to the problematic prescription.

There are some protections for beneficiaries in emergencies. Pharmacists can fill a 72-hour emergency prescription and Express Scripts' first response to a prior authorization request must occur within 24 hours. Express Scripts has 3 days to make a decision on the first appeal and Medicaid has 10 days on the second level appeal but the process rarely takes that long if the prescriber provides documentation of medical necessity.

Education about Prior Authorization

Pharmacists and practitioners receive notification about changes to the procedure through "banners" that come with their weekly Medicaid payments; the same banner continues for eight weeks and banners have new information added to them on a regular basis. The state also conveys important changes to the process by faxing every participating pharmacist and, sometimes, every practitioner in the state. In addition, the medical society, pharmacy association, and manufacturers let providers know about changes to the process. The state also holds periodic meetings with physician and pharmacist groups to educate them about Medicaid procedures and policies; at these meetings, providers can bring up problems. Beneficiaries receive their Medicaid cards monthly and receive notification of changes to the prior authorization process in these mailings.

State officials consider education about the process to be effective. However, some stakeholders complained that the banner messages come on the last page of a lengthy explanation of benefits for Medicaid patients in a small type that practitioners

rarely see. Medicaid meetings generally are about billing issues and administrative matters and practitioners rarely attend these meetings. Other stakeholders took a different view and said that education is appropriate, with the banner messages and the faxes to all participating physicians and pharmacists being quite effective.

Prior Authorization Process Monitoring

In a study of Georgia's prior authorization process using data from 1994, Kotzan and colleagues compared the market share of medications requiring prior authorization under the Medicaid program to the same medications' market share among patients paying cash for their prescriptions.² Prescription drugs requiring prior authorization represented 2.41 percent of Medicaid prescriptions and 7.93 percent of Medicaid expenditures; the same figures in the cash market were 5.63 percent and 10.93 percent respectively. The authors concluded that Medicaid prior authorization requirements reduced use of prescriptions compared to the comparison population but acknowledged that the populations compared were different.

Monitoring of the prior authorization process relies on reports that Express Scripts provides on approval and denial rates, and reasons for denial as well as receipt of complaints from beneficiaries and providers. Complaints can come via several channels including local welfare offices, letters, and educational meetings for providers. According to state officials, the prior authorization process for PPIs has received very few written complaints.

Observers' Perspectives on Prior Authorization

Most stakeholders had complaints about Express Scripts' staffing of the process for PPIs. Providers reported remaining on hold for several minutes at a time, not being able to discuss medical necessity with the company's staff, and not having easy access to a pharmacist or a nurse who could discuss the nuances of a patient's condition. Express Scripts prior authorization staff is composed of both pharmacists and "call center associates." These associates have defined criteria for each medication that requires prior authorization. If, after initial review with a provider, the request does not meet the medical necessity criteria, an Express Scripts pharmacist must review the information before a denial can be issued. There were also complaints that the manual governing the process does not have explicit instructions regarding emergencies and that it is not clear who gets to decide what constitutes an emergency. However, some

stakeholders said that Medicaid beneficiaries had sufficient access to prescriptions during emergencies.

Views about the process vary with one group of stakeholders believing that the process engenders behavior change so that only requests with real medical necessity come forward; other stakeholders believe that the prior authorization process is unnecessary because so many requests are being approved. The biggest current problem in the view of one stakeholder is that Medicaid beneficiaries do not receive a notice from the state when their prescription has been denied so they are dependent upon the prescriber or pharmacist to follow through with a prior authorization request.

Medicaid Managed Care Plans' Role in Prior Authorization

Georgia does not have capitated Medicaid managed care plans so prescription drug costs remain in the Medicaid fee-for-service system. This situation may change somewhat when Georgia sets up its disease management programs for people with diabetes or asthma, and for those who wish to enter smoking cessation programs. At the time of the interview, disease management was still in the planning stage.

Observers' Recommendations

Stakeholder opinion about Georgia's prior authorization processes was divided with two groups recommending use of the DUR program to identify inappropriate prescription writing practices and education of those practitioners involved as possible alternatives to prior authorization. Another group of stakeholders viewed Medicaid's prior authorization process as more flexible than those of private managed care plans. This group approved of the state's clinically based approach to prior authorization but cautioned that the process should not be overly burdensome to the professionals who have to use it. Some stakeholders recommended Georgia's practice of applying prior authorization to state employees and others in addition to Medicaid beneficiaries because this step adds credibility to prior authorization. Most stakeholders agreed that contractors running the process should have a sufficient number of highly trained staff to deal with the volume of calls.

Oklahoma's Prior Authorization Process for Medicaid Prescription Drugs

Oklahoma's prior authorization process has become more restrictive over time as the state has struggled to contain Medicaid prescription drug costs. Most generics do not require prior authorization and many categories of brand name drugs do. Most stakeholders are not opposed to prior authorization because of the state's reliance on clinical evidence and pharmacists when making decisions about the process. The state has imposed relatively close regulation of managed care plans' formularies and plan enrollees have better drug benefits than their fee-for-service counterparts.

Evolution of Prior Authorization in Oklahoma

Oklahoma's Drug Utilization Review Board (DURB) was created in the wake of OBRA 1990 to make recommendations about Medicaid prescription drug use and cost containment. By 1993, the Board had recommended and the state had instituted prior authorization for a number of different medications including benzodiazepines, growth hormone, and proton pump inhibitors to ensure their clinically appropriate use.

Several pressures led to Oklahoma extending prior authorization to more categories of medications. During FY 1998, the Medicaid budget exceeded its target, largely because fee-for-service pharmaceutical costs rose 20 percent, compared to the projected 12 percent increase. This occurred because overall use of medications rose and many Medicaid beneficiaries with low use of health services had begun enrolling in managed care plans, leaving aged or disabled Medicaid beneficiaries, who tend to be high users of services, in the fee-for-service system.

In response to these trends, the state implemented the Preferred Product Initiative in July 1999, which required, among other things, step therapy for certain medications, including proton pump inhibitors. One of the manufacturers of these medications – Astra Zeneca – successfully challenged the rule in court on procedural grounds and the program shut down in September 1999.

The state reacted by using a rulemaking process to implement the Product Based Prior Authorization (PBPA) procedure in January 2000. The goal of the procedure is to ensure that Medicaid beneficiaries have the optimal, cost effective drug therapy for their conditions. The PBPA initially focused on two therapeutic classes: 1)

non-steroidal anti-inflammatory drugs, and 2) H2 antagonists/proton pump inhibitors; the state has since has added angiotensin-converting enzyme (ACE) inhibitors and calcium channel blockers to PBPA.

At the time of the interviews, the state's executive branch had a permanent rule request in place to authorize additions to the PBPA without going through the standard rule-making process. This request passed and has been implemented, freeing the state to make changes to PBPA without having to get the legislature's approval for each one.

Most stakeholders agree that manufacturers were and remain the primary opponents to Oklahoma's prior authorization requirements. Consumer advocates have not been involved in the debate to any great degree and other stakeholders have generally been supportive of the state's efforts because they recognize that the state is facing growing pharmaceutical expenditures in the fee-for-service system and must act to keep costs under control.

Role of the Drug Utilization Review Board

Oklahoma's DURB makes recommendations to the Oklahoma Health Care Authority, which administers Medicaid, about prior authorization requirements. The Board's recommendations are based on an analysis of one to two years of claims data, the cost to Medicaid of a day's treatment, the availability of medications from multiple sources, lowest net cost of drug therapies, and clinical reviews of data regarding differences in treatment outcomes.

Medicaid's DURB has 10 members – four physicians, four pharmacists, one lay person with relevant experience, and one manufacturer representative who meet monthly. The Board makes recommendations to Medicaid's Medical Advisory Committee and from there to the Oklahoma Health Care Authority's Board of Directors.

Most stakeholders said that the DURB has well qualified members and staff and generally makes careful recommendations. However, one stakeholder said that the board is not considering clinical factors when making recommendations about the prior authorization process and that there is little discussion at board meetings.

Prescription Drugs Requiring Prior Authorization

All medications are potentially subject to prior authorization to control the use or scope of prescriptions. The prescription drugs subject to these types of controls include:

Toradol, a painkiller; H2 antagonists/PPI; smoking cessation products; benzodiazepines, barbiturates, and hypnotics; antihistamines; anorexants; and growth hormone.

The state also has the PBPA for 4 categories of medications. Tier 1 products in these categories are generic drugs and do not require prior authorization. Brand name drugs are in Tier 2 and thus require prior authorization, except under certain clinical conditions; use of Tier 2 drugs may not require prior authorization. In addition, non-sedating antihistamines are available to Medicaid beneficiaries who are under age 21 without prior authorization.

Prior Authorization Process

When a beneficiary comes to fill a prescription that requires prior authorization, the pharmacist will receive electronic notice of a denial. Either the pharmacist fills out a prior authorization form in consultation with the prescriber or the form is faxed to the practitioner's office, which then takes responsibility for faxing the completed form to the University of Oklahoma College of Pharmacy for a decision. A pharmacy technician or intern at the College reviews the form and, if the decision is clear, approves the prescription. All decision-makers have the patient's entire claims history and previous prior authorization requests on-line when reviewing a new request. For example, the decision-maker can tell if a patient has failed on H2 antagonists and thus can have access to PPIs. If there is any doubt about the decision, the form goes to the College's pharmacists for consideration and only pharmacists can deny a request for prior authorization. Pharmacy technicians are licensed on the basis of their on-the-job training, which involves working through a standard training manual.

Decisions are issued on or before the next business day, within 24 hours, and faxed to the pharmacy. A College pharmacist is available during regular pharmacy hours for decision-making. However, on weekends, a pharmacist must decide whether the prescription constitutes an emergency and, if this is the case, the pharmacist can dispense 72 hours worth of medication and will receive reimbursement for doing so.

The College approves about 80 percent of the prior authorization requests it receives. Of the 20 percent denied, about 40 percent of denials occur because the originating pharmacist doesn't realize that a prior authorization has already been approved, and about one-third of forms do not have enough clinical information about the patient. The rest of the denials are due to failure to try Tier 1 drugs first or the inappropriateness of a medication given a person's clinical condition.

Education about Prior Authorization

Education for the two categories of medications recently made subject to prior authorization under PBPA was designed to alert providers to changes well before they occurred. Information included a general form letter sent to all physicians and pharmacists, a provider-specific letter that listed the affected patients a month before the requirements were effective, and a “fax blast” which involved sending faxes to all pharmacies reminding them of the changes one week before they became effective. There have also been banner messages included with the pharmacists’ reimbursement checks.

The state plans to implement a provider education and profiling program designed to identify practitioners who may be prescribing medications inappropriately. The program is being hampered by the fact that physician identifier information is wrong in 30 to 40 percent of claims, making quick identification of practitioners who may need education difficult.

Prior Authorization Process Monitoring

Process monitoring includes requiring the University of Oklahoma College of Pharmacy to report prior authorization approval rates and reasons for denial to the state. There is also a monthly random call back of people who have had a prescription denied to determine if the beneficiary experienced negative outcomes due to denial. So far, these surveys of 100-150 people a month have not turned up any problems. The response rate to these surveys is about 25 to 30 percent because, observers contend, many beneficiaries lack telephones or are suspicious of phone calls from strangers.

One study prepared for the Oklahoma Health Care Authority compared Medicaid costs for certain types of Medicaid beneficiaries before and after introduction of the state’s prior authorization requirements.³ The pre-post comparison showed that overall payments for medications, physician and hospital services decreased by 6.65 percent for users of NSAIDS, 3.48 percent for users of anti-ulcer drugs and 6.79 percent for users of both types of medications, compared to cost increases in a randomly selected control group not using these types of medications. However, use of hospital inpatient services increased for some types of beneficiaries. When examining prescription drug costs only, expenditures declined by .26 percent for NSAID users, 6.84 percent for anti-ulcer users and 4.24 percent for users of both types of medications. . A critic of the study asserted that the cost analysis of Medicaid beneficiaries’ total health care costs

did not include nursing home expenditures or the costs of the prior authorization process itself.

Observers' Perspectives on Prior Authorization

Most stakeholders are generally supportive of Medicaid's prior authorization processes, in part because most other payers have similar procedures. However, there are some complaints related to the paperwork burden and some fears about whether reimbursement will be forthcoming when emergency prescriptions are filled. One provider group believed that the process is useful in educating practitioners about less expensive alternative therapies. The state's system is considered a relatively good one because operations are, for the most part, smooth, and criteria for prior authorization are reasonable and well thought out. The fact that pharmacists staff the process and control denials is another plus in most stakeholders' opinions.

Medicaid Managed Care Plans and their Prior Authorization Procedures

About one-third of Medicaid beneficiaries are in capitated managed care plans and another third are enrolled in the state's primary care/case management program. In urban areas, beneficiaries are generally enrolled in managed care organizations, where there are no limits on the number of prescriptions they may receive. However, in Oklahoma's rural areas, which are served primarily by a primary case management program, beneficiaries have a limit of three prescriptions per month, although the prescriptions can be filled for up to 100 units or 34 days, whichever is greater. State officials point out that, if a patient is taking several medications only once per day, they can "stagger" their prescriptions up to a total of nine medications a month. Despite the ability to stagger medications, there is a two-tiered Medicaid pharmaceutical benefit -- one for fee-for-service beneficiaries and the other for managed care enrollees. However, not all aged and disabled beneficiaries who remain in fee-for-service Medicaid are subject to this limit because some are nursing home eligible and thus exempt. These nursing home eligible beneficiaries are either enrolled in the state's home and community services waiver or are residents of a long term care facility.

Medicaid managed care plans must make all medications Medicaid covers available to beneficiaries but they can impose prior authorization requirements, promote generics, and require practitioner documentation of the need for certain medications. Prior authorization requirements can only be imposed when there are at least two

medications available in a therapeutic class. There are no rules governing the prior authorization processes plans use. The processes can vary within plans by type of medication and among plans. Most plans rely on a pharmaceutical benefit manager to manage their prescription drug benefits.

The Drug Utilization Review Board must review all plan formularies, prior authorization processes, and changes to them, while the Oklahoma Health Care Authority retains final approval over changes to the plans' procedures. The state conducts on-site audits of managed care plans at least twice a year, reviews a random sample of complaints at least annually, and has an independent private agency do a quality review once a year. These reviews are done using the Quality Improvement System for Managed Care (QISMC) – a quality improvement system for managed care that the federal government developed.

Complaints about managed care plans revolve around errors. For example, a plan was said to have mistakenly informed pharmacists that it would not cover a mental health drug. This decision had been made for the commercial line of business but had been transmitted to pharmacists as a change that also applied to Medicaid beneficiaries.

Observers' Recommendations

Most stakeholders had few recommendations for improvement to Oklahoma's prior authorization procedures. A key recommendation from one stakeholder to other states considering prior authorization was to have the patient's claims history available to decision-makers and to have one entity handle all interactions with pharmacists so they do not have to make numerous phone calls to determine why a claim has been rejected (e.g., lack of Medicaid eligibility or coverage, or a prior authorization requirement).

Several stakeholders recommended weighing the cost savings of the prior authorization process against other costs to the system such as the potential for increased doctor and hospital visits. Disease management and educational efforts directed toward providers with prescription writing practices outside the norm were also recommended.

Oregon's Prior Authorization Process for Prescription Drugs And the Preferred Drug List

Oregon's approach to managing Medicaid prescription drug use has three interacting elements: a standard prior authorization process, limitations on coverage imposed by the Oregon Health Plan, and the Practitioner-Managed Prescription Drug Plan for those in fee-for-service Medicaid. The state has had at least some standard prior authorization requirements in place for such medications as growth hormones since 1993; now about 20 categories of medications are subject to this process.

The Oregon Health Plan (OHP) was implemented in 1994. The OHP operates under an 1115 demonstration waiver and uses a prioritized list of condition/treatment pairs to define the benefit package under its fee-for-service Medicaid program. Effective treatments based on the value to society overall are prioritized near the top of the list, treatments that don't meet this criteria are prioritized lower on the list (cosmetic services, infertility treatment, viral sore throat, etc.). Drugs are not included on the prioritized list as they are considered an ancillary service. Thus, drugs for the treatment of a non-covered condition are not covered. For example, non-sedating antihistamines are not covered if a person only has allergic rhinitis.

Oregon's latest effort – the Practitioner Managed Prescription Drug Plan (PMPDP) – is designed to educate practitioners about cost-effective prescription writing practices rather than imposing additional prior authorization requirements. The PMPDP first identifies clinically effective drugs within a therapeutic class and then, among these drugs, the program identifies the most cost effective medications. The program then educates physicians about these medications, in the hope that this will contain Medicaid fee-for-service prescription drug costs. Physicians can prescribe medications that do not appear on PMPDP's list simply by indicating this on the prescription. There is no further review of the physician's decision.

A series of financial pressures lead Oregon to develop the new plan. In the 2001-03 biennium Oregon saw its drug budget grow by 60% from the 1999-01 biennium. The state was spending more on drugs than any other area of health care. Finally, because of Oregon's heavy reliance on the income tax, the state is facing a particularly severe budget crisis due to the economic downturn. The state hopes to save \$7 million in state funds in the first year after implementation of the PMPDP.⁴

Standard Prior Authorization Process

The state has long imposed prior authorization on certain medications, over time amounting to about 20 drugs in such categories as non-sedating antihistamines, Accutane/Retin A (acne medications), oral/nutritional supplements, selected anti-fungals, weight reduction drugs, and narcotics. The state also has quantity limits, which are in place to assure appropriate use of the medications, on certain nasal sprays and non-steroidal anti-inflammatory drugs, and is planning to require prior authorization on certain muscle relaxants and benzodiazepines because these medications are prone to abuse.

When a beneficiary presents a prescription to the pharmacist, a hard edit will come up if prior authorization is necessary. Unless the physician has already obtained prior authorization, the pharmacist contacts the prescriber, who then must call First Health – Oregon Medicaid's pharmaceutical benefit manager – for approval. If First Health denies the prescription, then the beneficiary can appeal to Medicaid's Medical Director and, if denied, can request a formal hearing.

Provider education for the standard prior authorization process involves monthly newsletters and provider notices to pharmacists and doctors. For the two new prior

authorization requirements – muscle relaxants and benodiazepines – the state will also identify high prescribing practitioners and educate them about the new requirements.

Issues arising from the standard prior authorization process include beneficiaries having to make multiple trips to the pharmacy or to the practitioner if he or she has not obtained prior authorization. Stakeholders consider this to be particularly burdensome for people who are aged or disabled or who have transportation difficulties.

Development of Oregon's Practitioner-Managed Prescription Drug Plan

Over time, most beneficiary and provider groups became convinced that fee-for-service prescription drug costs were going to crowd out other needed benefits or would prevent provider payment increases. The governor responded to these concerns and asked Dr. John Santa, head of the state's health policy office, to convene a group of key stakeholders to consider cost containment options.

The state was successful in building a broad coalition of providers, payers, and advocates to support the PMPDP, including physicians, unions, business, some but not all consumer advocates, hospitals, and some of the major health plans in the state. Stakeholders agreed that manufacturers opposed the effort and pharmacists remained neutral about the plan. Those consumer advocates opposing the plan generally represented disease groups.

Physician groups supported the PMPDP because it meets certain conditions important to their constituents including: 1) physicians can easily write a prescription for a drug that does not appear on the preferred drug list (PDL) on medical necessity grounds; and, 2) the medications that appear on the PDL do so based on clinical evidence about their efficacy; with cost as a secondary concern. Physicians also wanted to avoid additional administrative burdens on their practices.

Beneficiary and labor groups generally supported the PMPDP while other beneficiary groups, working with manufacturers, were key to getting exemptions for psychiatric medications, and drugs that treat HIV/AIDS and cancer.

The manufacturers initially participated in discussions about methods of containing prescription drug costs but ended up opposing the legislation. Most stakeholders said that the manufacturers were instrumental in keeping HB 3300, the legislation authorizing PMPDP, locked up in legislative committees. Not until the governor threatened to veto the entire Department of Human Services budget did the House and Senate agree to "closed-door negotiations" between the governor and

legislators to come up with SB 819, which contained the exemptions from the PMPDP, such as psychiatric medications. Stakeholders expect the manufacturers may try to repeal the law through an initiative process.

Pharmacists objected to a prior authorization process in the absence of broader cost containment measures, because of the increased workload for pharmacists. However, their association remained neutral on SB 819 because the final legislation did not impose prior authorization.

The state is in the process of implementing other measures such as disease management programs, and a pharmacy lock-in program that would help manage the medications of Medicaid beneficiaries who use a high number of prescriptions. The state is also considering whether to extend the PMPDP to other groups such as state employees. While the state would like all Medicaid managed care plans to use the PMPDP's preferred drug list, plans will not be forced to do so.

Development of the Preferred Drug List

The goal of the PMPDP system is to contain Medicaid fee-for-service prescription drug costs by creating a preferred drug list containing the most clinically effective, least expensive medications. Oregon modeled its approach to determining the list after British Columbia's system and the consensus method the state used to develop the Oregon Health Plan's list of covered services.

The Health Resources Commission was given the task of making recommendations to the Department of Human Services regarding the most effective drugs in each therapeutic class under consideration. The Commission, which is composed of pharmacists, doctors, citizens, and consumers created four subcommittees that started by analyzing non-steroidal anti-inflammatory drugs (NSAIDs), cholesterol drugs, anti-ulcer medications, and long-acting analgesics. State officials and stakeholders cited several different reasons for choosing these categories. The state focused on these four first because there are many clinically effective alternatives within each therapeutic class and large price differentials among the medications. Stakeholders added that utilization of and expenditures for medications played a role in the choice of categories.

The subcommittees are composed of clinical experts – pharmacists, physicians, and nurse practitioners – as well as “disease advocates” who only evaluate the clinical effectiveness of medications. Between 50 to 75 physicians served on these four

subcommittees voluntarily. The subcommittees' information came from objective reports on clinical evidence that Oregon Health and Sciences University Evidence-Based Practice Center (OHSU-EPC) prepared. Manufacturers were able to present evidence to these subcommittees, but had to do so must do so using a specified format.

After receiving subcommittee recommendations in the spring and summer of 2002, the Commission made its recommendations to Medicaid regarding the effectiveness of each drug in each therapeutic class; recommendations were based solely on evidence about clinical efficacy. Medicaid then took into account price when determining the benchmark drug. This drug and any other effective drugs in the class with a price near the benchmark are included in Medicaid's preferred drug list. If pharmaceutical manufacturers are willing to offer rebates that bring the price of their medications at or below the benchmark, the drugs will be added to the list only if they are found to be therapeutically effective. The list will evolve over time by the addition and reevaluation of therapeutic categories.

Description of the PMPDP Process

The PMPDP plan began on July 1, 2002 by providing pharmacists with a "soft edit," saying that a prescription is not on the preferred drug list and in the future the prescriber would need to approve an exception for the drug. These soft edits or warnings did not require any action on the part of the pharmacist but were part of the state's education program about PMPDP. Effective August 1, 2002, a hard edit was added that denies the prescription unless the prescriber has approved an exception. When these hard edits occur, the pharmacist must call the doctor's office and educate the doctor about the alternatives that are on the preferred drug list or ask that the doctor indicate that the prescription is an exception. All the doctor has to do is fax a copy of a prescription with a note to dispense as written, the acronym BMN (brand medically necessary) or similar language. This procedure is modeled on the method Medicaid practitioners use to override Medicaid generic substitution rules. Prescribers have the option of making special arrangements with pharmacists to have them substitute medications on the preferred drug list automatically under certain conditions. State officials and most stakeholders contend that there is no need for emergency or appeals procedures because practitioners can easily override the hard edits.

Education about the New PMPDP

The education plan commenced during the Governor's speech to an audience composed of Oregon and Washington officials, managed care plans, pharmaceutical benefit manufacturers, physicians, and legislators on May 17, 2002. The state also held meetings with provider groups throughout the state to educate them about the new system and sent the preferred drug list to every physician office and pharmacist in the state.

PMPDP Monitoring

Although there are no formal plans to monitor the effects of the PMPDP on beneficiaries, pharmacists, or practitioners, the program will receive and respond to complaints from providers and others. First Health will also provide reports to the state detailing how prescribing practices change over time.

Medicaid Managed Care Plans and their Prior Authorization Procedures

About 75 percent of Oregon's Medicaid beneficiaries are enrolled in managed care plans under the Oregon Health Plan. The Plan operates under a 1115 waiver that requires managed care plans to cover "condition and treatment pairs," which include the medications that are part of the treatment. There are no contractual requirements regarding availability of specific medications so plans are free to have formularies but must have an prior authorization process that follows federal requirements. Kathy Weaver, M.D. from the staff of the Health Resources Commission reported on five plans' formularies for eight classes of drugs.⁵ The report noted great variability in the medications on the formularies and that some new medications such as COX-2 inhibitors did not appear in some formularies.

Medicaid has staff who each monitor 5 or 6 managed care plans to determine whether they are complying with contractual requirements; staff meet regularly with plans and go on-site to monitor compliance with requirements. Staff find out about beneficiary experiences because plans must report all enrollee grievances to the state and Oregon has a client advocate program for managed care enrollees with a toll-free number. The state also conducts beneficiary satisfaction surveys using the Consumer Assessment of Health Plans, which the federal government developed. Finally, enrollees can resort to a fair hearing process before an administrative law judge if they are not satisfied with their benefits.

It is important to note that mental health drugs are carved out of Medicaid managed care plans' capitated payments, so plans do not manage this category of expenditures for their Medicaid enrollees.

Observers' Recommendations

Most stakeholders agreed that states considering Oregon's approach should engage in an open decision-making process with stakeholder participation based on clinical evidence about the efficacy of medications. Practitioner education about efforts such as Oregon's also should include evidence that changing prescribing practices can contain costs without harming patients and trusted opinion leaders should present this evidence. These steps were seen as crucial to the integrity of any program.

Stakeholder groups had opposing recommendations about disease management. While one group advocated disease management programs that involve "one on one" education where professionals coach patients about the management of their conditions, another group opposed them because of the layer such programs can impose between practitioner and patient.

Washington's Prior Authorization Process for Medicaid Prescription Drugs

Since the early 1990s, Washington has used prior authorization to help control prescription drug costs for Medicaid's fee-for-service beneficiaries. This state has one of the more complex approaches among the five study states, combining prior authorization for several thousand drugs, an expedited review process for other drugs, and a new Therapeutic Consultation Service (TCS). TCS involves reviews of all of a beneficiary's prescriptions under certain circumstances; some stakeholders have objected to the glitches surrounding implementation of this process in 2002. All of these procedures have evolved in reaction to concerns about burdensome paperwork requirements, patient safety, and escalating drug costs. Medicaid managed care plans are able to create their own formularies and prior authorization processes, which primarily affect Medicaid families; most aged and disabled Medicaid beneficiaries remain in the fee-for-service system. The major concerns about plans' processes are the problems that can arise when an enrollee needs medications for a mental health condition.

Evolution of Prior Authorization in Washington

Washington established its prior authorization process in 1993 to contain costs and ensure that prescription drugs are used appropriately. The state has changed its process several times in response to problems and complaints. Between 1993 and 1994, the state required prior authorization for manufacturers' products when the manufacturers did not agree to a supplemental state rebate, in addition to the standard federal rebate. This requirement ended when the legislature found that savings due to the process were less than expected. In the mid-1990s, the state instituted an expedited review process for drugs where immediate access is critical for patients; this occurred in response to provider complaints about the burdensome nature of the prior authorization process and concerns about beneficiaries having immediate access to certain drugs. Currently, about 140 drugs can have expedited reviews. In the late 1990s, the state imposed prior authorization on most drugs carrying a black box warning, meaning that misuse of these drugs could seriously harm or kill patients; about 400 drugs require prior authorization for this reason. Currently about 3000 drugs require prior authorization, about 2000 of which are rarely prescribed.

In 2002, groups representing doctors, pharmacists, unions, nurses and many consumer groups proposed a state preferred drug list that would offer an additional way of containing pharmacy costs. Senate Bill (SB) 6368 would have created a preferred drug list with a “reference drug” in each therapeutic class, chosen for its clinical effectiveness. Other drugs could have gone on the preferred drug list if their manufacturers agreed to price medications no higher than the reference drugs. Doctors would have had the ability to prescribe a non-preferred drug if medically necessary. The legislation also would have applied to all state purchasers, including Medicaid, the state employee benefits system, other state medical assistance programs, and worker compensation, which is operated by Washington state.

The broad support for SB 6368 stemmed from fear of the benefit and provider payment cuts that could have resulted from failure to control Medicaid prescription drug cost increases and some stakeholders believed that the bill would have introduced some competition among manufacturers. SB 6368 died without a final vote in the House and most stakeholders believe that the biotechnology industry, in cooperation with manufacturers, was largely responsible. Other opponents of the bill included advocates for persons with mental health conditions, some advocacy groups representing minorities, and some business groups.

Despite the bill’s failure, the state Medicaid program was able to preserve some of its goals in the TCS, which applies to about 437,000 fee-for-service patients. Each month, TCS flags the 15,000-17,000 of these beneficiaries who attempt to fill more than four brand name prescriptions in a month.⁶ Under TCS, an attempt to fill a fifth brand name prescription or a prescription for a drug that does not appear on the preferred drug list triggers a consultation between a clinical pharmacist and the prescriber. The consultation involves a review of lower-cost alternatives as well as patients’ entire drug-use history. This gives the prescriber a chance to review the prescription in context and to consider drug interactions and other potential problems. The practitioner retains the final authority over the prescription.

Role of the Drug Utilization and Education Committee in Determining the Medications Subject to Prior Authorization and TCS

Every new drug is initially subject to Medicaid prior authorization and the state considers whether to maintain the requirement on a case-by-case basis. The state has two types of reviews that can affect the final decision. Medicaid’s internal drug utilization

review team first analyzes the clinical research on new drugs and makes preliminary recommendations about prior authorization. If Medicaid considers it necessary, the program's Drug Utilization and Education Committee (DUEC) will receive information about the new drugs and have the opportunity to make its own recommendations about the appropriate use of medications. The DUEC has three physicians, three pharmacists, one nurse practitioner, and one physician assistant. A patient advocate does not sit on the Committee but serves as a resource. Meetings include time for manufacturers and stakeholders to comment on the committee's deliberations or actions. The DUEC considers three criteria when making recommendations – potential for misuse, potential for abuse, and whether the drug has a narrow therapeutic index. Medicaid considers the Committee's recommendations and cost when making its final decision about prior authorization and TCS. Although the state relies on the DUEC for recommendations about the new TCS process, the state contracts with Washington State University's Drug Information Center to prepare clinical evidence about the drugs for the Committee.

Several stakeholders were critical of the DUEC decision-making process because Medicaid can ignore the Committee's advice. Another stakeholder complained that DUEC members do not have sufficient time to process the clinical evidence about the medications under consideration; state officials point out that committee materials are sent out a month in advance of the DUEC meetings for members' review.

The TCS preferred drug list encompasses two therapeutic classes of drugs: proton pump inhibitors and H2 antagonists. In addition, the program has launched a voluntary, preferred drug list that includes two new classes – non-sedating antihistamines, and statins. The addition of other therapeutic classes to this voluntary process is under consideration.

The drugs appearing on TCS' preferred drug list are those within each category that have the lowest cost among therapeutically equivalent drugs; generics are automatically on the preferred drug list. The following classes of drugs are currently exempt from TCS: anti-psychotics, anti-depressants, contraceptives, anti-convulsants, HIV drugs, chemotherapy drugs, immunosuppressants, and anti-hypoglycemics.

Prior Authorization Processes and TCS

The standard prior authorization process, the expedited review process, and the TCS work differently. The standard process largely relies on pharmacists calling the physician, obtaining the reasons for the prescription, and then calling Medicaid to get an

override number. Some pharmacists are “pushing back” by putting the onus on the physician to contact Medicaid for the number. The state staffs the standard process with four full-time equivalent staff who receive on-the-job training. A registered nurse manages this staff and a pharmacist is available for consultation. If the state denies the prescription, the patient gets a written denial that can be appealed to an administrative law judge. Critics say the biggest problem with the standard process is that thousands of drugs require authorization and most get approved, resulting in a “virtually meaningless exercise for pharmacists.” The state defends the system by pointing out that it oversees what otherwise would be an uncontrolled flow of high-priced and potentially troublesome medications. Although most prescriptions are authorized, a small but significant number are not. In addition, prior authorization guides appropriate use of medications by tracking beneficiaries’ use of prescriptions and practitioners’ prescription writing practices.

Most stakeholders prefer the expedited review process, which permits the local pharmacist to determine whether a patient meets certain pre-set criteria for appropriate use of 140 drugs. When the pharmacist receives a prescription for one of these drugs, the pharmacist is allowed to determine whether the patient’s condition meets the criteria for approval of the prescription. In the course of this process, the local pharmacist may (but is not required to) gather information from the prescribing physician. About 70 percent of prescriptions are approved in this way; the rest go through the standard prior authorization process.

TCS, which began in February 2002, requires that ACS – the Medicaid pharmaceutical benefit manager – assess the beneficiary’s entire set of medications if his or her prescription triggers a review. The pharmacist then must consult with the prescriber and provide information about generic or therapeutic alternatives to the patient’s brand-name prescriptions. The practitioner has the authority to insist that the patient get the original prescription; when this happens, ACS notifies the pharmacist that the prescription can be filled. Because prescribers retain this authority, TCS does not have an appeals process. Contract provisions require the company to dedicate at least six pharmacists to Washington state’s TCS program. In the first few months after TCS’ implementation, the system was generating enough consultations that the contractor had to dedicate as many as 27 pharmacists to the process. The volume of consultations had decreased by the fall of 2002, according to state officials.

The emergency procedures are the same for the prior authorization processes and TCS. Under Washington law, the pharmacist can decide that a prescription is an emergency and supply the quantity of medications necessary to meet that urgent situation. The pharmacist will be reimbursed for the emergency supply even if the drug is later denied, provided the pharmacist contacts the department, reports the decision, and files for reimbursement within 72 hours of providing an emergency supply. Some stakeholders report that pharmacists are still afraid of not being reimbursed and often are unwilling to supply emergency medications. State officials say that when this complaint surfaced as an early criticism of TCS, the Medicaid program countered it publicly by describing the emergency supply rules, distributing a news release clarifying pharmacists' authority, and outlining the reimbursement procedure.

Education about Prior Authorization and TCS

Education about changes to the standard and expedited processes is basic while education about TCS is more complex. Information on changes to the first two processes goes on the first page of providers' reimbursement statements each month. Some stakeholders said that these messages are difficult to read and pharmacists often learn about changes only when they run up against hard edits at the point of sale.

Physicians and pharmacists received information about the new TCS system from memoranda the state mailed out in December 2001. Ongoing education associated with TCS has two features. Up to 1,000 of the state's heaviest users of prescriptions are identified monthly and their records analyzed so that TCS pharmacists can consult with the patients' prescribers about proper use of medications and any potential problems. The program also has clinical pharmacists on the road in Washington State, conducting face-to-face discussions with Washington prescribers in their offices about new or cost-efficient medications and helping to prevent problems. State officials report that TCS pharmacists have received generally positive reception in physician offices.

Monitoring of the Prior Authorization Processes and TCS

Monitoring of all the processes relies on receipt of complaints. However, the state plans to contract with an outside research group to assess the TCS program's effects on pharmacists, physicians, and beneficiaries. TCS cost-savings data have not yet been publicized, although the state maintains savings appear to be on target with the expectations -- approximately \$12 million a year in state funds. State budget analysts

say Medicaid pharmacy data requires at least a five-month lag between receipt of claims and analysis to ensure accuracy and analysts need six months of data to validate a trend. These factors mean that it may be early in 2003 before the program can identify any savings with precision.

Observers' Perspectives on Prior Authorization and TCS

Stakeholder complaints about the prior authorization processes and TCS' implementation centered on the administrative burden for providers and their resulting avoidance behavior. Beneficiary complaints about problems accessing their medications mostly related to TCS. Initially, providers opposed TCS because of their belief that it would prove to be burdensome and providers complained that the Department implemented it with very little discussion or education of providers. During TCS' initial months of operation, many physicians complained that they were not able to contact the clinical pharmacists and wasted time on hold or waiting for callbacks. State officials said that these complaints declined over time as the system ironed out wrinkles and solved problems. In recent months, the state contends that pharmacists and physicians have found TCS somewhat less burdensome than they had feared.

According to state officials, during the first month of TCS' operation, ACS received about 6000 phone calls, many more than originally anticipated. Statistics for February 2002 showed that average answering speed was almost three minutes with an average abandonment time on the part of prescribers of almost two minutes. The heaviest call volume was due to problems with dual eligibles' prescriptions. In reaction to these problems, after the first month, HIV patients were excluded from TCS, dual eligibles were temporarily excluded, and pharmacies were allowed to call TCS for authorization for emergency prescriptions.

In March 2002, phone calls were answered on average after 30 seconds, and calls lasted on average three minutes. The situation continued to improve in April, May and June, with wait times stabilizing. By June, the figure had fallen to 14 seconds, with call lengths still averaging three to four minutes. Fewer complaints are being fielded; in February 2002, Medicaid's pharmacy section received 51 TCS complaints from prescribers but the number of complaints decreased over time to reach five in August 2002.

Some of the initial problems with TCS appear to have created avoidance behavior among some providers. Since physicians face multiple, public and private prior

authorization processes, formularies, and other procedures related to their patients' prescriptions, they tend to find out about a problem when they run up against it and then change prescriptions to avoid the procedures. One example given was of a patient with eight or nine drugs who brushed up against the four brand name prescription threshold; the physician switched as many prescriptions as possible to generics to avoid TCS altogether.

The threshold appears to be problematic for consumers too. An example given was of a patient who appeared at the pharmacy, found she was subject to TCS and then had to visit her doctor to change her brand name drugs to generics. Use of two of the generics failed, requiring yet another visit to her doctor. Some patients also have difficulty getting transportation to their providers so that multiple trips to pharmacies and physicians are problematic.

Some stakeholders did point to a benefit of the four brand name threshold, noting it triggers a comprehensive review of the patient's drug regimen to determine if there are any polypharmacy concerns. They also said that physician education is an important aspect of the process.

Medicaid Managed Care Plans and their Prior Authorization Procedures

Managed care plans must cover at least one drug in every therapeutic class that Medicaid covers. Once a year the state reviews each plan's formulary for compliance and must approve any changes to it in the interim. Plans must also submit information about their prior authorization processes to the state. Plans have flexibility in creating their formularies and the trend is for managed care plans to rely more on strict formularies and less on prior authorization because this is an expensive process requiring medical judgment. One stakeholder asserted that HMOs are largely monitored through receipt of complaints.

Some stakeholders said that they had heard few complaints about the managed care plans' formularies, perhaps because most of the beneficiaries in the plans are children and do not use many medications. Aged and disabled beneficiaries largely do not participate in managed care plans and are the clients most likely to have multiple prescriptions.

There appears to be some difficulty in coordinating Medicaid managed care plan enrollees' use of mental health medications with the managed behavioral health contract the state has for some mental health services. The pharmacist is not always aware that

the beneficiary is entitled to certain medications through the managed behavioral health entity. Additional coordination problems result from the fact that managed care plans are only financially responsible for the mental health services and drugs that can be delivered in 12 outpatient visits. This means some clients with severe and persistent mental illness who participate in managed care plans take their prescriptions to pharmacists who then bill the managed care plans, when the plan is not financially responsible for the prescription. Acknowledgement of this problem appears to be widespread but a workable solution has not yet been found.

In the latest managed care development, the state started disease management plans for diabetes and asthma in 2000, which could lead to some drug cost savings. The state is requiring that these plans more intensively manage patients with multiple conditions, seeing that they receive timely and cost-efficient treatment.

Observers' Recommendations

Some stakeholders would like to have as much standardization as possible across payers' formulary and review processes so as to reduce providers' administrative time and expenses. These groups also recommended that all stakeholders work together and take into account clinical evidence when determining how to contain Medicaid prescription drug costs. Stakeholders also recommended to other states that they educate those physicians with poor or costly prescription writing habits and target patients with potential polypharmacy problems for intervention.

¹ California State Auditor, Department of Health Services: Drug Treatment Authorization Requests Continue to Increase, August 2000. accessed on 5/17/02 from www.bsa.ca.gov/bsa/

² Kotzan Jeffrey A, Perri III Matthew, Martin Bradley C., "Assessment of Medicaid Prior-Approval Policies on Prescription Expenditures: Market Share Analysis of Medicaid and Cash Prescriptions," Journal of Managed Care Pharmacy, 1996, 2 651-656.

³ Narine Lutchie, Evaluation of the Effects of the Oklahoma Medicaid Program's Prior Authorization Policy on Nonsteroidal Anti-Inflammatory (NSAID) and Anti-Ulcer Medications, University of Oklahoma Health Sciences Center, prepared for the Oklahoma Health Care Authority July 27, 2001.

⁴ BNA Inc, Legislature, Governor Reach Compromise on Medicaid Prescription Formulary Plan, Pharmaceutical Law and Policy, vol.1 no.2, Thursday July 19, 2001. Downloaded from subscriber.bna.com/samples/plp.nsf/a190caa on 2/26/02.

⁵ Minutes from the Health Resources Commission Meeting on May 8, 2000 at the Clackamas Community Center. accessed on June 17, 2002 from http://www.ohppr.state.or.us/hrc/pdf/Min_05-08-00.PDF

⁶ Associated Press, "Medicaid Drug Plan a Worry for Doctors," Seattle Times February 01, 2002. accessed from seattletimes.nwsourc.com on 2/26/02.

Appendix 2
Interview Protocol and Discussion Guide for
Fee-for-Service Prior Authorization (PA) Processes

Process Development

1. How long has the state been using PA?
2. Why did the state decide to go with PA?
3. What are the PA process' goals?
4. What factors led to and affected the development of the state's PA process?
5. Who were the key actors in the development of the process and what were their positions regarding it? How do they view the PA process now?

Preferred Drug List/Formulary

1. How does the state determine which drugs require PA (i.e., are not on the formulary or preferred drug list)?
2. What is the composition of the pharmaceutical and therapeutics committee? How effectively has the committee operated? How are members of the P&T committee chosen? How often do they meet/have opportunities to change the list?
3. Which drugs require PA and why?
4. If drugs are not on the preferred list, are there arrangements manufacturers can make with the state to get their drugs on it?
5. Are there categories of drugs are exempt from PA? Which ones and why? Which stakeholders were responsible for these exemptions and what arguments did they use to obtain the exemptions?

Process Structure

1. How does PA work operationally for beneficiaries, physicians and pharmacists when patients want access to a non-preferred drug?
2. Who makes the decisions regarding whether to grant authorization and what are the decision-making guidelines?
3. What kind of patient protections (e.g., appeal rights) does the PA process have? Are these protections used?
4. Who staffs the PA process and how many staff are devoted to it?
5. What are the responsibilities of pharmacists regarding PA?

6. How does the state inform beneficiaries, physicians, and pharmacists about the PA process and any changes to it? How effective are these educational efforts?
7. How does PA interact with other utilization management strategies?
8. In emergency cases, who determines the emergency? How are emergency cases handled differently than other cases?

PA Process Monitoring

1. How is the state monitoring the effects of the PA process on beneficiaries, especially the aged and disabled?
2. How is the state monitoring the effects of the PA process on physicians, and pharmacists?
3. What data are available regarding requests for prior authorization and approval rates for non-preferred drugs?
4. What data are available regarding cost savings due to the PA process?
5. Can we obtain access to these data? If so, how?
6. Are there data regarding the administrative cost of PA?

Future Plans and Recommendations

1. Does the state anticipate changing the PA process? If so, how and why?
2. Does the state have any plans to use a PA process in other state programs providing drug benefits, such as to pharmaceutical assistance programs for Medicare beneficiaries or to the state employees' health plans?
3. Has the PA process (or the formulary/PDL) been subject to legal challenge and what is the status of this challenge?
4. Overall, how does PA rate as a utilization management tool? How could it be improved?
5. Are there any recommendations for states considering PA procedures?

Medicaid Managed Care Plans

1. What are the rules governing Medicaid managed care plans' formularies and PA processes?
2. How do these rules differ from those applicable to the fee-for-service system?
3. How does the state monitor managed care plans' compliance with the rules regarding formularies and PA processes?

4. How is the state monitoring the effects of managed care plans' formularies and PA processes on beneficiaries, physicians, and pharmacists?
5. What data does the state collect from managed care plans regarding their formularies, and PA processes?
6. Can we obtain access to these data? If so, how?

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