STATE MEDICAID PROGRAM ISSUES: PREFERRED DRUG LISTS

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Preferred Drug Lists Defined

In the Medicaid program, preferred drug lists (PDLs) indicate which drugs providers are permitted to prescribe without seeking prior authorization (PA). For drugs not included on the PDL, providers “must obtain approval from the state Medicaid agency (or its contractors) before a particular drug can be dispensed.”\(^1\) Decisions about which drugs to include on a PDL are usually based on the Medicaid program’s assessment of relative clinical benefit within a therapeutic class and judgment about the value to the state based on total cost, including all manufacturers’ rebates.

Background

States have used PA as a utilization management tool for many years; however, it was commonly reserved for specialized and/or high cost drugs. Recently, states have restricted access to commonly prescribed drugs to control costs.\(^2\) As of 2003, approximately 29 state Medicaid fee-for-service programs have obtained legislative approval for a PDL and/or are in the process of implementing a PDL with expanded PA.\(^3\) California, Florida, Michigan and Oregon were the first states to implement these programs and their experiences provide us with several important observations. Other states including Georgia, Oklahoma, and Washington have significantly expanded their PA programs providing useful data as reflected in case studies published by the Kaiser Commission on Medicaid and the Uninsured.\(^4\)

Medicaid fee-for-service beneficiaries typically have different demographic characteristics and disease prevalence than other beneficiaries, particularly those enrolled in Medicaid managed care and commercial health plans. National data from the Centers for Medicare and Medicaid Services (CMS) show 86 percent of all prescription drug expenditures in fee-for-service Medicaid programs is spent on the elderly, blind/disabled and medically needy. These beneficiaries have multiple chronic diseases that require patients to take numerous medications for appropriate treatment. Their more costly annual per patient drug expenditures are evident in the expenditure comparisons in Figure 1.

**Figure 1. National Medicaid Drug Expenditures, 2000\(^a\)**

Aged/Blind/Disabled + Medically Needy = 86% of Drug Expenditures

<table>
<thead>
<tr>
<th>% Expenditures by Eligibility Group of Drug Recipients(^a)</th>
<th>Average Annual $ per Drug Recipient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aged 23%</td>
<td>$2,262</td>
</tr>
<tr>
<td>Blind or Disabled 53%</td>
<td>$1,871</td>
</tr>
<tr>
<td>Medically Needy 10%</td>
<td>$1,199</td>
</tr>
<tr>
<td>Children 7%</td>
<td>$359</td>
</tr>
<tr>
<td>Adults 6%</td>
<td>$189</td>
</tr>
</tbody>
</table>

Source: CMS, 2000 National Medicaid Statistical Information System Data
\(^a\)Data represent fee-for-service Medicaid population
\(^a\)Numbers do not add to 100 due to rounding
Published Program Principles and Models

Several recently published documents outline sound principles, regulatory requirements, case studies, and models for PDLs and PA programs. Publications by The National Patient Advocacy Foundation, and the Kaiser Commission on Medicaid and the Uninsured are cited below.

The National Patient Advocacy Foundation (NPAF) developed principles for PDL implementation to ensure that patient access to appropriate medications is not compromised. The principles state that PDLs should include sufficient options from all drug classes in each therapeutic category, and that drugs used by patients with chronic or life threatening diseases (e.g., mental illness, HIV/AIDS, cancer, diabetes) should automatically be included on the PDL and exempt from prior authorization. Additionally, the NPAF principles state that PDLs should recognize the expert judgment of physicians, allowing them to prescribe non-PDL drugs without prior authorization if that drug better addresses the “specific clinical situation and patient characteristics.”

A model prescription drug prior authorization process for state Medicaid programs was developed by the National Health Law Program and published by the Kaiser Commission on Medicaid and the Uninsured, which details appropriate procedures and policies to assist programs with federal compliance issues and clinically sound principles. The model includes basics of implementation and operations, due process procedures, health care provider relations, and monitoring and evaluation of the program. The model was developed with input from patient advocates, providers and state officials, and includes references to recent court cases, federal statutes, CMS guidance/communications to states, and other requirements.

Federal Approval Process

States are required to obtain CMS approval for prior authorization programs by submitting a state plan amendment. If a state already has CMS approval for its PA program and, for the first time, would like to use its PA authority to obtain supplemental rebates, it must amend the state plan and resubmit for CMS approval. Supplemental rebates are rebates in addition to the federally required rebates necessary for coverage by state Medicaid programs. Many states also require legislative authority to create and enforce a PDL.

Federal Provisions for Patient Protection

Patient protections are built into the federal Medicaid Act, which requires states to follow “due process” when prescriptions are “denied, reduced, terminated, or delayed.” Due process involves issuing a notice of fair hearing and appeal procedures to each beneficiary/patient when a claim is denied or is not acted upon with reasonable promptness. Patients have the right to receive continued benefits pending the result of a hearing, and must be given prompt access to all covered treatments under the state Medicaid program. Services should only be denied pursuant to an individualized determination of medical necessity and in compliance with due process.

However, some states have failed to comply with these requirements in the administration of pharmacy benefits by not offering patients the right to appeal pharmacy claims denied at the point of care. This common practice was finally challenged following the implementation of a PDL and prescription limit policy in the patient lawsuit, Hernandez v. Meadows, filed against the Florida Medicaid agency. This lawsuit, certified as class action, was settled by the parties stipulating the following provisions:

• Patients will receive written notice of denial at the point of sale in the pharmacy.
• Services of an ombudsman under contract with the Agency will be required to mediate resolution of any denials or complaints, and to provide assistance with fair hearing requests.
• Notice of their right to fair hearing will be provided to patients at the time of notice of denial.
• A temporary medication supply to cover three business days will be dispensed in the event of a claim rejection.
• Ongoing claim reimbursement (for continuation of therapy) will be provided after a hearing is requested and while awaiting a hearing decision.
• All Medicaid HMOs will be required to comply with the settlement provisions or provide functional equivalents in the new contracts with the Agency beginning 2004.

Patient Access and Safety

Despite federal provisions, some patients have experienced access and quality of care problems with PDLs, which have resulted in increased health care costs and, in some cases, serious harm. These cases are described in the Kaiser Commission on Medicaid and the Uninsured: Michigan Case Study Report and Multi-State Case Studies Report and the Florida patient lawsuit, Hernandez v. Meadows.

The Kaiser Report on Michigan’s PDL program details examples of patients who did not receive their medications and were hospitalized due to denied access and operational failures during the onset of the PA process. A detailed flow chart in that report depicts the complex process required to obtain prior approval for non-PDL drugs. Some Florida Medicaid patients experienced problems that are detailed in the class action suit, Hernandez v. Meadows, and in various news publications. For example, patients were denied critical anti-infective drugs used to prevent organ transplant rejections and other life saving drugs, resulting in organ rejections, unnecessary hospitalizations, and other negative clinical events.

Provider Issues

Administrative burdens and increased costs for providers have been routinely documented. In fact, high volume providers have reported hiring extra office staff to process the required paperwork, coordinate with other providers, and make phone calls to request exceptions for non-PDL drugs. Providers have also noted the need for increased office visits and lab tests to re-stabilize patients when changing the complicated drug regimens of this primarily elderly and disabled population. Providers surveyed in the Michigan program complained that the administrative burdens took time away from direct patient care and harmed vulnerable patients.

Surveyed providers suggested automating the PA process as much as possible by utilizing new technology (e.g., Internet based communications and on-line prescribing) to reduce unnecessary delays in treatment and to reduce provider workload. Another suggestion was to limit the number of times a year that changes can be made to the PDL, except for the addition of new drugs. The provider community desires easily accessible and frequently communicated PDL updates using Internet sites, quick reference cards, and other periodic provider communications.

Provider groups have been studying PA programs and their effects for several years. The American Medical Association (AMA) has defined criteria for prescription drug cost containment programs such as PDLs, formularies and prior authorization programs. The AMA policy states that physicians should have significant input into the development and maintenance of such programs to ensure optimum prescribing practices and quality of care. The AMA policy further states that such programs should allow all patients to have access to all prescription drugs necessary to treat their illnesses; and should give physicians the freedom to prescribe the most appropriate drugs and methods of delivery for the individual patient.
Administrative Policy and Operational Procedures

PDL implementation requires a substantial administrative burden associated with negotiating supplemental rebates with manufacturers for each drug. Additional employees or an outside contractor have been necessary to date in states that have implemented a PDL. Other issues requiring administrative resources include programming and system changes to create restrictions on non-PDL drugs. These changes can be expensive and must be included in the direct administrative costs.

State Medicaid agencies should also consider policies regarding the grandfathering of current patient therapy and the exemption of specific drug categories and high-risk patient groups. Patients stabilized on a drug regimen should not be switched to a different drug without prescriber approval. Many providers and patient advocates believe current patient therapy should be grandfathered and only new patients or new therapies should fall under PDL restrictions. For example, some states have implemented exemptions for patients who are being treated for mental health conditions, HIV, cancer, and other extremely fragile conditions, as well as patients who are post-transplant. This approach might have prevented the problems cited in the Florida patient lawsuit and Michigan program surveys.

Preferred Drug List Selection Process

States developing a PDL should structure a clinically sound approach and consider the demographics, disease conditions, and current utilization characteristics of the elderly, blind and disabled and medically needy population most often subjected to prescribing limitations and policies. A pharmacy and therapeutics (P&T) committee often selects the drugs placed on a PDL. States should appoint a P&T committee that includes clinicians with experience in Medicaid populations, including experts in the management of geriatric and disabled patients with complex health care needs. P&T committees should allow adequate time to take testimony and receive input from providers, patient advocates, and experts in pharmacology during the decision-making process. These deliberations and decisions should be open to the public, and vendors that support the P&T process should operate with transparency. The PDL should provide an adequate array of medicines in each therapeutic category to assure that patients can be treated effectively with those choices. States that establish an arbitrary small number of preferred drugs in a category are assuring that a significant number of patients will find that the choices available to them may be ineffective or cause intolerable side effects. In addition, the state will incur excessive administrative costs due to providers requesting numerous exemptions to the PDL.

Savings Estimates

The top therapeutic drug classes by expenditure include mental health (antipsychotics, anticonvulsants, and antidepressants), organ transplant, diabetes, and anti-viral drugs. Because these drugs are used by patients with chronic or life-threatening diseases, both the NPAF Principles for Implementation of PDLs and the Kaiser Model Prescription Drug Prior Authorization Process for State Medicaid Programs recommend these drugs be exempt from prior authorization. When these medications are appropriately exempted, PDL restrictions attempt to produce savings in a much smaller segment of the drug budget.

On average, states already collect Medicaid rebates equal to approximately 20 percent of their total annual drug expenditures.15 The savings accrued from additional rebates in the PDL program will be reduced by increased administrative costs, additional patient follow up to address potential clinical events, and patient and manufacturer lawsuits. States are also required to refund to the federal government a percentage of those rebates equal to their current Federal Medical Assistance Percentage (FMAP) rate. That rate currently ranges from 50 to 75 percent.16
**Contract and Payment Collection Issues**

Administrative resources needed to develop and administer a PDL/supplemental rebate program are significant. Most states will choose to procure a vendor to perform the negotiations between the parties and complete the legal agreements which can take many months due to the process complexity. States that procure a vendor through a competitive bid process must obtain CMS approval, another potentially lengthy process. The federal law requires that rebate payments be calculated at the end of each quarter based on prior utilization data. This process results in rebates not actually being received from the manufacturer for six months or more following the end of each quarter. These unavoidable delays — in negotiations, rebate reporting and collection — can affect budgets that are accruing administrative costs within the current fiscal year. States must anticipate longer time frames for any savings to actually occur.17

**Program Evaluations**

Programs implemented to control costs and/or limit utilization of services should be formally and regularly evaluated. This includes PA, PDLs, and any other programs that restrict access to services (e.g., co-payments, step-therapy and prescription limits). The development of an internal continuous quality improvement (CQI) plan is imperative for program evaluation. In addition, regular provider and patient surveys can help to identify and target problems quickly and efficiently.

States should periodically review denial/approval reports for prescription claims, making special note of specific therapeutic class/product denials and approvals. States should evaluate the appropriateness of drug therapy limitations for patients with chronic diseases and high severity-of-illness indicators and modify cost control policies/programs as necessary to ensure continuity and quality of care, as well as impact on total health care costs.

States are encouraged to allow independent, external evaluations of programs that take a broader and more scientific approach in their methods. These evaluations would include measures and statistical methods to examine system-wide administrative and service costs, adverse clinical events, and service utilization shifts that could be correlated with policy changes affecting access to pharmaceuticals. Additionally, state and federal officials should collaborate on these evaluations since many of the affected are elderly and blind/disabled patients with dual coverage under Medicaid and Medicare. Medicare may often be the payor with the most at risk from cost shifting of pharmaceutical expenditures at the state level to other more costly services covered under Medicare such as hospitalizations, emergency room and physician visits. For example, when a patient is denied a specific drug and required to change to a completely different drug the physician will appropriately schedule a follow up office visit and may prescribe lab work be done to ensure that the new drug is working properly and that the dosage of the new drug is correct. There are expenses associated with both the extra office visit and the requested lab work that shift savings from the Medicaid drug budget to Medicare covered medical services which may or may not be equally offset.
There are no formal studies to date that show significant savings in Medicaid programs’ total costs from implementing a PDL and some evidence that shows preferred drugs lists can adversely affect patient access and safety. Providers themselves have expressed concern about hampered access to appropriate medications. States already receive rebates that exceed the mandated minimum of 15.1 percent, and any savings accrued from rebates, mandated and supplemental, must be shared with the federal government. States must weigh the short and long term consequences of implementing a PDL by looking at other health care and non-health consequences of restricting access.

In summary, there are many issues for states considering the implementation of a preferred drug list with prior authorization and supplemental rebates. These issues — including federal plan approval, policies and operational procedures, regulatory compliance, patient access and safety, provider acceptance, contract negotiations, payment provisions, and program evaluations — must be addressed in depth and integrated into the state’s design and implementation plans in order to ensure both cost efficiency and quality of care.
