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# medicaid and the uninsured

State Medicaid Outpatient Prescription
Drug Policies: Findings from a National Survey,
2005 Update

Prepared by

Jeffrey S. Crowley and Deb Ashner Health Policy Institute, Georgetown University

and

Linda Elam, Kaiser Commission on Medicaid and the Uninsured



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The Kaiser Commission on Medicaid and the Uninsured provides information and analysis on health care coverage and access for the low income population, with a special focus on Medicaid's role and coverage of the uninsured. Begun in 1991 and based in the Kaiser Family Foundation's Washington, DC office, the Commission is the largest operating program of the Foundation. The Commission's work is conducted by Foundation staff under the guidance of a bipartisan group of national leaders and experts in health care and public policy.

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#### **ACKNOWLEDGMENTS**

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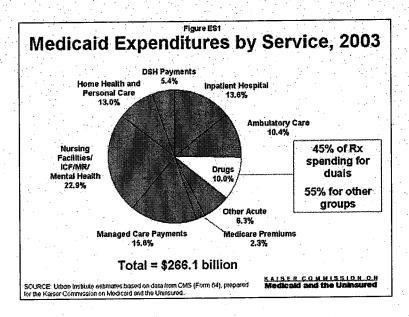
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#### **EXECUTIVE SUMMARY**

The populations served by Medicaid and the diversity and intensity of their health care needs make Medicaid a major purchaser of prescription drugs. In 2003, Medicaid spent \$33.7 billion on prescription drugs, accounting for 19% of national spending for this service. Comprehensive prescription drug coverage is an essential benefit for Medicaid's 58.5 million low-income beneficiaries, including 9.2 million non-elderly people with disabilities and 5.4 million seniors, cohorts that are especially reliant on pharmaceuticals for the management of chronic illness. In 2003, Medicaid spent \$1.000.

In 2005, a broad spectrum of policy makers is focused on ways to reduce Medicaid spending growth. At the federal level, the Congressional budget resolution for fiscal year 2006 (which began on October 1, 2005) calls for the Senate Finance Committee to achieve savings of \$10 billion over the next five years by identifying savings in the programs under its jurisdiction (and a corresponding level of savings is required from the House Energy and Commerce Committee). Even amid the changing priorities prompted by Hurricane Katrina, it is believed that a significant portion of these savings will come from Medicaid—and several policy makers have identified prescription drug policy changes as one of the primary ways that the Congress could meet the budget resolution's budget reduction target.

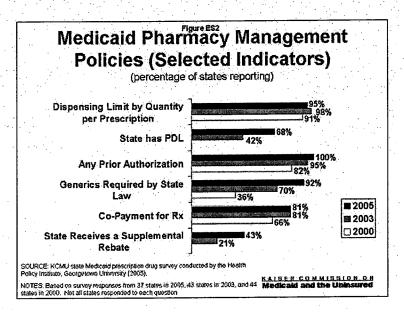
Medicaid will undergo additional changes as a result of the implementation of the Medicare Modernization Act (MMA)<sup>iii</sup>. On January 1, 2006, an estimated 13.6% of current Medicaid beneficiaries, who account for 48% of Medicaid prescription drug spending, will be transitioned to Medicare prescription drug coverage.<sup>iv</sup> Medicaid programs will have continued responsibility for meeting the long-term services and supports needs of dual eligibles and will continue to fill in for other gaps in Medicare coverage, even though they are barred by the MMA from receiving federal Medicaid financing for filling in any gaps in Medicare drug coverage (Figure ES1). They will also be responsible for continuing Medicaid drug coverage for those beneficiaries who are not dual eligibles, but the amount spent and the mix of drugs purchased through the program will change considerably.



In the first half of 2005, the Kaiser Commission on Medicaid and the Uninsured conducted a survey of state Medicaid prescription drug policies that was carried out by the Health Policy Institute at Georgetown University. Thirty-six states plus the District of Columbia responded to the survey. This survey updates and supplements work conducted for the Commission in 2003 and 2000 and covers key elements of utilization management, drug purchasing and potential impacts of the implementation of Medicare Part D. VI

#### Summary and Highlights from the 2005 Survey

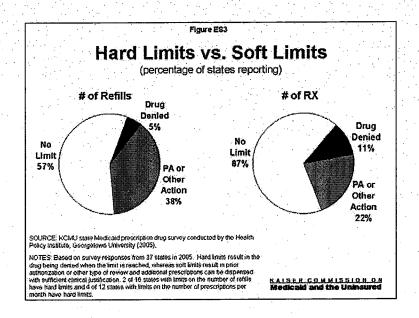
States have several tools available to them to manage the pharmacy benefit and to control costs. Increased health care costs and recent fiscal constraints have led most state Medicaid programs to use many of these tools. Medicaid programs anticipated 14.3% growth in drug spending in fiscal 2005, continuing a trend of double-digit growth. Consequently, in 2005, among responding states, nearly all programs used dispensing limits; roughly two-thirds operated preferred drug lists (PDLs); all required some prior authorization; nearly all required the use of generics, and four in five states charged copayments for prescription drugs (Figure ES2).



**Dispensing Limits**: In 2005, nearly all programs (35 of 37) reported that they impose limits on the amount of a drug that can be dispensed per prescription; lesser numbers imposed limits on refills per prescription (16 of 37) or number of prescriptions (12 of 37).

#### New Finding in 2005: Most states with dispensing limits apply soft limits

Policy makers and beneficiary groups have focused on the imposition of hard dispensing limits in a small number of states, where beneficiaries may be denied medically necessary drugs above the established limit. While the ability of states to establish limits on dispensing is not new, the use of hard limits versus soft limits may reflect a new policy direction. In states with hard limits, Medicaid will not pay for drugs dispensed to an individual above a certain number of prescriptions or refills. Under soft limits, when individuals reach the established limit, their subsequent prescriptions typically become subject to prior authorization. Providers are given the opportunity to provide clinical justification for prescribing drugs above the limit, but drugs may be denied at this stage. States were asked in 2005 what action they take when beneficiaries hit the limits on the number of refills and the number of prescriptions. In most cases, individuals are subject to some form of prior authorization. In only 13% of responding states (2 of 16 states in 2005) are individuals automatically denied drugs (i.e., a hard limit is imposed) with respect to the number of refills and in only 33% of responding states (4 of 12 states in 2005) are individuals automatically denied drugs with respect to the number of prescriptions (Figure ES3).

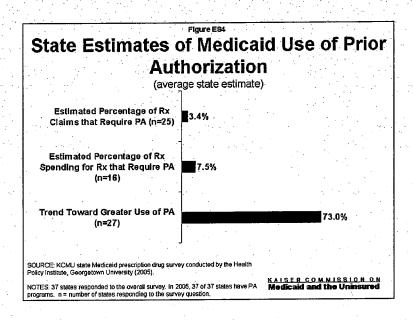


Preferred Drug Lists (PDLS): In 2005, more than two-thirds of responding states operated PDLs. Of those with PDLs, most states provide for public input into drugs that should be on the PDL, and 40% use the same PDL for other state programs such as the State Children's Insurance Program (SCHIP) or the State Pharmacy Assistance Program (SPAP).

**Prior Authorization (PA)**: In 2005, all responding states required PA for certain drugs paid for by Medicaid, and roughly three-fourths reported that the recent trend has been toward a greater reliance on PA. Three-fourths also indicated that they exempt certain classes of drugs from PA.

 New finding in 2005: While all surveyed states use prior authorization (PA), states apply it selectively

While PA has become a central pharmacy cost containment strategy in virtually all states, PA is used selectively. On average, states estimate that only 3.4% of prescription drug claims are for drugs that require PA (based on estimates from 25 states in 2005) (Figure ES4). Additionally, the average estimate is that only 7.5% of Medicaid prescription drug spending is for drugs that require PA (based on estimates from 16 states). Some policy makers may interpret these low percentages to indicate that states could require PA for far more drugs. The success of PA programs, however, may rely on targeting efforts appropriately. Nonetheless, roughly three-fourths of respondents (27 of 37 states in 2005) reported that the recent trend has been toward a greater reliance on PA.



Generic Substitution: In 2005, nearly all states (34 of 37 responding) reported that they require generics to be dispensed when available, but the majority of these states (30 of 34) permit the requirement to be overridden if the prescriber requests. States estimated that 52% of prescriptions are filled with generics and that 19% of Medicaid drug spending is for generics.

**Cost Sharing**: In 2005, four in five states (30 of 37 responding) charged co-payments for Medicaid prescription drugs. Seven of those 30 report that they permit prescription drugs to be withheld for non-payment of cost sharing.

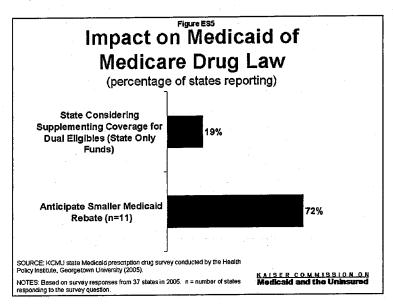
High Cost Management: In 2005, 23 of 37 responding states reported that they operate special programs targeting high cost patients who are identified sometimes using claims data or by chronic condition (e.g., diabetes or asthma). States typically use strategies such as disease management and provider education to address these groups.

*Drug Purchasing:* While the proportion of states receiving supplemental rebates has increased over time, fewer than half (16 of 37 responding in 2005) reported receiving them. A little more than half of responding states (20 of 37) reported returning rebate payment to Medicaid, with the remainder applying rebate payments to the state general fund. Six of 37 states reported pooling drug purchasing across several states, and three of 37 reported pooling drug purchasing across several state programs.

Impact on Medicaid of Medicare Drug Coverage: Early in Medicare drug coverage implementation, a minority of states reported considering using Medicaid to fill gaps in coverage for dual eligibles, yet the majority of surveyed states anticipated that the MMA will lead to smaller Medicaid rebates.

The implementation of the Medicare Modernization Act (MMA) has the potential to improve access to prescription drugs for millions of Medicare beneficiaries. The impact on dual eligibles, however, is unclear. CMS in its rulemaking and subsequent guidance has taken steps to ensure that Medicare Part D plan formularies are comprehensive, including the requirement that plans cover substantially all drugs in six key classes: anticonvulsants; antidepressants; antineoplastics; antipsychotics; antiretrovirals, and immunosuppressants.

Nonetheless, states and many other stakeholders are concerned that coverage gaps will arise for dual eligibles, both because plans will not cover necessary medications or because drugs will be denied due to the inability to pay cost-sharing. Some states (7 of 37 states in 2005) reported that they are actively considering using state-only funds to fill in gaps in Medicare coverage (Figure ES5). While many state respondents said that they could not anticipate the impact of the implementation of the MMA on Medicaid, of those responding, nearly three-fourths indicated a belief that their Medicaid program would receive smaller rebates due to the loss of market share (8 of 11 states responding to this question in 2005).



#### Conclusion

Until now, Medicaid has played a unique role in providing access to prescription drugs to the needlest and costliest cohorts of Americans (low-income people with severe disabilities and low-income elderly individuals). Beginning in 2006, this responsibility will be shared with the Medicare Part D prescription drug program. Medicaid programs will grapple with the impact of the MMA on prescription drug costs and access for the remainder of the Medicaid population. Meanwhile, the Congress is considering changes to some of the basic approaches to purchasing prescription drugs in Medicaid and sharing responsibility for costs with beneficiaries. What will not change is the

central role that prescription drugs have come to play in modern health care and their vital role in the health and functioning of many of the poorest and sickest Americans.

The results presented are based on self-reported data by state Medicaid pharmacy officials. Participating states responded to a written survey or provided information through telephone interviews in the first half of 2005. Participating states were given the opportunity to review their responses for accuracy in July-August 2005, and states were asked to ensure that policies were up-to-date in cases where policies may have changed since originally completing the survey. Multiple efforts were made to secure the participation of all states.

ii Congressional Budget Office, March 2005 Baseline.

<sup>&</sup>lt;sup>i</sup> National Health Expenditures Tables, 2003, Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group, January 2005.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), also called Medicare Part D (Public Law 108-173), creates a right for Medicare beneficiaries to purchase Medicare prescription drug coverage beginning on January 1, 2006. While technically voluntary, low-income Medicare beneficiaries who also receive Medicaid (dual eligibles) will lose their Medicaid drug coverage and will be automatically enrolled in a Medicare prescription drug plan.

<sup>&</sup>lt;sup>iv</sup> John Holahan and Arunabh Ghosh, *Dual Eligibles: Medicaid Enrollment and Spending for Medicare Beneficiaries in* 2003, Kaiser Commission on Medicaid and the Uninsured, July 2005.

Y For ease of reference, throughout this report, references to "states" should be inferred to include the District of Columbia.

<sup>&</sup>lt;sup>vi</sup> For 2003 survey, go to <a href="http://www.kff.org/medicaid/4164.cfm">http://www.kff.org/medicaid/4164.cfm</a>. For 2000 survey, go to <a href="http://www.kff.org/medicaid/2225-index.cfm">http://www.kff.org/medicaid/2225-index.cfm</a>.

#### INTRODUCTION

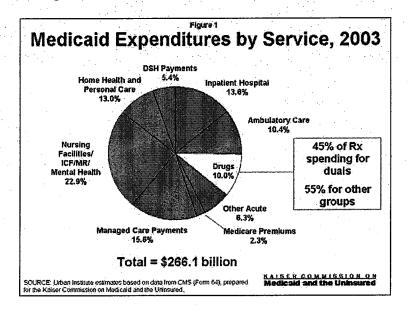
Increasing health care costs and numbers of uninsured or under-insured individuals are placing the nation's health care payers under great stress, whether public programs such as Medicaid and Medicare or the private insurance system. As a consequence, policy makers are continually looking for new and better strategies for improving care and controlling costs. Prescription drug spending has been a major target in recent years because of its double-digit growth rates over several years. In 2003, national spending on prescription drugs totaled \$179.2 billion, accounting for 11% of national spending on health care and related services, and spending growth on prescription drugs was 10.7% greater than in 2002. This increase is driven by an increasing number of prescriptions per person; changes in the types of drugs used—with an increased reliance on newer and more expensive drugs, and manufacturer price increases.

Although low-income children and parents make up three quarters of the Medicaid population, they account for only 31% of Medicaid spending. The other 69% of program spending is attributable to the elderly and people with disabilities, who make up only one-quarter of the Medicaid population. These populations and the diversity and intensity of their health care needs make Medicaid a major purchaser of prescription drugs. Medicaid programs accounted for 19% of national spending on prescription drugs in 2003 (\$33.7 billion). Comprehensive prescription drug coverage is an essential benefit for Medicaid's 58.5 million low-income beneficiaries, including 9.2 million non-elderly people with disabilities and 5.4 million seniors, cohorts that are especially reliant on pharmaceuticals for the management of chronic illness.

In 2005, a broad spectrum of policy makers is focused on ways to reduce Medicaid spending growth. At the federal level, the Congressional budget resolution for fiscal year 2006 (beginning on October 1, 2005) calls for the Senate Finance Committee to achieve savings of \$10 billion over the next five years by identifying savings in the programs under its jurisdiction (and a corresponding level of savings is required from the House Energy and Commerce Committee). Even amid the changing priorities prompted by Hurricane Katrina, it is believed that a significant portion of these savings will come from Medicaid—and several policy makers have identified prescription drug policy changes as one of the primary ways that the Congress could meet the budget resolution's budget reduction target. However, the climate for Medicaid cuts may have chilled given changing priorities in the wake of Hurricane Katrina.

Other changes to the Medicaid program will follow the implementation of the Medicare Modernization Act (MMA) which has significant implications for Medicaid programs and beneficiaries. Medicaid currently provides drug coverage for low-income Medicare beneficiaries (dual eligibles) which will end on December 31, 2005, with Medicare prescription drug coverage beginning on January 1, 2006. Dual eligibles constitute an estimated 13.6% of current Medicaid beneficiaries, responsible for roughly 45% of Medicaid prescription drug spending. Medicaid programs will have continued responsibility for meeting the long-term services and supports needs of dual eligibles

and will continue to fill in for other gaps in Medicare coverage, even though they are barred by the MMA from receiving federal Medicaid financing for filling in any gaps in Medicare drug coverage (Figure 1). They will also be responsible for continuing Medicaid drug coverage for those beneficiaries who are not dual eligibles.



In the first half of 2005, the Kaiser Commission on Medicaid and the Uninsured conducted a survey of state Medicaid prescription drug policies that was carried out by the Health Policy Institute at Georgetown University. Thirty-six states plus the District of Columbia responded to the survey.<sup>8</sup> This survey updates and supplements work conducted for the Commission in 2003 and 2000.<sup>9</sup> The supplement examined enrollment and state Medicaid policies in the following areas:

- 1. Outpatient Drug Spending
- 2. Dispensing Limits
- 3. Preferred Drug Lists (PDLs)
- 4. Prior Authorization
- 5. Generic Substitution
- 6. Cost-Sharing
- 7. High Cost Management
- 8. Purchasing Policies
- 9. Impact on Medicaid of Medicare Drug Coverage

The results presented are based on self-reported data by state Medicaid pharmacy officials. Participating states responded to a written survey or provided information through telephone interviews in the first half of 2005. Participating states were given the opportunity to review their responses for accuracy in July-August 2005, and states were asked to ensure that policies were up-to-date in cases where policies may have changed since originally completing the survey. Multiple efforts were made to secure the participation of all states.

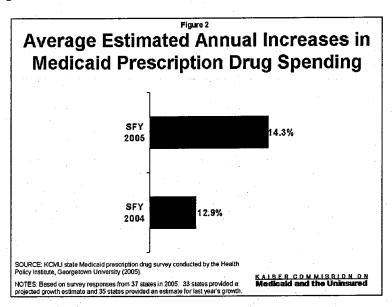
The appendix includes tables of survey responses from individual states (tables 1-19). Throughout the survey, respondents were asked to provide quantitative responses. In some cases, these data were readily available; in others, respondents provided their best estimates based on their professional experience. While some of these data are estimates rather than precise figures, they nonetheless offer important insights on some of the most pressing prescription drug policy issues facing Medicaid programs.

As a starting point toward understanding differences in the use of Medicaid pharmacy services, states were asked to provide their Medicaid enrollment and the average number of monthly prescriptions dispensed to all Medicaid beneficiaries, by dual eligibles, and by Medicaid beneficiaries residing in nursing homes and other institutions. Table 1 provides summary data on Medicaid enrollment. While states do not uniformly track prescription drug use by the requested measures, a subset of survey respondents was able to provide estimates for their state (Table 2).

#### **DRUG SPENDING**

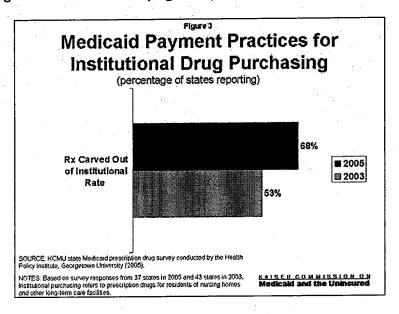
Table 3

Medicaid officials expected prescription drug costs to continue to increase at double digit rates. On average, states estimated that drug spending will increase 14.3% in the current state fiscal year (based on estimates provided by 33 states in 2005) (Figure 2). States also estimated that Medicaid spending grew 12.9% in the last fiscal year (based on estimates by 35 states in 2005). These estimates are consistent with previous state estimates. In 2003, state estimates of recent past spending and spending over the current year ranged from 13.8% to 14.7%.



Payments for most Medicaid services for beneficiaries residing in the community are based on individual claims for services they use, and payments for prescription drugs are based on individual claims for products that were dispensed or paid as part of a

capitation rate to a health plan. States take different approaches to purchasing prescription drugs in nursing homes and other long-term care facilities and these costs are often bundled and paid on a daily rate. While bundling prescription drugs into the daily rate may simplify administration, it also means that states cannot take advantage of Medicaid rebates for drugs reimbursed in this manner. Moreover, it means that states are dependent on institutional providers—or the long-term care pharmacies with which they contract—to take responsibility for ensuring the most efficient purchasing of prescription drugs. More than two-thirds of states (68%, 25 of 37 states in 2005) reported that they carve out (or pay separately for) prescription drugs provided to residents of long-term care facilities (Figure 3).



#### **DISPENSING LIMITS**

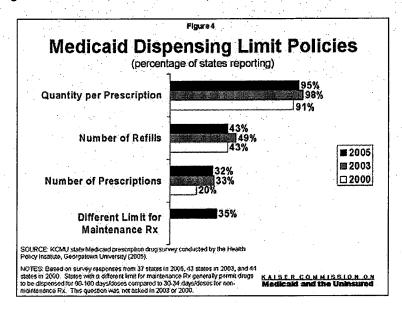
Tables 4-6

Federal Medicaid law requires states to ensure that benefits they provide are "sufficient in amount, duration, and scope to reasonably achieve (their) purpose". <sup>10</sup> However, under federal regulations, states may place "appropriate" limits on a service based on "medical necessity or on utilization control procedures". <sup>11</sup> The Medicaid law also permits states, "to impose limitations, with respect to all such drugs in a therapeutic class, on the minimum or maximum quantities per prescription or on the number of refills if such limitations are necessary to discourage waste". <sup>12</sup>

Dispensing Limits: State policies that restrict the quantity of prescription drugs that Medicaid will purchase for a Medicaid beneficiary.

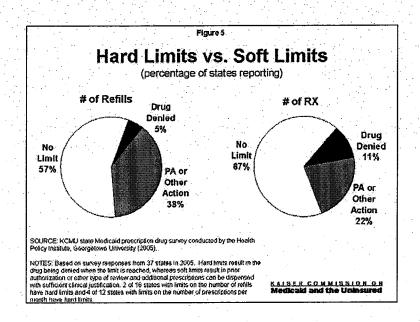
Nearly all Medicaid programs placed limits on the quantity of medication that can be dispensed per prescription (35 of 37 states in 2005) (Figure 4). Several states (16 of 37 states in 2005) also placed limits on the number of refills per prescription and on the number of prescriptions (12 of 37 states in 2005). In response to a question that had not been asked in

the previous surveys, roughly one-third of states (13 of 37 states in 2005) report that they maintain different dispensing limits for maintenance drugs (i.e., drugs taken for long-term management of chronic conditions).



Recent attention has been focused on the imposition of hard limits in a small number of states, in which beneficiaries may be denied medically necessary drugs above the established limit (i.e., Medicaid pays for only those prescriptions up to the limit). While the ability of states to establish such policies is not new, the use of hard limits versus soft limits may reflect a new policy direction. In states with hard limits, an individual cannot obtain drugs above the limit. In states with soft limits, when individuals reach the established limit, they become subject to prior authorization or some other form of review. Drugs may be denied at this stage, but individuals are given the opportunity to provide clinical justification for receiving drugs above the limit.

States were asked what actions they take when beneficiaries reach limits on the number of refills and the number of prescriptions. (Quantity limits do not generally present an access issue as the limit affects the amount of drug an individual can get at one time, but not whether they can obtain all of the drugs they have been prescribed). In most cases, drugs prescribed over the limit are subject to some form of prior authorization. In only 13% of responding states (2 of 16 states in 2005) are individuals automatically denied drugs (i.e., a hard limit is imposed) with respect to the number of refills and in only 33% of responding states (4 of 12 states in 2005) are individuals automatically denied drugs with respect to the number of prescriptions (Figure 5).



#### PREFERRED DRUG LISTS (PDLs)

Tables 7-8

Preferred drug lists (PDLs) are equivalent to formularies. The Medicaid law permits states to establish formularies subject to certain requirements. The formulary must be established by a Pharmacy and Therapeutics (P&T) committee that is appointed by the Governor (or the state drug use review board) and that must include physicians, pharmacists, and other appropriate individuals. The formulary must include all drugs made by manufacturers with rebate agreements in effect with HHS (except for drugs

excludable under Medicaid law)<sup>14</sup> unless the drug excluded from the formulary, "does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion".<sup>15</sup> The Secretary is also permitted to impose additional requirements to "achieve program savings consistent with protecting the health of program beneficiaries".<sup>16</sup>

The development and implementation of PDLs in some state Medicaid programs has met with controversy. Some beneficiary groups have opposed the establishment of PDLs siting notortial drug access problems. States may

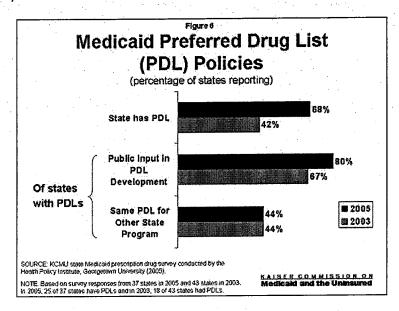
# Preferred Drug List (PDL):

A list of covered prescription drugs that a state Medicaid program agrees to provide without prior authorization.

All other medically necessary pharmaceuticals require prior authorization.

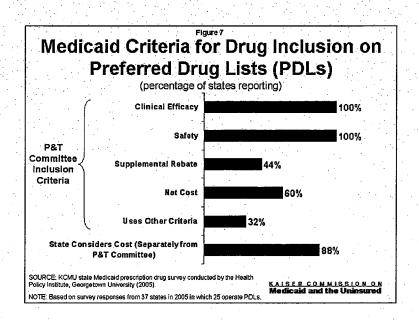
the establishment of PDLs citing potential drug access problems. States may consider several criteria for PDL inclusion, but many states have made a point of highlighting the significance of clinical evidence in constructing their PDLs. In some, but not all states with PDLs, the use of clinical evidence and transparency in the process for establishing the PDL have eased some concerns raised by beneficiaries and other stakeholders.

More than two-thirds of states operate PDLs (25 of 37 states in 2005), a significant increase over the 42% of states with PDLs in 2003 (18 of 43 states in 2003) (Figure 6). Of states with PDLs, most provide for public input into the process of determining which drugs will be included on the PDL (20 of 25 states in 2005). Forty percent (10 of 25 states in 2005) use the same PDL for other state programs, such as the State Children's Health Insurance Program (SCHIP) or the State Pharmacy Assistance Program (SPAP).



States were asked what criteria the P&T committee uses to decide which classes of drugs to place on the PDL and which specific drugs are included. Of those states with PDLs, all states (25 of 25 states in 2005) reported that the P&T Committee considers clinical efficacy and safety (Figure 7). Forty-four percent of states reported that the P&T Committee considers whether the state receives a supplemental rebate (11 of 25 states in 2005) and 60% indicate that the P&T Committee considers the net cost of drugs (15 of 25 states in 2005). Roughly one-third of states (8 of 25 states in 2005) reported that the P&T Committee also considers other factors, such as the availability of therapeutic alternatives.

The primary purpose of a PDL is to assist a state in controlling pharmaceutical spending. The net cost to the state is clearly an important consideration. In setting up their PDLs, however, several states do not permit the P&T Committee to see cost information, believing that the committee's role should be focused on providing an expert review of clinical evidence. In these states, the P&T Committee may determine whether a class of drugs should be placed on the PDL, and only after the fact does the state use cost considerations in determining which specific drugs in the class to include on the list. The majority of states (22 of 25 states in 2005) reported that the state considers the cost of drugs separately from the review conducted by the P&T Committee.



#### PRIOR AUTHORIZATION

Tables 9-11

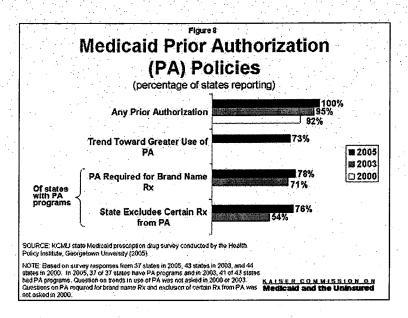
The Medicaid law permits states to subject any covered outpatient prescription drug to prior authorization (PA).<sup>17</sup> States must respond to requests for authorization within 24 hours (by telephone or otherwise) and, except for excludable drugs, they must dispense at least a 72-hour supply of a requested drug in cases of an emergency (as defined by the Secretary).<sup>18</sup>

#### Prior Authorization (PA):

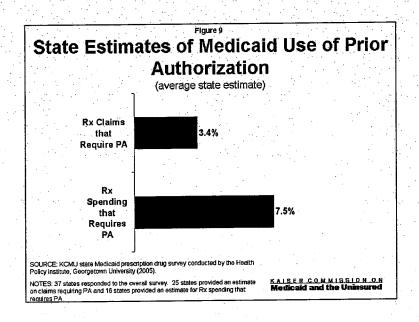
Policy of a state Medicaid program that requires a pharmacist to obtain approval from the state (or a subcontractor) before dispensing a drug.

In 2005, all 37 responding states required PA for at least some prescription drugs covered by Medicaid (Figure 8). Moreover, roughly three-fourths of respondents (27 of 37 states in 2005) reported that the recent trend has been toward a greater reliance on PA. One common practice is for states to require PA for brand name drugs when a generic equivalent is available. Most states (29 of 37 states in 2005) reported that they require PA in this circumstance for

at least some drugs. Additionally, most states (28 of 37 states in 2005) exclude certain classes of drugs from PA. States commonly exempted cancer medications, antiretrovirals used in the treatment of HIV/AIDS, and some or all classes of mental health drugs from PA.



PA is a central pharmacy cost containment strategy in virtually all states, but states use it selectively. The average estimate is that only 3.4% of prescription drug claims are for drugs that require PA (based on estimates from 25 states in 2005) (Figure 9). Additionally, the average estimate is that only 7.5% of Medicaid prescription drug spending is for drugs that require PA (based on estimates from 16 states). Some policy makers may consider these low percentages to indicate that states could require PA for far more drugs. The success of PA, however, may hinge upon targeting efforts appropriately because PA programs can be administratively cumbersome for states, and a greater use of PA may decrease support for the program from stakeholders including physicians, pharmacists and beneficiaries. The size and extent of state PA programs varies substantially. State estimates of the number of PA requests in the last year ranged from a low of 100 in South Dakota to nearly one million in California (see Table 10). Administrative capacity to review large volumes of PA requests (as in California, with its hundreds of thousands of requests per year) and how such capacity is financed is a factor in determining the extent of PA use in a given state.



#### **GENERIC SUBSTITUTION**

Tables 12-13

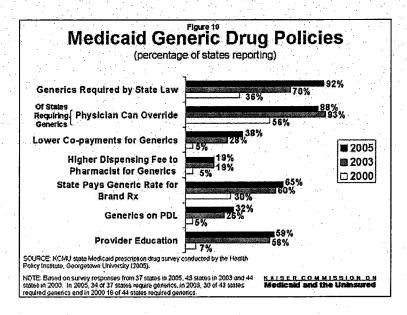
As discussed previously, Medicaid law generally requires states to provide coverage for all FDA-approved medications made by manufacturers with rebate agreements in effect with the federal government. Medicaid law does not, however, prevent states from requiring or encouraging the use of generic medications.

Since 2000, there has been a steady trend toward increased mandatory generic substitution. In 2005, nearly all states (34 of 37 states in 2005) reported that they require generics to be dispensed when available (Figure 10). The majority of these states (30 of 34 states in 2005), however, permit this requirement to be overridden based on the professional judgment of the treating physician. Generally, this requires the prescriber to write "Brand Medically Necessary" on the prescription.

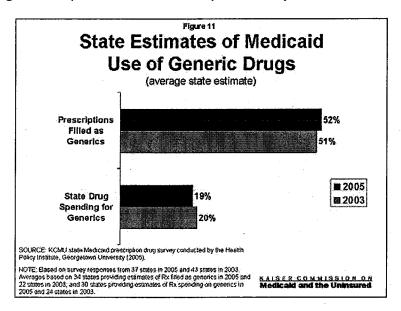
Additionally, states undertake a variety of strategies to encourage the use of generics. These include charging a lower co-payment for generics (14 of 37 states in 2005); paying a higher dispensing fee when pharmacists dispense generics (7 of 37 states in 2005); paying the generic rate for brand name prescription drugs (24 of 37 states in 2005); placing

Generic Drug: A generic drug is identical, or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. Although generic drugs are chemically identical to their branded counterparts, they are typically sold at much lower prices than branded drugs.

generics on the PDL (12 of 37 states in 2005); and engaging in counter detailing or taking other steps to educate providers (22 of 37 states in 2005).



On average, states estimate that 52% of prescriptions are filled with generics (based on estimates provided by 34 states in 2005) (**Figure 11**) and that 19% of Medicaid drug spending is for generics (based on estimates provided by 30 states in 2005).



#### **COST-SHARING**

Table 14

Medicaid permits states to charge "nominal" cost-sharing to certain groups of beneficiaries for certain services. Medicaid law prohibits cost-sharing for the following groups: children under age 18; pregnant women with respect to services relating to pregnancy or any other medical condition that may complicate the pregnancy; terminally ill individuals receiving hospice care; and inpatients in hospitals, nursing facilities, or

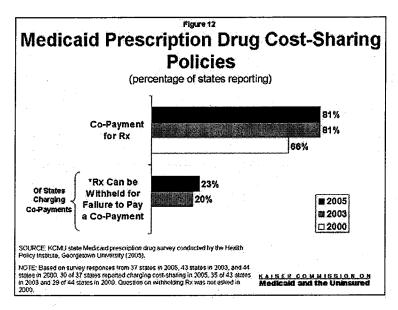
Cost-Sharing: Policy that requires a beneficiary to pay a portion of the cost of a service. In the case of prescription drugs, states may require certain Medicaid beneficiaries to pay a "nominal" copayment, although a state cannot deny a beneficiary a drug based on the failure to pay the co-payment.

intermediate care facilities for persons with mental retardation (ICF/MRs) who are required to contribute all but a minimal amount of their income for their medical care. 19

Four in five states charge co-payments for prescription drugs (30 of 37 states in 2005) (Figure 12).

When cost-sharing is permitted, providers are prohibited from denying care or services to an eligible individual on account of an individual's inability to pay a co-payment. Recently, CMS has taken the position that although states cannot refuse to provide prescription drugs or other services based

on non-payment, they can deny prescription drugs when the beneficiary owes a debt to a provider (i.e., a pharmacy) or where there is a history of non-payment. Twenty three percent of states that impose cost-sharing report that they permit prescription drugs to be withheld (7 of 30 states in 2005), although three of these states (California, Florida, and Nebraska) reported that their withholding policies were pursuant to federal approval through a waiver.

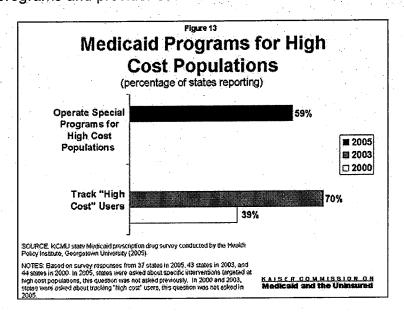


#### HIGH COST MANAGEMENT

Tables 15-16

As is the case with other Medicaid service use, prescription drug use is not distributed evenly among Medicaid beneficiaries. Rather, a relatively small number of people with disabilities and chronic conditions is responsible for a large share of overall Medicaid drug costs. Therefore, a number of states (23 of 37 states in 2005) report that they

operate special programs targeting high cost populations (Figure 13). States take a variety of approaches in defining the target population for these interventions and for shaping the type of intervention (see Table 15). Some states target high cost users based on claims data. Some states also identify certain chronic conditions (i.e., asthma, diabetes or congestive heart failure). States also employ a variety of strategies to address these populations. Common types of interventions include disease management programs and provider education.



#### **PURCHASING POLICIES**

Tables 17-18

States have considerable discretion in setting payment rates for Medicaid outpatient prescription drugs. The price Medicaid pays for drugs has three components:

- 1) the amount the state pays the pharmacist for the drug itself;
- 2) the amount of the dispensing fee that that state pays the pharmacist for filling the prescription; and,
- 3) the size of the rebate that the state receives from the drug manufacturer for purchasing the drug.

Payment for the drug itself: The Medicaid law does not set any minimum payment standards, but it does establish maximum payments for which states can receive a federal match.

For brand name drugs (i.e. drugs still under patent), and multi-source drugs with fewer than three therapeutically equivalent generics, the maximum payment cannot exceed the lesser of the drug's estimated acquisition cost (EAC) plus a dispensing fee or the provider's usual and customary charges to the general public. Each state determines its own EAC, which in most states is based on the average wholesale price (AWP).

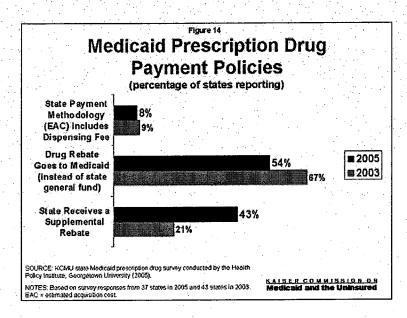
AWP is set by the drug manufacturer as a suggested price that wholesalers charge retail pharmacists for the drug. Most states set their EAC as AWP minus some percentage discount. The actual cost paid for drugs by pharmacies is generally believed to be well below AWP, providing a justification for the discount. A 1999 study by the HHS Office of the Inspector General estimated that the actual acquisition cost for pharmacies was AWP – 21.84%<sup>21</sup> which is considerably lower than what states typically pay. A smaller number of states set their EAC based on the wholesale acquisition cost (WAC), an estimate of the wholesaler's cost for the drug plus a percentage add-on. Recently, federal policy makers have considered proposals to set a federal standard for Medicaid pharmacy payments, relying on the average manufacturer's price (AMP) and the average sales price (ASP). Both of these measures have the advantage of being based on actual prices paid for pharmaceuticals.

For generic drugs (i.e., multi-source drugs with at least 3 therapeutic equivalents), federal matching payments are limited by the Federal Upper Limit (FUL). The FUL is set at 150% of the published price for the least costly therapeutic equivalent that can be purchased by pharmacists in quantities of 100 tablets or capsules. Medicaid regulations stipulate, however, that the FUL payment ceiling does not apply if a prescribing physician (in his or her own handwriting) specifies that a specific brand is medically necessary.<sup>24</sup>

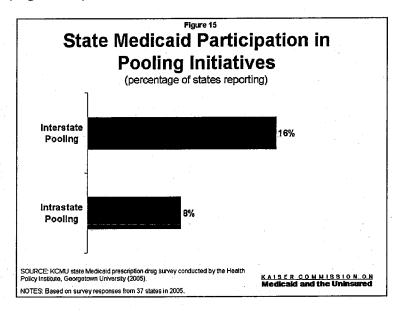
**Dispensing fee:** The Medicaid law and the payment ceilings described above permit states to pay a "reasonable" dispensing fee to the pharmacist. Federal regulations do not define what is reasonable, and there is significant variation in the fees paid by states.

**Drug rebates:** The actual cost to Medicaid for prescription drugs is reduced by manufacturers' rebates to states. The federal rebate is based on agreements between manufacturers and the Secretary of HHS, is uniform across the states, and is shared with the federal government. Some states, however, have negotiated supplemental rebates directly with manufacturers. The federal rebate extends only to drugs purchased by states on a fee-for-service basis. When states purchase drugs through capitated managed care programs, the managed care organizations are permitted to negotiate their own discounts.

When states receive drug rebate payments, it is at their discretion to return these funds to Medicaid or apply them to the state's general fund. A little more than half of the states return the rebate payment to Medicaid (20 of 37 states in 2005); a decline from 2003 when 29 of 43 states reported that rebate payments went to Medicaid. Fewer than half of the states, but a growing number, receive supplemental rebates (16 of 37 states in 2005, compared with 9 of 43 states in 2003). In addition, relatively few states (3 of 37 states in 2005) include their dispensing fee when calculating the EAC (Figure 14).



Recently, there has been a growing interest by states to try to leverage their market share by pooling programs to receive larger rebates or better prices on prescription drugs. States can do this by pooling purchasing across several states (6 of 37 states in 2005) and by pooling purchasing for multiple state programs, including Medicaid and other state programs such as State Pharmacy Assistance Programs (SPAPs) (3 of 37 states in 2005) (Figure 15).



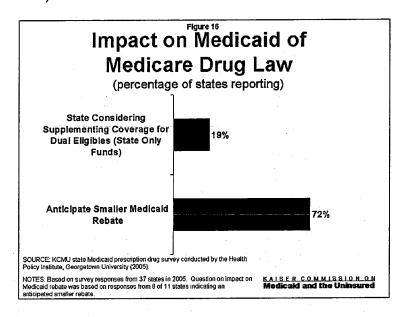
## IMPACT ON MEDICAID OF MEDICARE DRUG COVERAGE Table 19

The implementation of the Medicare Modernization Act (MMA) has the potential to improve access to prescription drugs for millions of Medicare beneficiaries. The impact

on dual eligibles, however, is unclear. Dual eligibles' prescription drug coverage through Medicaid will end on December 31, 2005 and Medicare Part D drug coverage will begin on January 1, 2006. CMS in its rulemaking and subsequent guidance has taken steps to ensure that Medicare Part D plan formularies are comprehensive. This includes telling plans that they must cover all or substantially all drugs in six key classes:

- · Anticonvulsants:
- Antidepressants;
- Antineoplastics;
- Antipsychotics;
- Antiretrovirals, and:
- Immunosuppressants

Nonetheless, states and many affected stakeholders are concerned that coverage gaps will arise for dual eligibles, both because plans will not cover necessary medications or because drugs will be denied due to the inability to pay cost-sharing. Some states (7 of 37 states in 2005) reported that they are actively considering using state-only funds to fill in gaps in Medicare coverage (Figure 16). While many state respondents said that they could not anticipate the impact on Medicaid of the implementation of the MMA, of those responding, nearly three-fourths indicated a belief that Medicaid programs would receive smaller rebates due to the loss of market share (8 of 11 states responding to this question in 2005).



Of the 35 states that listed issues they considered most important to the dual eligibles' transition from Medicaid to Medicare drug coverage, items related to education and communication ranked first, including beneficiary education, outreach to providers, and outreach to state employees. Issues related to enrollment, including auto-enrollment