



The Medi-Cal Prescription Drug Benefit: An Overview

Introduction

Medi-Cal spent an estimated \$4.4 billion on outpatient prescription drugs in 2007, not counting manufacturers' rebates.¹ This amount includes \$3.2 billion in fee-for-service (FFS) expenditures and \$1.2 billion in capitation payments to managed care plans for outpatient prescription drug coverage for beneficiaries enrolled in managed care. The implementation of Medicare Part D in 2006 dramatically lowered Medi-Cal's overall outpatient prescription drug expenditures, but Medi-Cal spending on outpatient prescription drugs for those Medi-Cal beneficiaries not enrolled in Part D continues to rise rapidly.²

This issue brief provides an overview of the Medi-Cal outpatient prescription drug benefits program, summarizes the impact of Medicare Part D on FFS drug utilization and spending, considers Medi-Cal's various approaches to managing pharmacy costs and utilization, and examines FFS utilization and spending in the Medi-Cal drug program from 2004 to 2007.³ The brief concludes with a discussion of issues to consider regarding the future of the Medi-Cal prescription drug program.

The brief's key findings include:

- Nearly 2 million beneficiaries used Medi-Cal FFS outpatient prescription drug benefits in 2007. Beneficiaries rely on these benefits to help them manage a wide range of medical conditions, many of them mental health and chronic conditions.
- On January 1, 2006, approximately 1.1 million dual-eligible beneficiaries—those enrolled in both Medicare and Medi-Cal—had their primary coverage for outpatient prescription drug spending shift from Medi-Cal to Medicare Part D. Prior to 2006, dual-eligibles were among Medi-Cal's highest-cost users of prescription drugs. With the implementation of Part D, Medi-Cal outpatient FFS prescription drug expenditures fell by \$2.8 billion between 2005 and 2006, a decrease of 57 percent.
- Medi-Cal FFS prescription drug expenditures continued to rise for the Medi-Cal-only population, increasing at an average annual rate of 12 percent between 2004 and 2007, to \$2.1 billion.^{4,5} This growth was driven by increases in both the number of prescriptions per beneficiary and the cost per prescription. Within this population, the highest-cost group in 2007 was Non-Elderly Adults with Disabilities, who averaged 42 prescriptions per person and accounted for 70 percent of total FFS drug expenditures.⁶
- Across the nation, state Medicaid programs have adopted various strategies for managing prescription drug expenditures, including: maximizing federal and supplemental manufacturers' rebates; using preferred drug lists (where cost-effective drugs are made available without prior authorization); using generic substitution policies; and creating state Maximum Allowable Cost (MAC) programs, in which states establish maximum Medicaid reimbursement prices for multisource (generic)

drugs and their brand name equivalents. The Medi-Cal program has stressed net pricing strategies through its preferred drug list—called the Contract Drug List (CDL)—to increase manufacturers’ supplemental rebates, and through its state MAC program—named the Maximum Allowable Ingredient Cost (MAIC) program—to limit the maximum reimbursement for generic drugs.⁷

- Opportunities to improve prescription drug management must focus on both pricing and utilization. In particular, there may be opportunities to reduce the rate of expenditure growth through care management and medical home models for individuals with chronic or disabling conditions, a targeted focus on utilization and pricing of the particular drug classes for which expenditures are rising most rapidly, and a reexamination of generic pricing. The Medi-Cal prescription drug program could also benefit from prescribers having increased access to comparative effectiveness information so as to assess new products as they are introduced to the market.

Overview of the Medi-Cal Drug Benefit

Outpatient prescription drug coverage is an optional Medicaid benefit under federal law, but all 50 states and the District of Columbia have elected to cover prescription drugs. Medi-Cal provides access to a comprehensive range of drug classes through both its FFS and managed care delivery systems. Drugs for treatment of HIV/AIDS, mental illness, including antipsychotic medications, and alcohol and drug abuse are “carved out” of the managed care benefit package, meaning that they are covered through FFS arrangements instead of through the managed care plan.

Medi-Cal FFS beneficiaries may receive up to six dispensed prescriptions within a calendar month without obtaining prior authorization. Selected medications are limited to a maximum 100-day supply per claim, and some to three claims per drug within 75 days. If a physician determines that a beneficiary’s conditions

Medi-Cal’s Range of Covered Prescription Drugs

Medi-Cal outpatient prescription drug coverage includes all federally required drug classes, among which are general therapeutic classes for common chronic conditions, such as heart disease and asthma, and a full range of therapeutic classes for treatment of acute conditions, including infections, pain, and cancer. Medi-Cal also covers optional drug classes like vitamins, benzodiazepines, barbiturates, and certain over-the-counter drugs, when determined by a physician to be medically necessary.

Within these classes of drugs, the California Department of Health Care Services (DHCS) has created a Contract Drug List (CDL), which consists of prescribed drugs that do not require prior program authorization. For a drug to be placed on the CDL, DHCS staff must review its efficacy, safety, potential for misuse, essential need, and cost.

require more than six prescriptions to be dispensed within a month, the physician may request a waiver of the six-prescription per month limit. A request to waive the limit requires the prescribing physician, or the pharmacist filling the prescription, to submit a Treatment Authorization Request (TAR), which is then reviewed, based on medical necessity, by the California Department of Health Care Services (DHCS) and/or its fiscal intermediary. In 2007, approximately 11 percent of beneficiaries who had an FFS drug claim were permitted to exceed the six-prescription per month limit.

The DHCS fiscal intermediary processes all FFS outpatient pharmacy claims, most of which are submitted electronically. The state’s Drug Utilization Review (DUR) process, which includes prospective and retrospective reviews of FFS drug claims, is managed by DHCS and supported by the fiscal intermediary.

Medi-Cal allows a pharmacy to collect a \$1.00 per-prescription copayment from some FFS beneficiaries.⁸ However, the pharmacy is required to dispense the drug even if the beneficiary cannot afford to pay the copayment.⁹

dual-eligibles dropped precipitously as a result of Part D implementation, dual-eligibles still represented 27 percent of all Medi-Cal FFS outpatient prescription drug users in 2007, demonstrating the significance of Medi-Cal coverage for drugs excluded under Part D, such as prescription vitamins and benzodiazepines.¹³ The overall number of beneficiaries with at least one drug claim declined only 14 percent from 2005 to 2006.

The average number of prescriptions per user in 2007 was nearly 13.7 per year, or slightly more than one prescription per month. For Medi-Cal-only enrollees, who were 73 percent of FFS prescription drug users in 2007, the average number of prescriptions per user was 14.9.¹⁴ Among subgroups of Medi-Cal-only enrollees, the average ranged from almost five prescriptions per year among Other Children (i.e., those without disabilities) to more than 41 per year among Non-Elderly Adults with Disabilities. (See Table 1.)

Table 1. FFS Prescription Drug Use, by Group, 2004 vs. 2007

	TOTAL RX USERS 2007	AVERAGE RXs PER USER		AVERAGE ANNUAL CHANGE
		2004	2007	
Medi-Cal Only	1,440,445	13	15	4.2%
Other Children	529,041	5	5	0.5%
Other Adults	491,008	6	7	3.6%
Non-Elderly Adults with Disabilities	311,625	35	41	6.0%
Elderly	63,234	25	29	5.8%
Children with Disabilities	45,537	16	18	3.5%
Dual Eligibles	546,019	39	11	-35.3%
TOTAL	1,986,464	22	14	-15.0%

Source: Authors' analysis of MIS/DSS data, 2004–2007 subset, provided by JEN Associates.

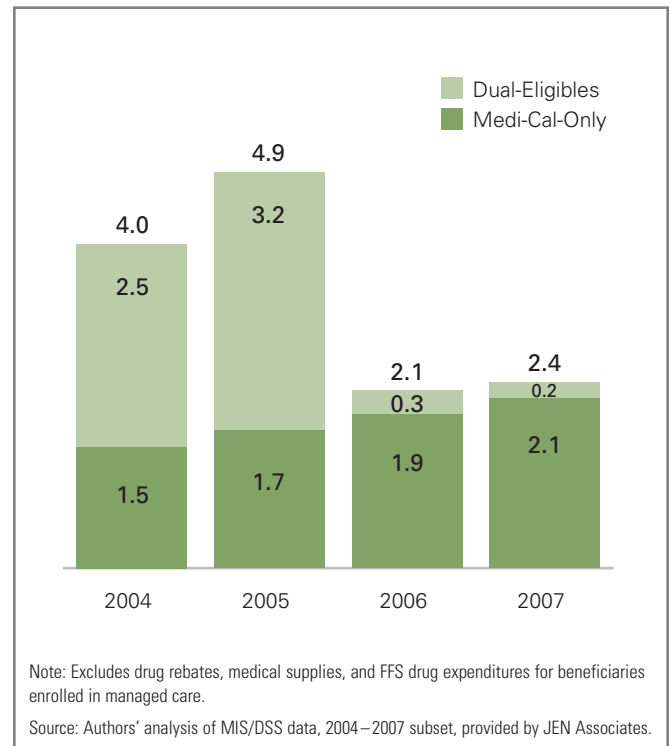
On average, about 14 percent of Medi-Cal-only FFS drug benefit users exceeded the standard monthly limit of six prescriptions per month in 2007; however, 42 percent of Non-Elderly Adults with Disabilities exceeded the limit.

Expenditures

Medi-Cal FFS payments for outpatient prescription drugs, not counting manufacturers' rebates, totaled \$3.2 billion in 2007. This total includes \$2.4 billion in payments for FFS enrollees' use of prescription drugs, an estimated \$121 million for the Family Planning Access, Care and Treatment Program (Family PACT), and an estimated \$326 million for injectables and pharmacy-related medical supplies. It also includes an estimated \$253 million in payments for managed care enrollees' use of mental health and other prescription drugs, which are carved out of the managed care pharmacy benefits package and paid as FFS.

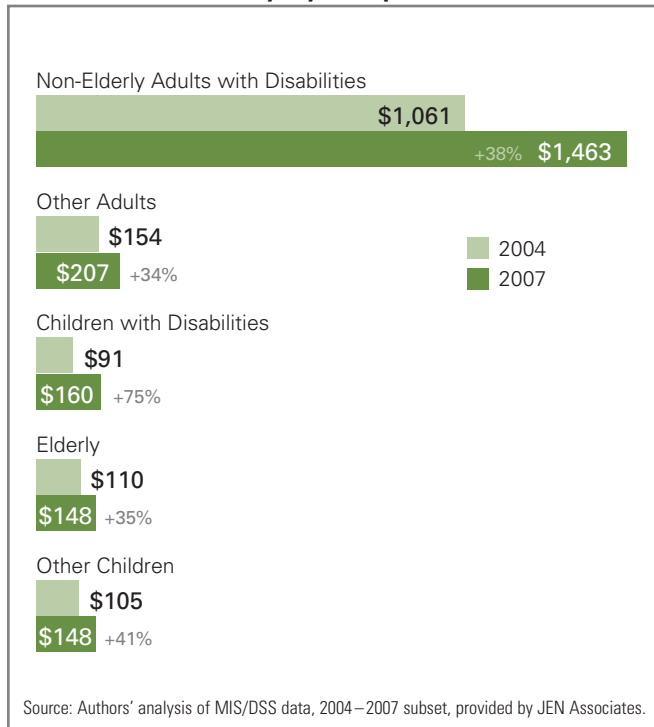
From 2004 to 2007, Medi-Cal FFS spending on prescription drugs for beneficiaries fell sharply from \$4.0 billion to \$2.4 billion (Figure 1), reflecting the implementation in 2006 of Medicare Part D. Similar decreases occurred for Medicaid programs nationally.

Figure 1. FFS Prescription Drug Expenditures (in billions), 2004–2007



For the Medi-Cal-only population, Medi-Cal spending for outpatient prescription drugs grew at an average annual rate of 12 percent between 2004 and 2007, from \$1.5 billion to \$2.1 billion. FFS drug spending grew fastest in the category Children with Disabilities (Figure 2). While Children with Disabilities represented only 3 percent of users and 8 percent of prescription drug expenditures in 2007, their total prescription drug expenditures rose from \$91 million in 2004 to \$160 million in 2007, an average annual increase of 75 percent. Most significantly, expenditures for Non-Elderly Adults with Disabilities, which represented 70 percent of total prescription FFS drug expenditures for the Medi-Cal-only population in 2007, increased at an average annual rate of 11 percent over the four-year period.

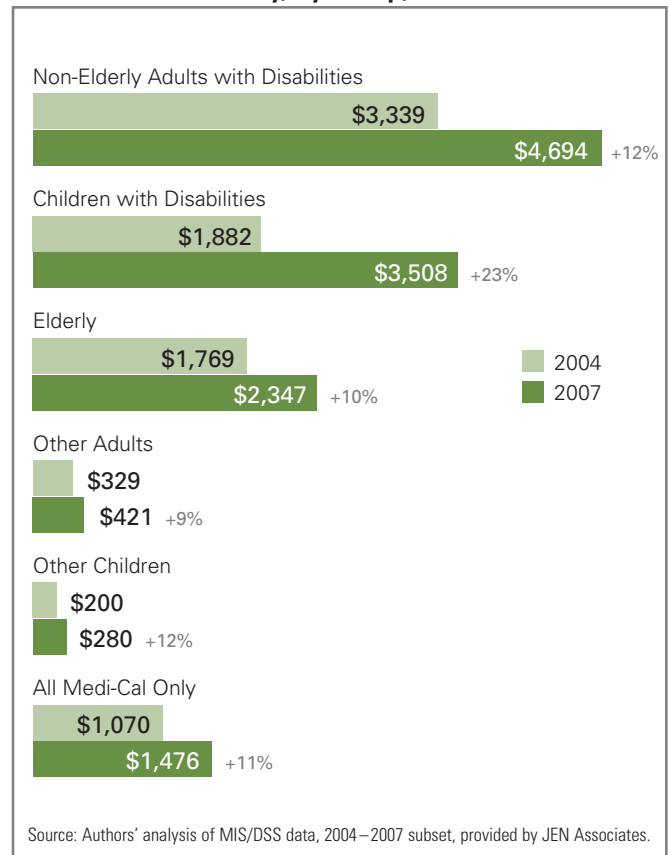
Figure 2. FFS Prescription Drug Expenditures (in millions), **Medi-Cal-Only, by Group, 2004 vs. 2007**



Average expenditures per person for Medi-Cal-only prescription drug users were \$1,476 per recipient, per year in 2007, but varied widely by category: from \$280 per recipient, per year for Other Children, to \$4,694

per recipient, per year for Non-Elderly Adults with Disabilities (Figure 3).

Figure 3. FFS Prescription Drug Expenditures per Person, Medi-Cal-Only, by Group, 2004 and 2007



Top Drugs Prescribed

The top ten therapeutic drug classes in 2007 accounted for 65 percent of outpatient FFS prescriptions (Table 2) and 74 percent of all expenditures (Table 3). Key findings, based on an analysis of drugs by class for all beneficiaries (dual-eligibles and Medi-Cal-only) with FFS drug expenditures, include the following:

- Psychotherapeutic drugs had the highest number of prescriptions and total expenditures in both 2004 and 2007. However, this drug class alone does not fully capture all Medi-Cal covered drugs associated with mental health conditions. Another class of drugs, which target the central nervous system (CNS), is also commonly prescribed for psychiatric disorders.

- The drug class Analgesics was second in the number of prescriptions and seventh in expenditures in 2007. That same year, the Cardiovascular drug class was second in expenditures and fourth in volume.
- The rankings of Medi-Cal drugs by volume and expenditures shifted only slightly with the implementation of Part D. Antiarthritics fell off the list of top ten drugs by expenditures in 2007, dropping from seventh in 2004 to fifteenth in 2007.
- Drug classes that rose in the rankings by total expenditures between 2004 and 2007 include Electrolytes, moving from eleventh to fifth, and Blood Products, which rose from tenth to sixth. As described in more detail in the Cost Driver section, below, the increase in Blood Product expenditures appears to be based in part on an increase in the price of certain products in this class.

Table 2. Top Ten Therapeutic Classes, by Total Prescriptions

2007 RANK	THERAPEUTIC CLASSIFICATION*	PRESCRIPTIONS		2004 RANK
		IN MILLIONS	PERCENT OF TOTAL	
1	Psychotherapeutics	3.3	12%	1
2	Analgesics	3.2	12%	3
3	Gastrointestinal	2.0	7%	4
4	Cardiovascular	1.9	7%	2
5	Electrolyte/Caloric/Water	1.5	5%	11
6	Antiinfective	1.5	5%	7
7	Central Nervous System	1.3	5%	8
8	Hypoglycemics	1.1	4%	5
9	Antiasthmatics	1.0	4%	14
10	Antiarthritics	1.0	4%	6
Top Ten Subtotal		17.6†	65%	
Medi-Cal Outpatient Total		27.2	100%	

*Classifications are based on First Data Bank's discrete General Therapeutic Classes. Antiinfective (Table 2) and Antiinfective/Misc (Table 3) are two separate and distinct First Data Bank classes.

†Subtotal differs from sum of individual figures due to rounding.

Source: Authors' analysis of MIS/DSS data, 2004–2007 subset, provided by JEN Associates.

Table 3. Top Ten Therapeutic Classes, by Total Expenditures

2007 RANK	THERAPEUTIC CLASSIFICATION*	EXPENDITURES		2004 RANK
		IN MILLIONS	PERCENT OF TOTAL	
1	Psychotherapeutics	\$520	22%	1
2	Cardiovascular	\$186	8%	2
3	Antiinfective/Misc.	\$177	7%	4
4	Gastrointestinal	\$170	7%	3
5	Central Nervous System	\$167	7%	5
6	Blood Products, including Blood Factor to treat hemophilia†	\$139	6%	10
7	Analgesics	\$123	5%	9
8	Hypoglycemics	\$95	4%	6
9	Electrolyte/Caloric/Water	\$95	4%	13
10	Antiasthmatics	\$89	4%	11
Top Ten Subtotal		\$1,761†	74%	
Medi-Cal Outpatient Total		\$2,359	100%	

*Classifications are based on First Data Bank's discrete General Therapeutic Classes. Antiinfective (Table 2) and Antiinfective/Misc (Table 3) are two separate and distinct First Data Bank classes.

†Subtotal differs from sum of individual figures due to rounding.

‡There is an estimated additional \$25 million for blood products for Medi-Cal FFS beneficiaries associated with injectables, and for users whose FFS claims are not linked to claims data. Medi-Cal uses National Drug Codes for all pharmacy-dispensed drugs, but not for provider-administered injectables. Therefore, injectables were excluded from this analysis.

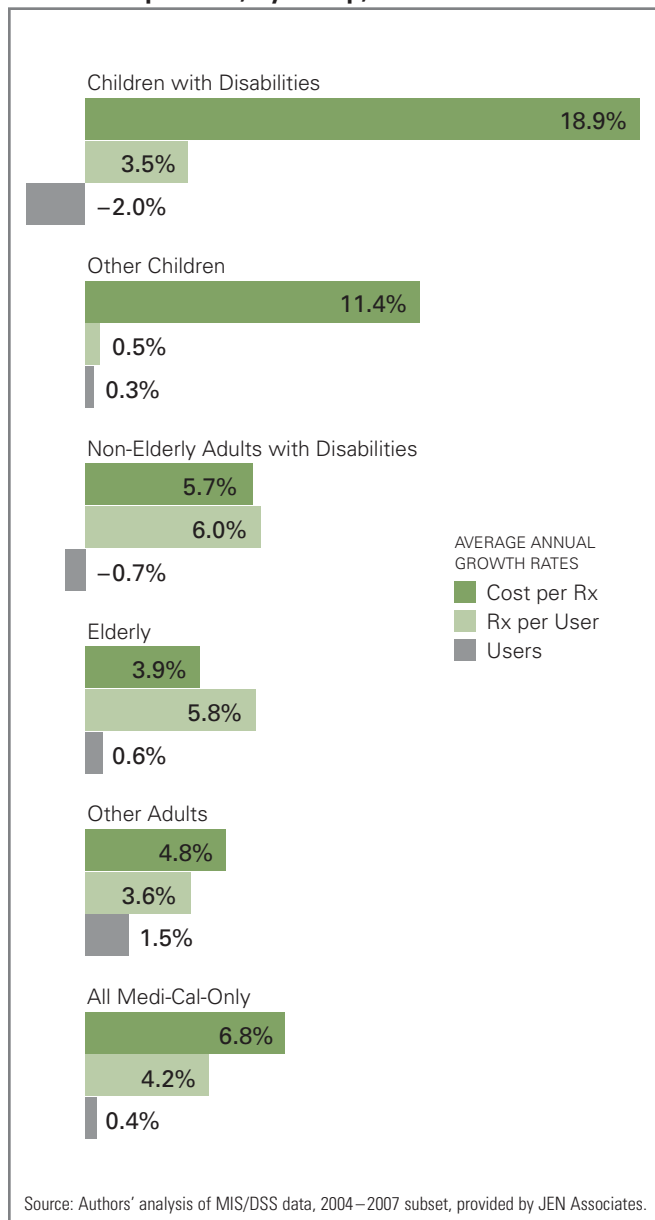
Source: Authors' analysis of MIS/DSS data, 2004–2007 subset, provided by JEN Associates.

Cost Drivers

The growth of Medi-Cal FFS expenditures for outpatient prescription drugs among the Medi-Cal-only population from 2004 to 2007 was driven by a combination of an increased number of prescriptions per user and an increased average cost per prescription: The number of prescriptions per user grew at an average annual rate of 4 percent over the four-year period, while expenditures per prescription grew by 7 percent (see Figure 4).¹⁵

Within the Medi-Cal-only population, beneficiaries in the Elderly and the Non-Elderly Adults with Disabilities categories accounted for the largest increases in the number of prescriptions per user, an average annual growth rate of 6 percent for both groups from 2004 to 2007. Children with Disabilities accounted for the largest increase in expenditures per prescription (19 percent annually), followed by Other Children (11 percent).

Figure 4. Components of Growth in FFS Prescription Drug Expenditures among Medi-Cal-Only Population, by Group, 2004–2007



The use of drugs in the Psychotherapeutic and CNS categories, often prescribed for mental health conditions, continues to be a significant driver of Medi-Cal's outpatient prescription drug spending for both adults and children. Between 2004 and 2007, spending on Psychotherapeutic drugs for Medi-Cal-only enrollees increased at an average annual rate of 9.1 percent, even though the number of people who received at least one prescription for Psychotherapeutic drugs declined by 1.4 percent per year. The average cost per prescription increased at an average annual rate of 6.0 percent, while the average number of prescriptions per recipient for Psychotherapeutic drugs increased by 4.4 percent per year. Expenditures for CNS drugs, often used to treat Attention Deficit Hyperactivity Disorder (ADHD), increased among Medi-Cal-only children by an average annual growth rate of almost 10 percent.

Among children, drugs in the general therapeutic class Blood Products appear to be a major cost driver, with an average annual increase of 197 percent in the cost per prescription and 225 percent in total expenditures from 2004 to 2007, with much of this increase centered on drugs for hemophilia. Some of this increase may be attributable to new, higher cost blood products used by hemophiliac beneficiaries and to greater use of products for bleeding problems unrelated to hemophilia. Blood Products as a class represented 6 percent of total FFS prescription drug expenditures for enrollees in 2007.

State Medicaid Strategies for Managing Prescription Drug Costs

State Medicaid programs have adopted numerous strategies for controlling prescription drug spending, and in some cases for improving access and proper utilization. Many of these strategies are also being used by commercial health insurers, while some are unique to Medicaid. These strategies include:

- Efforts to decrease the unit price, such as maximizing federal and state supplemental rebates;

- Efforts to limit utilization, such as imposing copayments and prior authorization rules; and
- Efforts to promote more cost effective utilization, such as use of preferred or contract drug lists, generic preference policies, medication management programs, and prior authorization requirements.

It is important to note that, while some strategies are complementary (e.g., a state supplemental rebate strategy in addition to maximized collection of federal manufacturers' rebates), others are alternative paths to cost management (e.g., the use of a manufacturers' rebate strategy instead of including outpatient pharmacy coverage in a full-risk managed care plan benefits package). Several of the more common Medicaid cost management strategies are discussed in more detail below.

Pricing Strategies

FEDERAL REBATES

Section 1927 of the Social Security Act, added by the Omnibus Budget Reconciliation Act of 1990, requires drug manufacturers to sign rebate agreements with the Centers for Medicare and Medicaid Services (CMS) or forego coverage of their drugs by state Medicaid programs. Imposition of these rebates does not preclude states from also implementing formularies (also known as preferred drug lists).¹⁶ All states and the District of Columbia participate in the federal rebate program, with the exception of Arizona, which does not participate because its entire Medicaid program is administered through full-risk managed care arrangements (see below).

Complex federal formulas are used to calculate the rebates that manufacturers pay directly to the states; rebates are shared with the federal government based on a state's FMAP rate. The formulas, which are standard for all states, differ for brand name and non-brand name (generic) drugs.¹⁷

Federal rebates are not available for drugs paid under capitated arrangements with managed care organizations for Medicaid beneficiaries, which means that the value of the federal rebate is diminished to the extent that states enroll Medicaid beneficiaries in full-risk managed care plan arrangements. In order to maintain the rebates, in 2006, 11 states carved out all outpatient prescription drugs from managed care plans (Medicaid continues to pay for outpatient drugs through FFS arrangements even for managed care enrollees), and seven other states report that this strategy is under consideration.¹⁸

In California, selected classes of drugs are excluded from managed care plan arrangements (see "Overview of the Medi-Cal Drug Benefit," above), but Medi-Cal administrators have not supported a full carve-out of outpatient prescription drugs, their reasoning being that integrating drugs within the larger benefits package supports a stronger approach to care management for the covered population. Medi-Cal currently collects the allowable federal manufacturers' rebates on drugs purchased through FFS and four of the five county-operated health systems.¹⁹ In Fiscal Year 2007–08, the Medi-Cal program received a total of \$756 million in these federal rebates.

President Obama's 2010 Executive Budget proposes to increase the value to states of federal rebates by increasing the rebate for brand name drugs (from Average Manufacturer Price [AMP] minus 15.1 percent to AMP minus 22.1 percent). The Obama Administration projects these reforms would save \$11.55 billion in federal Medicaid spending over ten years. State savings would be in addition to these federal savings. Also, the Executive Budget proposes to extend rebates to managed care plans for Medicaid outpatient pharmacy, with projected federal savings of \$8 billion over ten years. Health reform bills under consideration by Congress include similar provisions.²⁰ If enacted, they will make federal manufacturers' rebates an even more important source of cost control for Medicaid prescription drug programs.

SUPPLEMENTAL REBATES AND PREFERRED OR CONTRACT DRUG LISTS

California has been a national leader in the development of Medicaid supplemental rebate programs. The state introduced one of the nation's first programs to require drug manufacturers to pay state-negotiated rebates, in addition to federally-mandated rebates, in order to have their drugs on a preferred drug list (PDL), which means that the drugs are usually available without prior authorization.²¹ A PDL creates an incentive for manufacturers to offer supplemental rebates to improve the likelihood that a particular drug will be included on the state's PDL without prior authorization. By 2007, 44 states had developed such lists and were negotiating supplemental rebates directly with pharmaceutical manufacturers to reduce the net cost of many drugs.²²

Medi-Cal's CDL—the state's version of a PDL—is broad, including even psychotherapeutic drugs. This provides the state with a potentially better opportunity to manage these costs than in states where some mental health drugs are not included in their PDL. Criteria for inclusion of drugs on the Medi-Cal CDL include clinical efficacy, safety, essential need, misuse potential, and net cost. In Fiscal Year 2007–08, the Medi-Cal program received \$314 million in state supplemental rebates from pharmaceutical manufacturers. Taken together, the federal rebate and the state's supplemental rebate program generated over \$1 billion in revenue for California in Fiscal Year 2007–08, significantly offsetting gross FFS

outpatient pharmacy expenditures of \$3.2 billion that same year.

MULTI-STATE PURCHASING POOLS

In 2004, CMS authorized states to form multi-state prescription drug purchasing pools to negotiate supplemental manufacturer rebate contracts on prescription drugs purchased for Medicaid.²³ In 2007, 24 states reported participation in a multi-state coalition, with several states reporting increased savings as a result of participation.²⁴ Six states reported that their entry into a pool was triggered in part as a result of dual-eligibles moving to Part D for drug coverage, thereby reducing the volume of drugs for which the state was negotiating supplemental rebates. States that have not joined a multi-state pool offer a range of reasons, including a belief (especially among larger states) that their state-specific rebate arrangements are more or equally advantageous to a multi-state arrangement, an emphasis on a generic preference strategy over a supplemental rebate strategy, or a heavy dependence on managed care arrangements.²⁵ Medi-Cal does not participate in a multi-state purchasing pool.

GENERIC PRICING LIMITS

The federal government establishes a maximum price for generic drugs, called the Federal Upper Limit (FUL), which states cannot exceed in aggregate (meaning that a state can exceed the FUL on individual drugs as long as it pays equally less on other drugs with an FUL).²⁶

Commercial Insurance Cost Strategies

Commercial insurers, including managed care plans, use some cost management options which are uncommon among Medicaid programs. For example, commercial plans might offer a limited drug formulary, obtaining significant discounts from one manufacturer by not offering a competing manufacturer's drugs or by offering the competing manufacturer's drugs with a high copayment. Commercial plans are not bound by the regulations that require an inclusive Medicaid formulary and that limit beneficiary cost-sharing.

A common strategy used by many commercial plans is mail order pharmacies. Under these arrangements, plans may require that drugs to be taken on an on-going basis be purchased from mail order pharmacies, which can offer significant pricing discounts through large volume purchasing, eliminating the added overhead costs of retail pharmacies. However, strong objections from retail pharmacies, as well as concern over the security of mail deliveries for low-income beneficiaries, have restricted the use of mail order pharmacies by Medicaid programs.

Many states establish their own MAC programs for pricing individual generic drugs. States have greater flexibility in terms of the drugs they include on their lists and how they price the drugs, so state MAC lists usually include more drugs at much lower prices than do FUL lists. A MAC list therefore can be an important cost-saving feature of a state's Medicaid prescription drug benefit program. States with established MAC programs have reported annual pharmacy budget savings of up to 4 percent.²⁷ In 2006, 43 state Medicaid programs, including Medi-Cal, administered state MACs.²⁸ MAIC is the Medi-Cal MAC program. As of June 2009, Medi-Cal's reimbursement formula for generics is the lesser of the MAIC, the FUL, or the Average Wholesale Price (AWP) minus 17 percent.²⁹

Change in FUL Pricing Put on Hold

The Deficit Reduction Act (DRA) of 2005 mandated that CMS establish the FUL price for generic drugs using a newly defined AMP, instead of the existing practice of basing the FUL on the AWP. California was one of several states positioned to base its generic Medi-Cal pharmacy reimbursement on the new AMP. These reimbursement reforms were delayed until September 30, 2009, by the Medicare Improvements for Patients and Providers Act of 2008. However, an injunction against using the AMP to compute retail pharmacy reimbursements under Medicaid was in effect in November of 2009, so the state's plan to use AMP as the basis for reimbursement is on hold. Pharmacists, drug stores, and prescription drug supply chain organizations had urged congressional leaders to reform the reimbursement system for generic drugs in Medicaid, arguing that implementation of the current provisions of the DRA will result in "unsustainable cuts" to pharmacy reimbursement and could result in loss of access to pharmacies for Medicaid beneficiaries.

340B DRUG PRICING PROGRAM

Federal law provides an opportunity for discount pricing of prescription drugs through Section 340B of the Public Health Service Act.³⁰ This provision limits the price of outpatient drugs for 340B program-participating

Federally Qualified Health Centers (FQHCs), qualified Medicaid Disproportionate Share Hospitals, Title X family planning entities, comprehensive hemophilia diagnostic treatment centers, and, since 2005, certain qualified children's hospitals.³¹ The 340B prices are estimated to average 19 percent less than the average Medicaid price after federal manufacturers' rebates.

Some states are taking advantage of this program to increase access to clinic- or hospital-based pharmacies in underserved rural and urban neighborhoods, and for people with HIV and other conditions requiring expensive specialty drugs. To the extent that Medicaid beneficiaries use 340B sites to obtain covered drugs, a state's Medicaid program benefits from the low 340B prices. However, states cannot seek a 340B discount and a manufacturers' rebate on the same drug.³² Some states have acted to encourage the establishment of 340B pharmacy programs at qualified clinics. For example, Connecticut passed legislation in 2003 providing loans to FQHCs for them to establish a pharmacy facility or partner with a community pharmacy that would serve as a centralized prescription drug distributor.³³

California passed legislation in 2001 to expand dispensing options for California safety-net clinics by authorizing 340B-eligible clinics to contract with a community pharmacy to dispense 340B drugs.³⁴ As of January 2004, 59 clinics had such pharmacy agreements.³⁵ Legislation (SB 708) enacted in 2005 requires DHCS to develop a standard contract for private, nonprofit hospitals that requires the hospitals to provide medical care to indigent patients if they choose to participate in the 340B drug discount program.³⁶

Utilization Strategies

PRESCRIPTION LIMITS

Some states, including California, have adopted a limit on the number of dispensed prescriptions (some limit only brand name drugs, others limit all drugs) that an individual can receive during a month or over a

year.³⁷ In addition to limits on the number of drugs, many states impose minimum or maximum quantities per prescription or limit the number of refills, if such limitations are necessary to discourage waste, fraud, or abuse of medications.³⁸ Many states, including California, have a process by which the limitations can be overridden when medically necessary.

COPAYMENTS

Many states have adopted copayment requirements for prescribed drugs. In some states, copayments are applied across all drug classes as a way of passing some of the cost of prescription drugs to consumers. However, federal regulations restrict the amount of cost-sharing through copayments. For most Medicaid beneficiaries, only nominal copayments are permitted: no more than \$0.60 per service for services that cost the state \$10 or less, up to a maximum of \$3.40 per service for services that cost the state more than \$50.³⁹ These federal limits are indexed annually to reflect general medical inflation.

In some states, copayments vary by type of drug. For example, a state may apply a higher copayment to brand name drugs than to generic drugs, in order to encourage beneficiaries to choose generics. Medi-Cal applies the same \$1 copayment to all prescriptions. The DRA of 2005 provides states with the option of allowing pharmacists to require the payment of a state-established copayment prior to dispensing the drug, but most states, including California, require that drugs be dispensed if an individual cannot afford the copayment.

GENERIC SUBSTITUTION

The average cost of generic drugs is 80 to 85 percent lower than the cost of their brand name counterparts.⁴⁰ As a result, most Medicaid programs have adopted policies to promote the use of generics. In 2004, 41 state Medicaid programs required that, when available, generic drugs are to be dispensed to Medicaid beneficiaries in place of equivalent name brand drugs.⁴¹ Under these policies,

the brand name drug remains available to beneficiaries through prior authorization.

The Medi-Cal program does not require generic substitution for all multiple-source drugs. Rather, by state law, Medi-Cal is required to purchase the most cost-effective drug.⁴² Many times this will be a generic drug, but some drug manufacturers have agreed to pay such substantial supplemental rebates that the brand name drug's net cost to the state is lower than the generic drug cost.

Use of generics varies across state Medicaid programs. Arizona, which does not participate in the federal rebate program, has a mandatory generic substitution provision for Medicaid; the state reported 71 percent of all prescriptions filled in 2005 were generic.⁴³ By comparison, California, which relies heavily on a rebate strategy, reported that 52 percent of all Medi-Cal prescriptions filled in 2005 were generic drugs.⁴⁴

DRUG UTILIZATION REVIEW

DUR is a tool used by all state Medicaid programs and by all managed care plans to monitor outpatient pharmacy benefits. Medi-Cal and its fiscal intermediary work together to perform prospective and retrospective DURs of FFS prescription drug claims to prevent payment of duplicate claims, avoid dangerous drug interactions, identify potential abuse, and review requests by physicians who want to prescribe more than the allowed six prescriptions per month. The fiscal intermediary also identifies the highest-cost drug users and can implement case management interventions if appropriate.

In addition, states have adopted pharmacy utilization management (UM) strategies to encourage more appropriate medication utilization and control costs. Pharmacy UM tools include prior authorization, step therapy, quantity limitations, and generic substitution, and may also include "counter-detailing" efforts to educate prescribers regarding the most effective use of

medications.^{45,46} Utilization management initiatives may be administered by pharmacy benefit managers under contract with the state Medicaid program, or by state staff. For example, in April 2008, Florida Medicaid implemented a Comprehensive Hemophilia Disease Management Program in an effort to better manage hemophilia drug costs. Other states have adopted strategies that focus on improving effective use of high cost behavioral health drugs, including antipsychotics, by identifying prescribing patterns which fall outside of recommended utilization practices and by providing feedback to prescribers.

COMPREHENSIVE MANAGED CARE

Several states have introduced comprehensive care utilization strategies within FFS arrangements, integrating pharmacy utilization management strategies with coordination of all services necessary for the treatment and management of chronic or acute conditions. Medi-Cal is currently implementing care management pilots that target high cost Medi-Cal beneficiaries in four counties and a similar strategy in five counties for beneficiaries with serious mental illness.⁴⁷ Under the pilots, contracted care managers will encourage appropriate utilization of prescription drugs and other services as part of a holistic approach to improving care outcomes for individuals with chronic or disabling conditions who are in the FFS delivery system. Other states have adopted patient-centered medical home strategies, integrating chronic care services through coordination of primary and specialty services and through linking individuals to social supports within a regular source of care.

In addition, many states, including California, have used managed care plans to improve the cost-effectiveness of drug utilization. By including prescription drug coverage as part of the benefits package provided to Medicaid enrollees in full-risk managed care plans, health plans are able to integrate prescription drugs into care management strategies. Medi-Cal managed care plans

are required to perform utilization review, and they may develop their own formularies, pharmacy networks, and utilization controls. For example, Inland Empire Health Plan, a Medi-Cal contractor, generally requires the use of available generics for both its commercial and Medi-Cal plans. Brand name products, when generics exist, are available only through Inland's Pharmacy Exception Request process, which requires justification of use and proven failure of the generic version. A Pharmacy and Therapeutics Subcommittee appraises, evaluates, and selects pharmaceutical products for formulary inclusion and exclusion; the subcommittee meets at least quarterly to evaluate products based on efficacy, safety, ease of use, and cost. In addition, the subcommittee recommends disease management or treatment guidelines, including drug therapies, for specific diseases or conditions.

Looking Ahead

California has been a national leader in the development of effective strategies to control the growth of Medicaid spending for outpatient prescription drugs, especially regarding its use of a PDL and supplemental rebates. Despite these efforts, Medi-Cal pre-rebate spending for FFS outpatient prescription drugs among the Medi-Cal-only population grew an average 12 percent per year from 2004 to 2007.

An examination of current prescription drug expenditures identifies increases in both price and utilization as cost drivers, especially for populations with chronic and disabling conditions. While historically Medi-Cal has found success with strategies to lower net pricing, the effectiveness of these strategies can be offset by increases in utilization, or by inappropriate or ineffective utilization. New or revised strategies may be needed to assure continuing high value from the Medi-Cal prescription drug program.

As California considers options to control Medi-Cal spending on prescription drugs, several important findings emerge from the material analyzed for this brief:

- Medi-Cal-only beneficiaries with chronic and disabling conditions are responsible for approximately 77 percent of Medi-Cal FFS drug expenditures. DHCS is currently implementing care management pilots that target these high-cost beneficiaries in four counties, and the state is considering options that might incorporate a broader medical home approach to service integration and coordination.
- Medi-Cal spending per prescription for Medi-Cal-only children increased 53 percent between 2004 and 2007, with an average annual growth rate of 15 percent per year. The state may want to explore whether the federal and supplemental rebates on commonly-used drugs, and especially drugs in the Blood Products category, are significantly offsetting the (pre-rebate) price increases for these categories or whether additional strategies are needed to address cost drivers. The Health Trailer Bill of 2008 includes a provision allowing DHCS to enter into contracts with manufacturers of FDA-approved antihemophilic factors (a major cost driver in the category of Blood Products); supplemental rebate contracts for antihemophilic factors were implemented by DHCS during the third quarter of 2009, and initial rebates will be received beginning January 2010. Estimated savings from these contracts for Fiscal Year 2009–10 is \$1 million. In addition, the state may want to assess the cost effectiveness of new, higher-priced drugs and decide whether there might be additional strategies (e.g., increased use of prior authorization, 340B pricing opportunities, or counter-detailing) that might encourage more cost-effective use of drugs.⁴⁸
- Spending for two general therapeutic classes of drugs, Central Nervous System and Psychotherapeutics, comprised 30 percent of Medi-Cal FFS drug expenditures for Medi-Cal-only beneficiaries in 2007. Spending for these classes increased at an average annual rate of 11.9 and 9.1 percent, respectively, from 2004 to 2007. A better understanding of the

specific drugs, conditions, prescribing patterns, and patients associated with these classes could help focus on cost control and appropriate utilization. These patient populations, both adults and children, might benefit from improved medication management, disease management, or other strategies to improve care coordination and effectiveness. The state has already begun work in this direction through the California Mental Health Disease Management project (CalMEND), a consortium of publicly-funded providers and purchasers of mental health services whose goal is to improve both the quality and the cost of mental health services to persons served by these entities. This project was initiated in part as a result of concerns about the high cost of, and high unexplained variance in use of, psychotropic medications; its objective is to develop a care management program for individuals with mental illness.⁴⁹ Medi-Cal may also want to consider seeking comparative effectiveness reviews as new drugs are introduced for the treatment of behavioral health, so that prescribers would have increased access to information with which to assess new products as they are introduced to the market.

- Finally, as more high-volume trade name drugs lose their patent protection and additional generic options become available, Medi-Cal may want to revisit its approach to the use and pricing of generics. For example, Medi-Cal might find that more aggressive pricing for generics, whether through an improved state MAIC or through more aggressive negotiation and enforcement of manufacturer rebate agreements, may help slow the increase in program spending. This may require the state to strengthen the administrative infrastructure for generic pricing and controls, but such an investment could pay off in longer-term moderation of spending trends.

ABOUT THE AUTHORS

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ABOUT THE FOUNDATION

The California HealthCare Foundation is an independent philanthropy committed to improving the way health care is delivered and financed in California. By promoting innovations in care and broader access to information, our goal is to ensure that all Californians can get the care they need, when they need it, at a price they can afford. For more information, visit www.chcf.org.

Appendix: Methodology

DATA SOURCES

Data for this report reflect claims paid by Medi-Cal from January 2004 through September 2008 for prescription drugs dispensed from January 2004 through December 2007.

The claims include FFS payments for drug expenditures carved out of managed care benefits for beneficiaries enrolled in Medi-Cal managed care plans, as well as drug expenditures for beneficiaries in Medi-Cal FFS. Medi-Cal beneficiaries were included in the annual reports if they had at least one month of Medi-Cal eligibility in the year. The claims used for the tabulations included outpatient pharmacy records with a missing or '000' Plan Code value and a non-zero Medi-Cal paid amount. The claims evaluated include those adjudicated for California's Medical Care Services program (Medi-Cal), but do not include services authorized by the California Children's Services/Genetically Handicapped Persons program or the Child Health and Disability Prevention/Early and Periodic Screening, Diagnostic and Treatment program.

These data do not include prescription drug expenditures for managed care enrollees covered by the managed care plan. (It is difficult to capture the pharmacy benefits covered by managed care since Medi-Cal data for services provided through managed care plans are not reliably and consistently available across all plans.)

POPULATION GROUPINGS

For some analyses, the Medi-Cal population was grouped into categories based on age and aid code. Since a beneficiary can be eligible in more than one aid code, the claims were matched to eligibility information to determine the primary aid code. Persons eligible under any of the specified codes were grouped into one of the ABD (aged, blind, disabled) categories.⁵⁰ The groups were also divided by age: Children were defined as under age 18; Adults were defined as ages 18 through 64; and persons age 65 and older were put in the Elderly category. Age was determined based on end-of-year status.

The five assigned categories were:

- Elderly;
- Non-Elderly Adults with Disabilities;

- Children with Disabilities;
- Other Adults; and
- Other Children.

Beneficiaries were classified as dual-eligibles if they were eligible for full-scope Medi-Cal and had at least one month of Medicare coverage during the year.

DRUGS INCLUDED AND EXCLUDED

Drugs provided in a hospital or facility setting were not separately identified in the data source and were not included in this report unless they were provided by a community pharmacy. For example, chemotherapy or other therapies administered by a physician were not reported in the tabulations. However, self-administered drugs used by nursing home residents were. Additionally, medical supplies other than nutritional supplements were not counted, drug rebates were not included, and payments for drugs covered by the Family Planning Access and Treatment program were not included in the detailed cost and user analyses.

Injectables dispensed at a pharmacy, e.g., insulin, were included. Injectables administered in a physician office or clinic were not included since they are billed via a professional or facility claim. While this report's analyses were restricted to prescribed therapies (as opposed to administered therapies), it should be noted that non-pharmacy claims for these payments can include very expensive therapies, e.g., Erythropoietin and chemotherapy. However, this is not an unusual distinction made in pharmacy analyses, and the First DataBank SmartKey General Therapeutic Class Codes used in these analyses do not include a separate class for injectables.

CLAIMS LAG

Although pharmacy claims normally have a very short time between billing and payment, a one-year lag was used when selecting claims for analysis, with the exception of 2007, for which a nine-month lag was used. For example, to identify claims for services in calendar year 2004, the claims paid from January 2004 through December 2005 were reviewed. This allowed for inclusion of late billing, and claims for services which were later adjusted were matched to the final, adjusted amount.

ENDNOTES

1. The data on which the analysis in this issue brief is based comes from Medi-Cal paid claims for 2004–2007, as provided by JEN Associates. (See Appendix for a description of the brief’s methodology.) These figures do not include amounts that come into the program through rebates from pharmaceutical manufacturers. Manufacturers’ rebates are discussed later in the brief, under the section titled “Managing the Cost of Prescription Drugs.”
2. This decrease in expenditures is significantly offset by state funds which must now be paid to the federal government for Medicare Part D benefits going to Medi-Cal beneficiaries who are also enrolled in Part D. This matter is discussed later in the brief, under the section titled “Medicare Part D.”
3. Complete and reliable claims data are not available for all managed care beneficiaries. Consequently, this brief focuses on FFS beneficiaries’ pharmacy utilization and expenditures.
4. “Medi-Cal-only” refers to Medi-Cal beneficiaries who do not have Medicare coverage.
5. Throughout this issue brief, the term “average annual rate” (or “average annual growth rate”) refers to the compound average growth rate.
6. “Prescriptions per person” refers to the number of pharmacy claims paid per beneficiary.
7. MAIC is the maximum amount Medi-Cal will reimburse pharmacy providers for generically equivalent drugs. Federal law permits states to set their own payment limits, known as MAC; California applies such limits under its MAIC program.
8. Medi-Cal prohibits the charging of copayments for certain populations, based upon traditional federal exclusions. These include pregnant women, children under age 18, residents of hospital and nursing facilities, and for prescriptions related to family planning or emergency services.
9. The Deficit Reduction Act of 2005 (DRA) permits states to implement alternative cost sharing that makes payment of any copayment a requirement prior to dispensing, but Medi-Cal has not implemented this option.
10. For a complete list of optional drugs covered under Medi-Cal, see *Medi-Cal Provider Manual*, Part 2, Drugs: Contract List Introduction. Pharmacy 667, November 2007.
11. *Medi-Cal Local Assistance Estimates, 06-08* (www.dhcs.ca.gov/dataandstats/reports/mceestimates/pages/default.aspx).
12. DHCS. *2009–2010 Governor’s Budget Highlights* (www.dhcs.ca.gov/documents/2009-10_gov_budget_highlights_dept_of_health_care_services.pdf); DHCS. *Medi-Cal May 2009 Local Assistance Estimate for Fiscal Years 2008–09 and 2009–10, Base Policy Changes* (www.dhcs.ca.gov/dataandstats/reports/mceestimates/documents/2009_may_estimate/m09_06_base_policy_changes_tab.pdf).
13. This number does not include individuals who are enrolled in managed care who received an FFS prescription for mental health or other carved-out drugs.
14. Ibid.
15. A complete analysis of the impact that changes in the costs of specific drugs and classes of drugs have on the growth of Medi-Cal FFS drug expenditures should include the rebates, paid to the state, associated with these drugs, as discussed in the section “Pricing Strategies,” below. However, due to confidentiality agreements between DHCS and manufacturers, drug-specific rebate information was unavailable for the analysis in this brief.
16. If a state Medicaid program imposes a formulary, it must provide for prior authorization for non-preferred drugs and clinical utilization review within 24 hours of receipt of a request.

17. For name brand drugs, the rebate is the larger of 15.1 percent of the Average Manufacturer Price (AMP) per unit, or the difference between the AMP and the best price per unit, adjusted by the CPI-U based on launch date and current quarter AMP; for generic drugs, the rebate is 11 percent of the AMP per unit (www.cms.hhs.gov/MedicaidDrugRebateProgram). AMP means the average price paid to the manufacturer for a drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, without regard to customary prompt pay discounts extended to wholesalers. See 42.CFR 447.504 (a).
18. Health Management Associates. *2007 State Perspectives Medicaid Pharmacy Policies and Practices*. National Association of State Medicaid Directors, November 2007.
19. Four of California's County Operated Health Systems (COHS), which deliver managed Medi-Cal services to all beneficiaries in the county, are organized as "health insuring organizations" and are therefore not subject to the federal rebate exclusion. The exception is the San Mateo COHS, which is organized as a managed care plan.
20. H.R. 3962 (House Democrats), introduced October 29, 2009, and S. 1796 (Senate Finance Committee), introduced October 19, 2009.
21. Section 1927(d) of the Social Security Act provides that states may establish certain restrictions of their own on covered drugs, including the use of formularies and prior authorization, and may establish limits on the minimum or maximum quantities prescribed, as long as certain conditions are met (e.g., timeliness of processing prior authorizations).
22. Crowley, J.S., D. Ashner, and L. Elam. *State Medicaid Outpatient Prescription Drug Policies: Findings from a National Survey, 2005 Update*. Kaiser Commission on Medicaid and the Uninsured.
23. In April 2004, Health and Human Services Secretary Tommy Thompson approved the first of these arrangements, a proposal by Michigan, Vermont, New Hampshire, Alaska, and Nevada to pool their purchasing power for purposes of negotiating supplemental pharmacy manufacturers' rebates (www.hhs.gov/news/press/2004pres/20040422.html).
24. Health Management Associates. *2007 State Perspectives: Medicaid Pharmacy Policies and Practices*. National Association of State Medicaid Directors/APHSA, November 2007.
25. Ibid.
26. Section 1928(e) of the Social Security Act.
27. Wimpee, A., T. Zuchlewski, and R. Kerber. Washington Medicaid program. Telephone interview. Olympia, Washington. July 31, 2002.
28. General Accounting Office, report number GAO-07-239R, "Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs," January 22, 2007.
29. AWP means the average price at which wholesalers sell drugs to physicians, pharmacies, and other customers. In practice, it is a figure reported by commercial publishers of drug pricing data. According to the *Red Book*, published by Thomson Medical Economics, the pricing information is "based on data obtained from manufacturers, distributors, and other suppliers."
30. Details on the 340B Drug Pricing Program are available at www.hrsa.gov/opa/introduction.htm.
31. Section 6004 of the Deficit Reduction Act of 2005. Public Law 109-171.
32. Cohen, Andrea G. *The Federal 340B Drug Discount Program: A Primer*. Presentation to the National Medicaid Congress, June 13, 2007.
33. Ibid.
34. National Legislation Association on Prescription Drug Prices. 340B Policy Background, accessed September 15, 2009 (www.reducedrugprices.org/340b_policy.asp).
35. Ibid.
36. Ibid.
37. Section 440.230 of the Social Security Act provides that states may specify the amount, duration, and scope of services available under Medicaid, provided the scope of service available is sufficient to reasonably achieve its purpose.

38. Section 1927(d)(6) of the Social Security Act details permissible restrictions states may apply to covered drugs under Medicaid.
39. Medicaid Program. *Premiums and Cost Sharing, Final Rule* (CMS 2244-F). Federal Register, 73 (228), November 25, 2008 (edocket.access.gpo.gov/2008/E8-27717.htm).
40. United States Food and Drug Administration. *Facts and Myths About Generic Drugs* (www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm).
41. National Pharmaceutical Council. *Pharmaceutical Benefits Under State Medical Assistance Programs, 2005–2006*.
42. California Administrative Code, Title 22, Section 51313(c)(1)(B).
43. Crowley, J.S., D. Ashner, and L. Elam. *State Medicaid Outpatient Prescription Drug Policies: Findings from a National Survey*. Kaiser Commission on Medicaid and the Uninsured, 2005, Update 2007.
44. Crowley, J.S., D. Ashner, and L. Elam. *State Medicaid Outpatient Prescription Drug Policies: Findings from a National Survey*. Kaiser Commission on Medicaid and the Uninsured, 2005.
45. Prior authorization requires that the physician obtain approval for payment of a drug by documenting the medical necessity of the drug to a pharmacy benefit manager, a managed care organization, or the Medicaid agency. Step therapy is a pharmaceutical utilization management tool that requires prescribers to first treat certain conditions using one set of (generally older and less expensive) drugs before using other (generally newer, sometimes riskier or more expensive) drugs. Step therapy programs typically promote the use of generics or other cost-effective alternatives as the first choice drug before progressing to more costly alternatives.
46. Counter detailing is an approach to educating prescribers and to countering the marketing directed to prescribers by pharmaceutical representatives. Consultants inform prescribers about what drugs work best, with messages, backers of this approach explain, that are driven by unbiased peer-reviewed research rather than by pharmaceutical company earnings reports.
47. Medi-Cal is implementing two Coordinated Care Management Projects in early 2010. One project will be focused on Aged, Blind, or Disabled beneficiaries in Butte, Contra Costa, El Dorado, and Placer counties; the second project will be focused on individuals with serious mental illness and will be offered in Kern, Kings, Madera, Stanislaus, and Tulare counties.
48. Health Management Associates. *Considerations for Redesign of the California Children's Services Program*, September 2009.
49. Knapp, Penny, M.D., medical director, California Department of Mental Health, NASMHPD. Presentation titled *Transition to Recovery in California: Psychiatrists' Response, 9/9/07*.
50. ABD Aid Codes include: 1, 10, 13, 14, 16, 17, 18, 1D, 1E, 1H, 1U, 1X, 1Y, 20, 23, 24, 26, 27, 28, 2D, 2E, 36, 60, 63, 64, 66, 67, 68, 6A, 6C, 6D, 6E, 6H, 6N, 6P, 6S, 6U, 6V, 6W, 6X, 6Y, 80, and 8G.