California State Auditor

BUREAU OF STATE AUDITS

Department of Health Services:

Its Efforts to Further Reduce Prescription Drug Costs Have Been Hindered by Its Inability to Hire More Pharmacists and Its Lack of Aggressiveness in Pursuing Available Cost-Saving Measures

April 2003
2002-118

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April 30, 2003 2002-118

The Governor of California
President pro Tempore of the Senate
Speaker of the Assembly
State Capitol
Sacramento, California 95814

Dear Governor and Legislative Leaders:

As requested by the Joint Legislative Audit Committee, the Bureau of State Audits presents its audit report concerning our review of the Department of Health Services' (Health Services) practices for containing Medical Assistance Program (Medi-Cal) pharmaceutical costs. This report concludes that Health Services may not fully achieve the roughly $104 million cost savings to the State's General Fund that it predicted for fiscal years 2002–03 and 2003–04. Health Services' inability to generate the full savings stems from a lack of pharmacists, a failure to consider fully the consequences of some of its planned activities, and a lack of reliable data to support its estimates. Further, although it appears that California was one of the first states to use cost-saving strategies, such as its List of Contract Drugs and pursuit of supplemental rebates to contain prescription drug costs, Health Services has not adopted certain techniques other states use. For example, some states use disease management programs or target their educational efforts toward providers whose prescribing or dispensing patterns are inappropriate. Finally, Health Services may be able to achieve additional savings of up to $80 million by eliminating optional pharmacy benefits.

Respectfully submitted,

Elaine M. Howle

ELAINE M. HOWLE
State Auditor

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Our review of the Department of Health Services' (Health Services) practices for containing Medical Assistance Program (Medi-Cal) pharmaceutical costs found the following:

- ☑ *Health Services may not fully achieve the roughly $104 million General Fund cost savings it predicted for fiscal years 2002–03 and 2003–04 because it has been unable to hire pharmacists, has not considered fully the consequences of some planned activities, and has presented questionable estimates.*
- ☑ *Although Health Services employs some cost-saving strategies, such as the List of Contract Drugs, it has been slow to consider or adopt others.*
- ☑ *Its efforts to educate physicians and pharmacists about inappropriate or medically unnecessary drug therapy are limited.*
- ☑ *Health Services has not sought funding for disease management pilot projects that could potentially benefit the Medi-Cal population.*

RESULTS IN BRIEF

The Department of Health Services (Health Services) is responsible for administering the federal Medicaid program in California, the Medical Assistance Program (Medi-Cal). Although federal law does not require the State to provide prescription drugs under its Medicaid program, California has chosen to do so for more than 6 million residents at a cost of $2.7 billion. The cost to the State for drugs it provides beneficiaries under the Medi-Cal Fee-for-Service system has risen as dramatically, as have drug costs nationwide over the last several years. Currently, half the Medi-Cal population has migrated to the State's managed care system. The remaining 3 million beneficiaries who continue to participate in the traditional Fee-for-Service system can obtain services or supplies from any provider who has agreed to serve them. Health Services establishes reimbursement rates, and providers bill Health Services. As California struggles with its budget deficit, concerns have been raised as to whether Health Services is doing all it can to contain drug costs under the Medi-Cal Fee-for-Service system.[1]

Health Services estimated that it could generate cost savings to the State's General Fund of roughly $104 million for fiscal years 2002–03 and 2003–04. However, because Health Services has been unable to hire pharmacists, has not considered fully the consequences of implementing some of its planned activities, and has presented unsupported or inaccurate estimates in its annual budgets, it might not fully achieve the estimated cost savings, or they might be delayed. Specifically, Health Services has not been able to fill 13 pharmacist positions approved during budget negotiations for fiscal years 2001–02 and 2002–03 to meet increases in its workload and to implement several cost-saving proposals. Consequently, Health Services has not been as prompt as it could be in performing some of its ongoing duties that could reduce costs. Lacking sufficient staff, Health Services has not negotiated state supplemental rebates with all drug manufacturers, promptly renegotiated existing rebate contracts, and consistently tracked rebate payments. Health Services has further limited its ability to reduce Medi-Cal drug costs by not aggressively pursuing other cost-saving measures, such as disease management programs.

[1] For the purposes of this report, all references to Medi-Cal relate solely to the Fee-for-Service system.

Health Services' pharmaceutical unit is responsible for developing Medi-Cal's List of Contract Drugs (drug list)—the list of drugs that physicians can offer Medi-Cal beneficiaries and for which pharmacies receive reimbursement without first having to get Health Services' approval. The drug list was initiated in 1992 as a cost-saving measure because, as the Legislature originally intended, to have a drug included on the list, the manufacturer had to contract with Health Services to pay a supplemental rebate. However, because it lacks sufficient staff, the pharmaceutical unit has taken up to two years to add drugs to the drug list, and it has negotiated rebates primarily with manufacturers of brand name drugs, not the more common generic drugs. Although Health Services indicated that drug manufacturers often delay the negotiation process, its inability to fully staff its pharmaceutical unit is the primary reason Health Services has failed to negotiate supplemental rebates with all drug manufacturers and has delayed negotiating contracts and making additions to the drug list. As a result, Health Services may be paying more for drugs than it should and ultimately not making the best use of State resources.

According to Health Services, it has failed to increase its pharmacist staff because its ability to recruit individuals with the appropriate knowledge and skills is hampered by the disparity between the salaries it can offer and those offered in the private sector, and there is a shortage of pharmacists in the State. Our review confirmed that generally the salaries of pharmacists hired by Health Services are significantly lower than the base salaries of pharmacists hired by the University of California and the average private-sector salary. Attempting to address its difficulties in attracting qualified pharmacists, in August 2002, Health Services began developing a proposal for reclassifying its pharmacist positions and submitted the proposal to the Department of Personnel Administration for its review and approval on March 25, 2003.

In its original budget for fiscal year 2002–03, Health Services anticipated savings totaling $127 million in the cost of providing Medi-Cal pharmacy benefits. By November 2002, however, when Health Services began its budget process for fiscal year 2003–04, some activities related to these cost savings had not been implemented, requiring Health Services to reduce the estimated savings to about $80 million for fiscal year 2002–03; but it estimated savings of $127 million for fiscal year 2003–04. Because about 50 percent of its cost savings belong to the federal government, the November 2002 estimated savings to the State's

General Fund would be roughly $104 million over the two fiscal years. A significant portion of the estimated savings for the State—about $40 million for fiscal years 2002–03 and 2003–04—could be realized if Health Services aggressively pursued supplemental rebate contracts with manufacturers of generic drugs. Although Health Services has clear authority to establish such contracts with all drug manufacturers, it has not routinely done so for generic drugs in particular. Health Services told us that it has not aggressively pursued supplemental rebates for generic drugs because of its inability to hire pharmacists and the reluctance of generic drug manufacturers to negotiate lower prices.

Further, in a March 1996 audit, we reported that Health Services did not prepare invoices specifically for supplemental rebates but instructed manufacturers to calculate and submit required supplemental rebates along with their federal rebate payments. It also failed to monitor and track supplemental rebate payments. Therefore, Health Services could not ensure that it was making every effort to resolve rebate payment disputes within 90 days. We estimated that Health Services had not collected roughly $40 million in supplemental rebates owed to the State and the federal government. Health Services just recently received approval and hired four analysts to help resolve these issues, although it had requested approval to increase its staff of analysts for almost the past five years. During that time, the amount of unresolved rebates grew to more than $216 million, or 6 percent of the $3.4 billion invoiced between January 1991 and September 2001. Health Services estimated that it could achieve an additional $21 million, or a total of $10.5 million in savings to the State's General Fund, over the next two years by resolving some of these rebate disputes.

Although the supplemental rebates that Health Services negotiates with brand name drug manufacturers generally ensure that Medi-Cal incurs lower costs for drugs than do other state programs, Health Services does not have procedures to ensure that it accurately tracks the expiration dates of its supplemental rebate contracts and thus has ample time to renegotiate contracts. Our review of Health Services' drug prices found that it restricts its reimbursements to eight brand name drugs because it is generally able to obtain lower net costs[2] for them than for their generic counterparts after applying the supplemental rebates it receives from the manufacturers. In fact, for six of these eight drugs, we estimate that Medi-Cal

[2] For purposes of our report, net cost refers to the cost after reducing the drug ingredient cost by any applicable rebates.

saved more than $20 million in calendar 2002 by restricting utilization to the brand name drugs. However, we found two instances in which Health Services missed the opportunity to maximize its savings to the State. In each case, the net costs of the brand name drugs were actually higher than those of the generics because Health Services failed either to renegotiate the rebate contracts or to secure critical contract terms from the manufacturer. We estimate that these errors cost Medi-Cal roughly $57,000 in calendar year 2002. Health Services' net costs for drugs were typically lower than those purchased by Health Services' AIDS Drug Assistance Program and the Department of General Services.

Health Services generally reimburses pharmacies at higher rates compared with 17 states that responded to our survey. By state law, Health Services was required to reimburse pharmacies at the average wholesale price (AWP) minus 5 percent, while most other states offered reimbursements ranging from the AWP minus 10 percent to the AWP minus 50 percent. Legislation that took effect on December 1, 2002, reduced the amount that Health Services reimburses pharmacies to the AWP minus 10 percent. Additionally, at least one state Medicaid program has taken an aggressive approach toward collecting copayments from beneficiaries by placing the responsibility on the pharmacists to recover the copayments that the State now subtracts from their reimbursements. Medi-Cal could save $20 million annually by adopting this approach.

Although Health Services has implemented some cost control strategies, such as the drug list, it has been slow to implement other potential cost-saving measures. For example, California's drug utilization review (DUR) program—a mechanism to ensure that prescriptions for covered outpatient drugs are appropriate, medically necessary, and not likely to result in adverse medical results—has more dispensing alerts than do most other states' programs and more than federal law requires. However, unlike DUR programs in many states responding to our survey, California's program has not adopted step therapy protocols, which require physicians first to treat a medical condition with less expensive, though therapeutically equivalent, drugs and then to prescribe more expensive drugs only if the patient shows no improvement.

Health Services' retrospective DUR process monitors drug use and cost trends to identify misuses and educational needs. Through this process, Health Services has identified and

developed responses to costly Medi-Cal drug patterns. Currently, Health Services' educational program is restricted to periodically disseminating information to general audiences and to its few active and proposed projects that are heavily dependent on the expertise and resources of its DUR board members. Consequently, Health Services has only limited opportunities to educate physicians and pharmacists about inappropriate or medically unnecessary drug therapy and to capture cost savings that may result from changes in drug prescribing and dispensing behavior.

Although many states have implemented disease management programs, which are designed to improve the quality of care for Medicaid populations and ultimately contain costs for Medicaid overall, Health Services' progress toward a comprehensive disease management program is minimal. Recently, Health Services has collaborated with the California Pharmacists Association (CPhA) to develop Medi-Cal–specific pilot projects for disease management relating to asthma, diabetes, and hypertension. These projects lack the funding they need to begin because Health Services has chosen to rely on its nonprofit partners to secure funds. Consequently, until Health Services moves forward on funding the pilot projects, the potential benefits of a disease management program and its applicability to the Medi-Cal population will remain unrealized.

Finally, California offers coverage for certain drugs that the federal government considers optional. Eliminating coverage for these drugs could yield as much as $80 million in annual savings to Medi-Cal.

RECOMMENDATIONS

To improve its ability to realize potential cost savings and obtain lower net costs for drugs for Medi-Cal, Health Services should do the following:

- Revise its procedures for adding new drugs to the drug list to include a timeline for completing reviews and specific steps on how staff should address manufacturers' delays.

- Negotiate supplemental rebate contracts with manufacturers of generic drugs.

- Evaluate periodically the number of staff needed to resolve disputed rebates within 90 days.

- Establish a set of policies and procedures to ensure that it follows up on and renegotiates supplemental rebate contracts before their expiration dates.

- Evaluate the possibility of deducting copayments from its reimbursement rate and have pharmacies collect copayments from beneficiaries.

- Analyze the costs and benefits of adding step therapy protocols to its DUR program.

- Consider seeking funds to continue its collaboration with the CPhA for the proposed pilot projects for disease management.

- Conduct a study to identify the effect of eliminating coverage of all or a portion of the optional drugs currently included in its benefits.

AGENCY COMMENTS

Generally, Health Services agrees with our recommendations. Further, Health Services acknowledges that California can—and must—do even more to reduce drug costs. ■

INTRODUCTION

BACKGROUND

The Department of Health Services (Health Services) administers the federal Medicaid program in California, which is known as the Medical Assistance Program (Medi-Cal). Federal law requires Medi-Cal to provide a set of basic services, including doctor visits, laboratory tests, and hospital inpatient and outpatient care. Additionally, federal matching funds are available for any of several optional benefits, including payments for prescription drugs. Generally, Medi-Cal covers low-income individuals and families who receive public assistance or lack private health insurance coverage. State funding of Medi-Cal is supplemented by federal matching funds the State receives based on its per capita income.

Health Services estimates that almost 6.5 million Californians, or more than 15 percent of the State's residents, are eligible for Medi-Cal in any given month. Medi-Cal beneficiaries receive services through either a Fee-for-Service or managed care system.[3] Under the Fee-for-Service system, a Medi-Cal beneficiary can obtain services from any provider who possesses a valid Medi-Cal provider number; in turn, the provider bills Medi-Cal for any service provided to an eligible Medi-Cal beneficiary. Although not required to do so, all states offer coverage for prescription drugs. Medi-Cal provides prescription drugs to almost half the Medi-Cal–eligible population, which comprises primarily the aged, blind, and disabled. Like Medicaid programs nationwide since 1990, Medi-Cal has witnessed dramatic increases in its drug costs, which now represent a significant component of Medi-Cal's total costs. In fact, Health Services' average monthly payment per beneficiary receiving a prescription nearly doubled between October 1998 and April 2002, increasing from $158 to $301.

HEALTH SERVICES' ROLE IN CONTROLLING DRUG COSTS

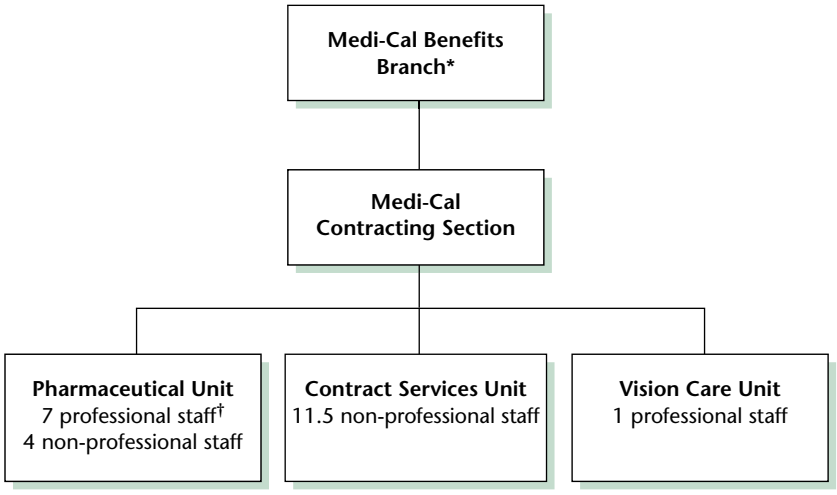
As part of the Medi-Cal Policy Division of Health Services, the Medi-Cal Benefits Branch develops policy and makes recommendations regarding the scope, quality, and methods of providing Medi-Cal benefits. Within this branch is the Medi-Cal

[3] For the purposes of this report, all references to Medi-Cal relate solely to the Fee-for-Service system.

Contracting Section, which administers policy for Medi-Cal's pharmacy, medical supply, and vision benefit programs. This section is divided into three units: the pharmaceutical unit, the contract services unit, and a very small vision care unit. Figure 1 shows an organizational chart and the number of employees in each unit.

FIGURE 1

The Medi-Cal Contracting Section Administers Policy for Medi-Cal's Pharmacy, Medical Supply, and Vision Programs



* The Medi-Cal Benefits Branch is within the Medi-Cal Policy Division, which is located within the medical care services area of Health Services.

† The professional staff include six pharmacists and one nurse.

Two of the techniques Health Services uses to control drug costs are its drug formulary, which is called the List of Contract Drugs (drug list), and the state supplemental rebate program, through which Health Services negotiates rebates with drug manufacturers.

Medi-Cal's Drug List

State law, enacted in 1992, authorizes Health Services to enter into contracts for state supplemental rebates with manufacturers of drugs and to maintain a list of those drugs for which it executes contracts. It was the Legislature's intent that, in implementing a list of drugs, Health Services would negotiate as aggressively as necessary to achieve the savings identified in the 1992 budget act. Health Services' drug list is a list of preferred

drugs from which a physician can prescribe and for which a pharmacy can seek reimbursement without first obtaining approval from Health Services. The pharmaceutical unit is responsible for developing and maintaining the drug list.

The pharmaceutical unit adds a new drug to the list in response to a request from the drug manufacturer, a physician, a pharmacist, or Health Services itself can initiate the addition. With the assistance of the Medi-Cal Contract Drug Advisory Committee (committee), which consists of at least one physician and one pharmacist, the pharmaceutical unit evaluates the drug using five criteria: safety, efficacy, essential need, misuse potential, and cost. Additionally, after receiving the committee's recommendations, the pharmaceutical unit meets with the drug manufacturer, if the manufacturer so requests, to discuss the drug's therapeutic aspects and any state supplemental rebate offers. Ultimately, the pharmaceutical unit and the chief of the Medi-Cal Contracting Section review the drug based on the five criteria and, by consensus, decide whether to add the drug to the drug list.

In addition, the pharmaceutical unit performs ongoing reviews of the drug list and periodically assesses whether to delete a drug. According to Health Services, it might identify a drug for deletion because, for example, studies show that more effective drugs are available, or the drug's rebate contract ends and there are enough other drugs on the drug list to meet the medical needs of beneficiaries. Before it can conduct a public hearing to discuss the removal of a drug, Health Services must provide a 30-day written notice to the drug manufacturer and to organizations representing Medi-Cal beneficiaries. The hearing panel consists of the chief of the Medi-Cal Contracting Section and members of the committee. During the hearing, the panel elicits comments from the public. Within 30 days of the hearing, each panel member must submit a recommendation to the chief of the Medi-Cal Contracting Section and ultimately to the director of Health Services, who decides whether or not to remove the drug.

Although Health Services can suspend or delete a drug from the drug list, the drug is still available to Medi-Cal beneficiaries through Health Services' treatment authorization request (TAR) process. The TAR process can be initiated by any one of the more than 5,800 pharmacists participating in the Medi-Cal drug program. Generally, when a beneficiary goes to a pharmacy with a prescription from a physician and presents a Medi-Cal card, the pharmacist inputs the prescription into the Medi-Cal on-line

claims adjudication system, which is maintained by Health Services' fiscal intermediary, the Electronic Data Systems Federal Corporation (EDS). The on-line system runs the claim through a series of edits and audits to determine the validity and propriety of the claim. The system first verifies the customer's status as a Medi-Cal beneficiary and then begins to check for criteria set by Health Services, such as inclusion of the drug on the drug list, limitations on the number of prescriptions per month per beneficiary, and restrictions on utilization of some drugs to treat certain conditions. A prescription that fails any of these edits or audits is denied and returned to the pharmacy for correction and resubmission, or the pharmacist initiates a TAR and sends it to one of Health Services' two field offices that process drug TARs. At the field office, one of Health Services' pharmacists reviews the claim to determine whether the prescription is medically necessary. If the TAR is approved, the beneficiary's pharmacist can fill the prescription.

Rebate Negotiations With Drug Manufacturers

One of Health Services' primary objectives when meeting with a drug manufacturer seeking to have its new drug added to the drug list is to obtain as significant a price discount as possible. This type of discount on the drugs prescribed for Medi-Cal beneficiaries are in the form of manufacturer rebates and are called supplemental rebates. State law directs Health Services to contract with all drug manufacturers to obtain discount prices at least comparable to those they offer to other high-volume purchasers of drugs.

In addition to the supplemental rebates it is supposed to negotiate when adding drugs to the drug list, Health Services receives federal rebates from drug manufacturers. In January 1991, the federal government implemented a nationwide mandatory drug rebate program. Under the federal program, a drug manufacturer must submit quarterly rebates directly to 49 states for each drug reimbursed through the federal Medicaid program, as described in the agreement between the manufacturer and the federal government.[4] Thus, all drugs on the Medi-Cal drug list are covered under a federal rebate agreement, and many are also covered under the state supplemental rebate program. Additionally, because the federal government and the State jointly fund Medi-Cal, Health Services must return to the federal

[4] Arizona has a waiver for which special rules apply. That state provides medical services to its indigent population in a managed care system rather than in a Fee-for-Service system.

government a portion of the federal and state supplemental rebates it collects, using its current federal reimbursement rates, which are generally about 50 percent.

Finally, the contract services unit of the Medi-Cal Contracting Section is responsible for administering drug rebate contracts. Using its Rebate Accounting and Information System (RAIS)—a system maintained by EDS—Health Services gathers drug utilization data from the Medi-Cal drug claims submitted by pharmacies. At the end of each quarter, the RAIS compiles the data and prepares invoices, which EDS sends to drug manufacturers for the federal and, if applicable, state supplemental rebates. A manufacturer that does not agree with an invoice can dispute the amount of the rebate due. It is the responsibility of the contract services unit to work with the manufacturer to resolve the disputed rebate.

RECENT COST-CUTTING LEGISLATION

On September 30, 2002, the Legislature approved a health trailer bill to the fiscal year 2002–03 budget act—Assembly Bill 442 (AB 442)—which amends certain provisions of the law covering Medi-Cal. The intent of the bill is to achieve additional savings for prescription drugs beginning in fiscal year 2002–03 for the State's General Fund. In the past, Health Services was not able to negotiate contracts for supplemental rebates for drugs used to treat cancer or acquired immune deficiency syndrome (AIDS). State law required Health Services to automatically add these drugs to its drug list once they were approved by the federal Food and Drug Administration. Because this process did not include negotiating supplemental rebates with the pharmaceutical manufacturers, Health Services could only receive federal rebates for these drugs. However, AB 442 amended California law to require all drug manufacturers to negotiate with Health Services to provide state supplemental rebates on AIDS and cancer drugs added to the Medi-Cal drug list. Health Services estimated savings to the General Fund of approximately $7 million in fiscal year 2002–03. Another cost-saving effect of AB 442 is reduced pharmacy reimbursement rates for both brand name and generic drugs, which Health Services estimated would save the General Fund approximately $5 million in fiscal year 2002–03.

SCOPE AND METHODOLOGY

The Joint Legislative Audit Committee (audit committee) requested that the Bureau of State Audits examine current practices for containing Medicaid pharmaceutical and related expenditures and to assess the extent to which these practices can be or are applied to Health Services' Medi-Cal drug program. As part of the audit, the audit committee asked that we conduct a survey of selected states' Medicaid program practices aimed at containing costs. Further, the audit committee requested that the survey include, but not be limited to, other states' pharmacy reimbursement practices, policies to encourage the use of generic drugs, drug formulary practices, timely collection of rebates from manufacturers, establishment of disease management programs, and the net costs of drugs. Additionally, we were to compare Health Services' current practices with the cost containment practices of the California Public Employees' Retirement System (CalPERS). Using the data obtained from the surveyed states and CalPERS, we were asked to assess the applicability of the data to Medi-Cal and, if applicable, determine the extent to which Health Services uses such practices. Finally, we were asked to assess Health Services' staffing levels and contracting needs for carrying out its Medi-Cal pharmaceutical functions.

To understand Health Services' responsibilities and the drug purchasing environment in which it operates as it relates to the Medi-Cal program, we interviewed Health Services' staff; reviewed its reimbursement policies and procedures; and reviewed all relevant federal and state laws, rules, and regulations. We also discussed with Health Services its practices to contain prescription drug costs and reviewed current literature to identify practices used by other states and health maintenance organizations to contain drug costs. Using this information, we developed our survey, which we sent to the other 49 states and the District of Columbia; only 17 states responded.

Using the survey results, we compared California's net costs of drugs per beneficiary or user with the net costs in other states. However, we found that most of the states responding to our survey do not maintain data files that would easily provide a drug's net cost. For purposes of our report, net cost refers to the cost after reducing the drug ingredient cost by any applicable rebates. Instead, similar to California, these states maintain separate files that include the amounts they paid to pharmacies for drugs and the amounts of their federal rebates and, if applicable, state rebates. Although we requested the two files so we could calculate the net cost of a specific drug, the states

responding to our survey were unwilling or unable to provide this information for several reasons, including confidentiality concerns, a lack of staff to prepare data for our request, and an inability to provide rebate data at the National Drug Code level. Therefore, we were unable to compare California's net drug costs with those of other states. However, we were able to use the survey results to compare other methods the responding states use to contain prescription drug costs with those used by California. Appendix A presents the reimbursement rates and rebating practices of the states responding to our survey.

We were also able to compare Health Services' net costs of drugs with the net costs of drugs purchased by Health Services' AIDS Drug Assistance Program (ADAP)—a program for individuals suffering from the acquired immune deficiency syndrome who are not covered by Medi-Cal and otherwise could not afford the drugs they need—and those purchased by the Department of General Services (General Services), which purchases drugs on behalf of other state departments such as the departments of Corrections, Developmental Services, Mental Health, and the Youth Authority. To perform these comparisons, we identified the 200 drugs that represented the largest share of Health Services' drug expenditures (top 200 drugs) for the period of January 1, 2001, through December 31, 2001. The top 200 drugs are listed in Appendix B.

To perform our comparison of Health Services' net costs with those of the ADAP, we needed to understand the ADAP's process for paying for prescription drugs and collecting rebates from manufacturers; therefore, we interviewed officials with the ADAP and reviewed the contract it has with its pharmacy benefits manager. We then compared the list of Health Services' top 200 drugs with those included on the ADAP's list. For drugs that the ADAP also covers, we obtained pharmacy claims, invoices to manufacturers for rebates, and payment documents from manufacturers to calculate the net costs of the ADAP's drugs for comparison. When we compared Health Services' net costs of drugs with the net costs of drugs purchased by General Services, we interviewed General Services' staff to determine if there had been any changes to its process for purchasing drugs for other state agencies since our audit issued in January 2002; we concluded that there were no significant changes. General Services also provided us with a data file of the prices it paid for the top 200 drugs on Health Services' list and identified the purchasing method General Services used to obtain those prices; however, we did not test the validity of General Services' data.

To compare Health Services' cost containment practices with those of CalPERS, we interviewed the staff responsible for the self-funded health benefit programs, PERSCare and PERS Choice. Because CalPERS contracts with Blue Cross of California (Blue Cross) to provide claims and administrative services, we reviewed its contract with Blue Cross. We also interviewed staff from Blue Cross and reviewed documentation to obtain information related to its disease management programs. In addition, because CalPERS also contracted with Merck-Medco Managed Care, LLC (Merck-Medco) until December 31, 2002, to provide pharmacy services, which included a drug utilization review program, we interviewed officials from Merck-Medco and reviewed relevant documentation related to its drug utilization review program. However, we were unable to compare the net costs of drugs paid by CalPERS through Merck-Medco with the net costs of Health Services' drugs. According to CalPERS, Merck-Medco considers confidential the rebates it negotiates with manufacturers and thus does not provide CalPERS access to its rebate information.

To assess Health Services' staffing levels and contracting needs for carrying out its pharmacy management functions, we focused on whether Health Services is able to effectively perform certain functions at its current staffing levels, such as reviewing new drugs and performing drug utilization reviews. In addition, we reviewed budget change proposals and other budget documents that Health Services prepared during the last six years to request additional staff as well as its proposal to reclassify its pharmacist positions. Furthermore, because cost savings presented in its budgetary documents for fiscal years 2002–03 and 2003–04 appeared to rely on Health Services having sufficient staff to perform certain activities, we obtained and analyzed the data used to support these documents. We then assessed whether Health Services would ultimately achieve the cost savings. We also determined whether it had addressed the collection of a backlog of state and federal rebates that we reported in a March 1996 audit.

Finally, we excluded enteral formulae—nutritional products needed specifically for beneficiaries who cannot eat regular food—from our review of prescription drugs and related budgetary savings, because enteral formulae, by federal definition, are not considered prescription drugs and therefore are not within the scope of our audit. ■

CHAPTER 1

Without Enough Staff Pharmacists, Health Services May Not Achieve the Cost Savings It Estimated

CHAPTER SUMMARY

The Department of Health Services (Health Services) has not been able to fill 13 pharmacist positions approved during budget negotiations for fiscal years 2001–02 and 2002–03 to meet increases in its workload and to implement several cost-saving proposals. Consequently, Health Services has not been as prompt as it could be in performing some of its ongoing duties that could reduce costs. For example, in some instances, Health Services has taken longer than two years to review new drugs prior to their inclusion on the Medi-Cal List of Contract Drugs (drug list). The purpose of the drug list is to ensure that Medi-Cal beneficiaries receive prescription drug benefits that are both safe and cost-effective. Also, as part of its review of new drugs, Health Services negotiates with drug manufacturers for state supplemental rebates. Delays in finalizing its negotiations with manufacturers could result in Health Services incurring higher costs for drugs than is necessary.

We also question whether Health Services will achieve certain cost savings it estimated for fiscal years 2002–03 and 2003–04. Originally, its fiscal year 2002–03 budget for Medi-Cal pharmacy benefits included cost savings totaling $127 million. Most of these savings would result from Health Services pursuing additional state supplemental rebates and from provisions of new legislation. By November 2002, however, when it began the budget process for fiscal year 2003–04, Health Services had not implemented activities related to these cost savings and had to reduce the estimated savings to about $80 million for fiscal year 2002–03; but it estimated savings of $127 million for fiscal year 2003–04. Because it must share 50 percent of its cost savings with the federal government, Health Services' estimated cost savings to the State's General Fund would be roughly $104 million over the two years. Although this amount is not significant in relation to Health Services' total budget of $2.7 billion to provide prescription drugs under the Medi-Cal Fee-for-Service system, the State is relying on the savings to close the gap between its estimated revenues and expenditures.

The reasons Health Services might not fully achieve the estimated cost savings, or they might be delayed, are that it has been unable to hire pharmacists, has not considered fully the consequences of implementing some of its planned activities, and has presented unsupported or inaccurate estimates. For example, Health Services has not routinely established supplemental rebate contracts with manufacturers of generic drugs, although it has clear authority to do so. Health Services told us that it has not aggressively pursued supplemental rebates for generic drugs because of its inability to hire pharmacists and generic drug manufacturers' reluctance to negotiate lower prices. Yet, Health Services estimated that it could save the State's General Fund roughly $40 million for fiscal years 2002–03 and 2003–04 by aggressively pursuing contracts with manufacturers of generic drugs. Until Health Services addresses the difficulties it has experienced in hiring pharmacists to perform this task, it is doubtful that it will fully achieve these savings.

Finally, as of December 2002, Health Services' records reflect that it received approximately $216 million less in federal and state supplemental rebates than the $3.4 billion it invoiced manufacturers between January 1991 and September 30, 2001, and Health Services just recently began to work with manufacturers to reconcile the difference. Further, although it implemented a new invoicing system beginning February 2002, Health Services has also only recently started to work with manufacturers to resolve disputed invoices resulting from more current billings. In response to a March 1996 audit in which we reported a similar issue, Health Services repeatedly requested approval of additional analyst positions in almost every subsequent fiscal year to perform this function, but it only recently received approval for four new positions that it had filled as of February 2003. Thus, cost savings projected by Health Services of $7 million and $14 million for fiscal years 2002–03 and 2003–04, respectively, might not be fully realized until subsequent fiscal years.

HEALTH SERVICES HAS BEEN UNABLE TO HIRE NEEDED PHARMACISTS

Health Services has not been able to fill pharmacist positions approved during budget negotiations for fiscal year 2001–02 to meet increases in its workload, and it is currently unable to fill positions approved during fiscal year 2002–03 for pharmacists needed to implement several budget reduction proposals.

Consequently, as described in a later section, Health Services has not performed some of its ongoing duties as promptly as it could. Further, we question whether Health Services will fully achieve the cost savings that it estimated for fiscal years 2002–03 and 2003–04.

According to Health Services, from about 1993 through fiscal year 2001–02, the number of pharmacists in its pharmaceutical unit remained relatively constant at eight approved and filled positions. Health Services reported in its budget change proposal for fiscal year 2001–02 that increases in the number of new drugs approved by the federal Food and Drug Administration was creating a backlog of drugs requiring Health Services' review prior to their addition to the Medi-Cal drug list. In addition, it reported that it has never had adequate staff to renegotiate supplemental rebate contracts before they expire.

For fiscal year 2001–02, Health Services received approval for four new pharmacists to ensure that it evaluates new drugs within a reasonable time frame, renews expiring supplemental rebate contracts, and performs other needed activities. As part of the State's efforts to reduce General Fund spending for fiscal year 2002–03, Health Services received approval to hire 10 additional pharmacists, a move designed to generate cost savings by changing or adding certain procedures related to the procurement of Medi-Cal prescription drugs and other activities. Additionally, Health Services contracted with its fiscal intermediary, Electronic Data Systems Federal Corporation (EDS), for the services of five more pharmacists. Despite having approval to hire 19 pharmacists, Health Services states that as of March 2003, it had only six pharmacists in its pharmaceutical unit, after reclassifying two pharmacist positions to nurse consultants and losing one position to another unit. Moreover, as of March 2003, EDS had not hired the five pharmacists approved under its contract.

Duties of Pharmacists in Health Services' Medi-Cal Contracting Section

- Develop and analyze policies for pharmaceutical services and benefits provided by Medi-Cal.
- Negotiate supplemental rebate contracts with drug manufacturers.
- Design and analyze drug utilization review studies that, when complete, will generate useful information for the management of the program.
- Act as consultant on projects that modify the Medi-Cal pharmacy claims processing system and the rebate accounting system.
- Set drug benefit policies by analyzing legislation; budgeting; and consulting with the administration, the Legislature, and other government agencies.
- Analyze and respond to provider appeals and fair hearings. In addition, develop alternate decisions to a fair hearing for consideration by the administrative law judge.
- Respond to correspondence from beneficiaries, providers, provider organizations, and legislators concerning the scope of pharmaceutical benefits.

Health Services told us that it has not been able to recruit pharmacists with the appropriate knowledge and skills. For example, pharmacists must be able to negotiate with manufacturers for supplemental rebates, which involves developing pharmaco-economic analyses of drugs and

strategies—that is, examining the clinical and economic impact of pharmaceuticals. Because of these unique duties, Health Services believes that its pharmacist applicants must possess a high level of knowledge and experience in all aspects of the pharmaceutical industry. Health Services attributes its inability to attract qualified pharmacists to the disparity between the salaries it can offer and those offered in the private sector, coupled with a shortage of pharmacists in the State. In fact, the Aggregate Demand Index, a monthly report of the difficulty in filling open pharmacist positions across the United States, found that the states with the highest unmet demand for pharmacists from August 1999 through July 2001 were California, Iowa, Kentucky, Minnesota, and Wisconsin.

Despite the reported shortage of pharmacists in the State, we believe that Health Services should broaden its recruitment efforts. Specifically, according to Health Services, its efforts to advertise open positions have consisted of sending more than 4,000 notices to licensed pharmacists in the counties surrounding Sacramento. Although EDS has yet to hire the five pharmacists approved under its contract with Health Services, in its status report to Health Services dated February 7, 2003, EDS requested approval to pursue the following options to increase its recruitment efforts: broaden its advertising beyond the counties of Sacramento and San Joaquin to all of California, further expand its efforts to include other states, and advertise in pharmacy periodicals. Health Services approved the expansion of recruitment efforts statewide by allowing EDS to send postcards to all licensed pharmacists advertising its vacant positions. EDS also received approval to advertise the vacant positions on a Web site. Health Services can also benefit from using these methods itself to hire pharmacists for the 13 unfilled positions.

Health Services attributes its inability to attract qualified pharmacists partially to the disparity between the salaries it can offer and those offered in the private sector.

Our review found that generally the salaries for Health Services' Pharmaceutical Consultant II, Specialist, classification—the highest nonsupervisory classification—were significantly lower than the salaries of pharmacists hired by the University of California and various cities and counties throughout California. For example, the University of California San Francisco Medical Center pays its highest-level nonsupervisory pharmacists a maximum of $10,075 per month. This salary is 52 percent more than the top salary Health Services pays a Pharmaceutical Consultant II, Specialist, which will increase from $6,323 per month to $6,639 on July 1, 2003. Additionally, preliminary data from a December 2002 survey conducted by the Department of Personnel Administration shows that the base amount for the average salary for journey-level

pharmacists in the private sector was $7,390 per month, or almost 36 percent higher than the average state salary of $5,439. Health Services told us that before last year's budget crisis, there was little or no acknowledgment of the discrepancy between state and private-sector salaries. Moreover, the budget crisis helped reinforce the importance of Health Services' need for enough staff to pursue various cost-saving ideas.

Health Services Has Several Options It Can Pursue to Meet Its Staffing Needs

To address its difficulties in attracting qualified pharmacists, in August 2002, Health Services' Medi-Cal Policy Division submitted a proposal to Health Services' personnel department for reclassifying the pharmacist positions. Health Services submitted the proposal to the Department of Personnel Administration for its review and approval on March 25, 2003. The proposal presents new pharmacist classifications with salaries that the Medi-Cal Policy Division believes are commensurate with the knowledge and skills needed to perform the duties of the pharmaceutical unit. The Medi-Cal Policy Division also believes that these new classifications will allow it to have the flexibility to obtain qualified pharmacists in a highly competitive job market. For example, the proposal includes suggested salaries that are equivalent to those generally offered to pharmacists with comparable experience and duties at the University of California San Francisco Medical Center. Further, Health Services' Medi-Cal Policy Division indicates that this reclassification will result in salaries that will more closely approximate the salaries and benefits offered to pharmacists in similar positions in the private sector. Seeking additional recruitment incentives, Health Services submitted a request on April 4, 2003, for a $2,000 per month recruitment and retention pay differential for pharmacists in its Medi-Cal Policy Division.

If Health Services filled all 16 of its approved pharmacist positions at the higher salary level in its reclassification proposal, the General Fund would pay an additional $165,000 annually.

Federal regulations require the federal Centers for Medicare and Medicaid Services (center) to reimburse Health Services 75 percent of the salaries of professionals who use their medical knowledge and skills to directly administer the federal Medicaid program. For example, if Health Services filled all its 16 approved Pharmaceutical Consultant II, Specialist, positions at the higher salary level included in its reclassification proposal, the State's General Fund would pay an additional $165,000 annually. Thus, any increase in pharmacists' salaries should not significantly increase the State's General Fund expenditures.

Besides increasing its staff and seeking a recruitment and retention pay differential, Health Services can take other actions to accomplish its required tasks and generate savings. Our review of the job descriptions for the pharmacist classifications found that some tasks appear to be less technical than others and may not require the expertise of a pharmacist. For example, one responsibility of the pharmacist—analyzing changes to state and federal laws, regulations, and policies that might affect Medi-Cal—is similar to a task that incumbents in the Associate Governmental Program Analyst classification are required to perform. Therefore, Health Services might be able to reassign general duties such as this to a nonpharmacist position that requires a lesser level of expertise and might be easier to fill.

Health Services agrees that it should pursue other approaches to attempt to meet its staffing needs. For example, Health Services recognized the potential for using a nonpharmacist to manage its enteral formulae benefit, and it reclassified a vacant pharmacist position to a public health nutritional consultant position. Health Services told us that this shift in duties will allow its pharmacists to focus on other responsibilities, such as prescription drugs and contracting issues. According to Health Services, it also plans to reevaluate the pharmacist duties and try to carve out those that could be performed by other classifications such as program and research analysts. However, Health Services does not believe this approach would significantly reduce the number of additional pharmacists it needs. Further, Health Services points out that the nonprofessional classifications have a federal reimbursement rate of 50 percent, 25 percent lower than the professional classifications, which may have a greater impact on the General Fund. Until Health Services reevaluates the duties of its pharmacist, it cannot determine the appropriate mix of pharmacist and nonpharmacist positions needed to meet its federal and state obligations or any impact the mix may have on the State's General Fund.

Other options are available for Health Services to address its inability to hire pharmacists such as reassigning general duties to a nonpharmacist position and using interns from a pharmacy school.

Another option available to Health Services is to use interns from a pharmacy school, such as the University of the Pacific in Stockton, to assist its pharmacists in performing some of their duties. In response to our survey, for example, Minnesota indicated that it uses students from the University of Minnesota's College of Pharmacy to assist its staff in performing analyses related to the use of drugs in its Medicaid population. According to Health Services, the dean of the University of the Pacific's pharmacy school has expressed interest in developing an internship

program with Health Services. Currently, however, neither Health Services nor the University of the Pacific has taken any steps toward developing a program.

Finally, another option available to Health Services is to use a pharmacy benefit manager (PBM) to provide or arrange for outpatient prescription drugs for its Medi-Cal beneficiaries. A PBM is a company that administers drug benefit programs for employers and health insurance carriers. A PBM develops and manages pharmacy networks by recruiting and credentialing pharmacies, negotiating discounts on drug prices, monitoring pharmacies for quality and customer services, auditing to prevent fraud and abuse, and providing technical support and training to pharmacists and pharmacies. It can also provide other services such as claims processing and adjudication, disease management, drug utilization reviews, drug list development and management, and prior authorization. In fact, seven of the 17 states responding to our survey indicated that they use PBMs to perform a variety of services for their Medicaid Fee-for-Service systems. For example, North Carolina uses a PBM to administer its prior-authorization program, and Colorado uses its PBM to process claims. South Carolina uses a PBM to establish the maximum allowable cost for its drug list, perform on-line adjudication of pharmacy claims, and administer its prior-authorization program. Kentucky uses a PBM for its second-level prior-authorization review and to conduct drug list reviews for its Pharmacy and Therapeutics Advisory Committee. Kentucky was the only state of the seven that indicated it achieves cost savings of roughly $80 million by using a PBM.

Although Health Services does not use a PBM, it does contract with a fiscal intermediary, EDS, to perform functions such as processing and adjudicating on-line pharmacy claims, invoicing federal and state supplemental rebates, and processing treatment authorization requests. In 1994, Health Services developed a proposal to grant a PBM the responsibility of providing outpatient prescription drugs to Medi-Cal beneficiaries under the Fee-for-Service system. Under the proposal, the PBM would define the prior-authorization program, the pharmacy network, the reimbursement levels paid to pharmacies for the prescription drugs, and dispensing fees. However, some pharmacists expressed concerns about Health Services' proposed use of a PBM, stating their belief that because PBMs focus on reducing costs, they routinely use restricted pharmacy networks and reduce access to services. According to Health Services, it proposed legislation, as part of the budget trailer bill, to allow it to contract

According to Health Services, it does not use a pharmacy benefit manager because its attempt to do so in 1994 was rejected by the Legislature.

with a PBM; however, the Legislature rejected its proposal. Consequently, without legislative authority, Health Services could not move forward on its proposal to contract with a PBM.

Another reason that using a PBM may not be an appropriate option for Health Services is that it may lose some control in monitoring the net cost[5] of Medi-Cal drugs. For example, the United States General Accounting Office (GAO) issued a report in January 2003 that reviewed the use of three PBMs by the Federal Employees' Health Benefits Program. The GAO found that, based on the total business these PBMs conducted with a particular drug manufacturer, a large portion of their earnings comes from rebates and other payments they receive from drug manufacturers. However, the GAO noted that the PBMs would not disclose the actual amounts of these rebates and payments because they are proprietary. The California Public Employees' Retirement System (CalPERS) also contracts with a PBM to manage the prescription drug program for its self-funded health plans, PERSCare and PERS Choice. CalPERS' prior PBM provided numerous services, including maintaining a network of participating retail pharmacies, providing a mail service for prescription drugs, and establishing a preferred prescription drug list. CalPERS' prior PBM was one of the three PBMs reviewed by the GAO that considers the rebate contracts it has negotiated with drug manufacturers to be proprietary information. Therefore, CalPERS also does not have access to the rebates its prior PBM received based on its total business conducted with drug manufacturers. If all PBMs consider their rebate information proprietary, Health Services would no longer be able to verify that it is receiving the lowest net cost for the drugs purchased for beneficiaries of the Medi-Cal Fee-for-Service system.

If Health Services were to use a PBM, it might not be able to verify that it is receiving the lowest net cost for drugs purchased.

HEALTH SERVICES' STAFF ARE UNABLE TO PROMPTLY PERFORM DRUG REVIEWS THAT COULD YIELD SAVINGS

Over the last several years, it has taken Health Services as long as, and in a few instances longer than, two years to review new drugs before adding them to its drug list. As part of its review of new drugs, Health Services negotiates with drug manufacturers for state supplemental rebates. Delays in finalizing its negotiations for the supplemental rebates could result in Health Services paying higher prices for the new drugs than it otherwise would pay. Furthermore, Health Services has

[5] For purposes of our report, net cost refers to the cost after reducing the drug ingredient cost by any applicable rebates.

only performed four therapeutic category reviews (TCRs) of the 113 classifications currently included on the drug list during the last five years. A TCR assesses the cost-effectiveness of all drugs within a therapeutic or chemical drug classification. By failing to subject the drugs included in 109 of the classifications to TCRs, Health Services may not be receiving the best prices for those drugs.

Health Services Does Not Complete Many Drug Reviews Promptly

State law requires Health Services to review each new-drug petition before adding the drug to the drug list, following the criteria of safety, efficacy, essential need, misuse potential, and cost. A new-drug petition occurs when Health Services receives a request to include a new drug on the drug list from a drug manufacturer, a physician, or a pharmacist; or Health Services itself can initiate an addition to the drug list. To improve its ability to monitor all new-drug petitions, Health Services replaced its manual tracking system with an electronic database during fiscal year 1999–2000.

Health Services took more than the required 120 days to complete reviews of five priority drugs and reviews of four other priority drugs have been pending completion for more than 120 days.

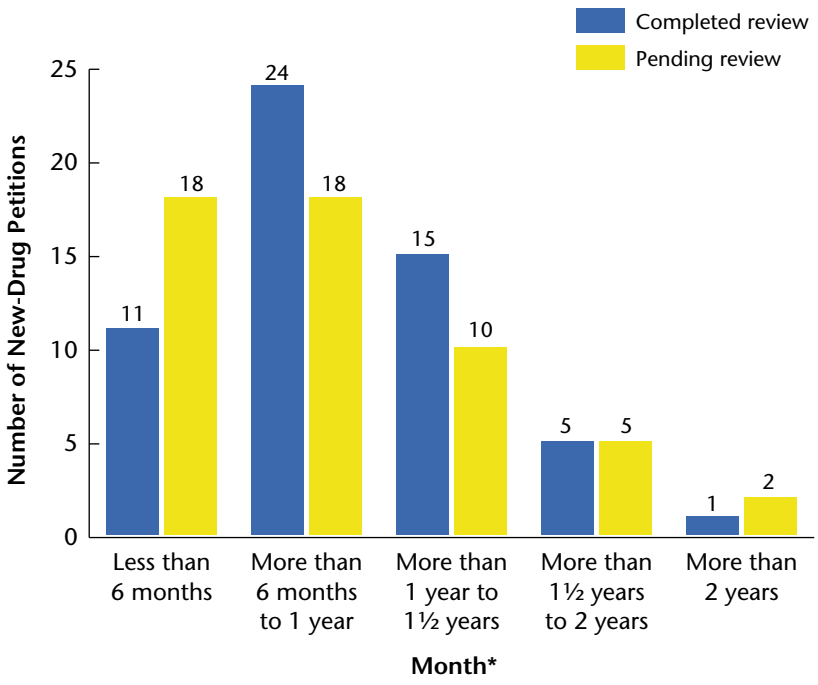
The Medi-Cal Drug Contract Advisory Committee (committee) is responsible for assisting the staff in the Medi-Cal Contracting Section in making recommendations and decisions regarding adding, deleting, or retaining drugs on the drug list. Health Services' procedures establish the following deadlines for evaluating a petition for a drug: the committee must be notified within 90 days of Health Services' receiving a new-drug petition, and the committee must submit its recommendations within 30 days of receiving notification; the entire process should take no more than 120 days for a drug designated as priority.

Using Health Services' electronic database, we identified 131 new-drug petitions received between October 1999 and November 2002. Twenty-two of these new-drug petitions were either withdrawn by the manufacturers or rejected by Health Services. Figure 2 on the following page indicates that Health Services took more than one year to complete 21 new-drug reviews, and 17 reviews have been pending completion for more than one year. Further, nine of the new-drug petitions had a priority designation. However, Health Services took more than the required 120 days to complete reviews of five priority drugs, and reviews of the other four priority drugs have been pending completion for more than 120 days. Health Services attributes many of the delays in completing new-drug reviews to the drug manufacturers' lack of responsiveness and difficulties

that arise during rebate negotiations. Another factor that Health Services indicates has significantly contributed to delays is its inability to hire pharmacists to perform the new-drug reviews.

FIGURE 2

Health Services Has Taken Two Years to Complete Some New-Drug Reviews for Petitions Received Between October 1999 and November 2002 (as of December 31, 2002)



Source: Database used by Health Services to track new-drug petitions.

* To determine the number of months needed to complete reviews, we compared the date that Health Services received the petition with the date that it added the drug to the drug list. For drugs not yet added to the list, we compared the petition date with December 31, 2002, the date we obtained the list.

Although Health Services has established some deadlines, it has not established a deadline that addresses how long the entire new-drug review process should take for drugs without a priority designation. Our review of federal and state laws, regulations, or guidelines did not find any restrictions on the length of time it can take to perform new-drug reviews. Health Services believes a reasonable time frame to conclude a new-drug review is roughly four to eight months. However, as Figure 2 indicates, Health Services is unable to complete some new-drug reviews within

this time frame. Further, its procedures do not identify the steps staff should follow when a manufacturer is unresponsive to staff's questions or requests, which increases the likelihood of delays in completing the new-drug review.

By not completing its new drug-reviews within a shorter time frame, Health Services may be paying a higher price for the new drugs until it finalizes the supplemental rebate contracts. For example, to review one new-drug petition and add the drug to the drug list, Health Services took one year and five months, during which time Health Services reimbursed pharmacies for about 3,930 prescriptions for the drug. In the first quarter after completing its new-drug review and finalizing a supplemental rebate contract with the manufacturer, Health Services collected almost $118,000 in supplemental rebates for 1,966 prescriptions for the drug. Our analysis does not take into consideration any differences that may arise from the shift in utilization from other drugs to the new drug. Nevertheless, for some portion of the 3,930 prescriptions for which Health Services reimbursed pharmacies before it finalized supplemental rebate contracts, Health Services may have lost additional rebates it could have collected if it had performed the required new-drug reviews more promptly.

Health Services Could Further Reduce Costs by Completing More Reviews of Entire Drug Categories

Health Services has only performed four therapeutic category reviews of the 113 classifications currently included on the drug list during the last five years.

Health Services has further limited its ability to reduce costs by not developing an annual schedule for the TCRs it is required to perform for the 113 classes of drugs on the drug list. Initiated by Health Services, a TCR entails reviewing all the drugs in one therapeutic or chemical drug category included in the drug list and negotiating supplemental rebate contracts for new or existing drugs on the drug list that are in that category. Health Services' procedures require it to develop a TCR schedule annually and make it available to the public on request. From 1998 to 2001, Health Services performed one TCR each year, but in 2002, Health Services did not perform a TCR or even develop a TCR schedule, as required. Health Services admits that, compared to a new-drug review, a TCR targets more products in a therapeutic category, whether on the drug list or not, and typically results in a reduced number of drugs on the list. However, without adequate pharmacy staff, Health Services says it cannot complete these labor-intensive reviews and thus has no reason to develop a schedule.

According to Health Services, a TCR can be an effective cost-saving tool because it essentially eliminates the higher priced drugs from the drug list. Typically, most drugs in a category are comparable in efficacy, safety, essential need, and misuse potential. Therefore, the major factor in determining whether the drug is retained on the drug list becomes its cost. For example, Health Services reported in its November 2002 budget estimate that by performing TCRs of the drugs included in the categories of atypical antipsychotics and nonsteroidal anti-inflammatory drugs, it could achieve cost savings of almost $39 million in fiscal year 2002–03 and more than $46 million in fiscal year 2003–04. This represents an overall cost savings to the General Fund of $42.5 million for the two years, assuming that 50 percent of any savings Health Services receives as a result of performing the TCRs will go to the federal government. In addition, Health Services told us that it would like to perform a TCR of the category of angiotensin converting enzyme inhibitors, which are drugs that prevent recurring heart attacks. However, according to Health Services, it has yet to perform any of these TCRs because under its current staffing situation, it is unable to do so. However, if it does so, Health Services can achieve additional savings that might occur by performing TCRs for other categories.

Health Services chose to renegotiate contracts instead of performing TCRs for the atypical antipsychotics and the nonsteroidal anti-inflammatory drug categories. Although Health Services estimates that its renegotiation efforts will be sufficient to cover the savings of $19.5 million to the State's General Fund, it recognizes that TCRs would generate a greater level of cost savings.

Health Services has chosen to renegotiate contracts with manufacturers rather than conducting TCRs for the atypical antipsychotics and nonsteroidal anti-inflammatory drug categories. Health Services estimates that its renegotiation efforts will be sufficient to cover the savings of $19.5 million to the State's General Fund reported in its November 2002 budget estimate. However, Health Services recognizes that TCRs would generate a greater level of cost savings than renegotiating the supplemental rebate contracts of a few drugs. Thus, it is missing opportunities to generate additional savings for the State.

THE STATE IS RELYING ON OTHER COST-SAVING STRATEGIES THAT MAY NOT BE FULLY REALIZED OR MAY BE DELAYED

Health Services' original budget for fiscal year 2002–03 included certain cost savings totaling $127 million for pharmacy benefits provided to Medi-Cal beneficiaries, as shown in Table 1. However, by November 2002, when it began the budget process for fiscal year 2003–04, Health Services had not implemented some activities related to these cost savings and

had to reduce the estimated savings to about $80 million for fiscal year 2002–03. It estimated savings for fiscal year 2003–04 of $127 million. If realized, the savings over the two fiscal years would translate into roughly $104 million for the State's General Fund. Independent of savings from the TCRs just discussed, the cost savings Health Services cites in its budget estimates come from rebate contracts with drug manufacturers and from provisions in new legislation. However, because Health Services has been unable to hire pharmacists, has not considered fully the consequences of implementing some of the cost-saving activities it has planned, and has presented unsupported or inaccurate estimates, it may not fully achieve the added cost savings identified in the November 2002 estimate, or the savings may be delayed.

TABLE 1

Health Services Revised Its Estimate of Cost Savings for Fiscal Year 2002–03 Because It Was Unable to Perform Some Planned Activities (in Thousands)

Activity	July 2002 Estimate*	November 2002 Estimate*	
	Fiscal Year 2002–03	Fiscal Year 2002–03	Fiscal Year 2003–04
Establish supplemental rebates with generic drug manufacturers	$ 53,455	$26,728	$ 53,455
Implement changes to its pharmacy reimbursement rates	20,000	10,000	20,000
Base the MAIC† for generic drugs on wholesale selling price	10,000	8,333	10,000
Create a list of preferred prior-authorization drugs	10,000	8,333	10,000
Prohibit manufacturers from making retroactive adjustments to federal and state rebates owed as a result of revisions to their AMP‡ or best price	14,000	11,665	14,000
Aggressively pursue supplemental rebate contracts	20,000	15,000	20,000
Totals	**$127,455**	**$80,059**	**$127,455**

Source: Health Services' estimate of its drug budget reductions for November 2002.

* The cost savings identified represent total federal and state cost savings; whereas, the savings to the State's General Fund is approximately 50 percent of these amounts.

† Maximum allowable ingredient cost

‡ Average Manufacturer Price

Generic drugs are comparable in dosage form, strength, route of administration, quality, performance, characteristics, and intended use to brand name drugs approved under the federal Food and Drug Administration's new drug application process. Although in July 2000 it signed two supplemental rebate

contracts for generic drugs, Health Services has not routinely established contracts with manufacturers of generic drugs despite having clear authority to do so. In fact, the Legislature has declared its intent that the list of contract drugs contain a mix of brand name and generic drugs. Moreover, Health Services has adopted regulations establishing the mechanism through which it enters contracts for generic drugs in order to obtain refunds, rebates, guaranteed prices, or other forms of preferential prices. We estimate that in 2002, Health Services collected approximately $29,000 in supplemental rebates under these two generic drug contracts. Despite such evidence of savings, Health Services told us that it has not aggressively pursued supplemental rebates for generic drugs because of its inability to hire pharmacists and the reluctance of generic drug manufacturers to negotiate lower prices. Yet, as shown in Table 1 on the previous page, Health Services reported in its November 2002 estimate that it could achieve cost savings of roughly $27 million and $53 million for fiscal years 2002–03 and 2003–04, respectively, by pursuing supplemental rebate contracts with generic drug manufacturers. Because it must return 50 percent of its supplemental rebates to the federal government, Health Services estimated cost savings of roughly $40 million to the State's General Fund for the two fiscal years.

Health Services' cost-saving estimates are based on the assumption that the supplemental rebates resulting from the generic contracts would equal approximately 7 percent of its total generic drug expenditures and that generic drugs would represent 20 percent of its total drug expenditures. In addition, the estimates rely on Health Services' ability to hire eight pharmacists, without whom Health Services would not be able to pursue the supplemental rebates from generic drug contracts it assumed it would have. However, because of the difficulties Health Services has experienced in filling the 13 vacant pharmacist positions that were approved for fiscal years 2001–02 and 2002–03, we question whether Health Services will achieve the savings it estimated for negotiating contracts with manufacturers of generic drugs.

Health Services' Three Predetermined Reimbursement Rates

Estimated acquisition cost (EAC) is Health Services' best estimate of the price generally and currently paid by pharmacies for a drug product sold by a particular manufacturer or principal labeler in a standard package. It can be either of the following:

- The direct price listed by Health Services' primary or secondary reference source or the principal labeler's catalogue for 11 specified pharmaceutical companies. Effective December 1, 2002, the direct price was eliminated from the EAC.
- The average wholesale price (AWP) minus 5 percent for all other drug products listed in Health Services' reference source. Effective December 1, 2002, the EAC is the AWP minus 10 percent. AWP is the price assigned to the drug by its manufacturer and is compiled by commercial organizations such as First DataBank.

Federal upper limit (FUL) is established by the federal Centers for Medicare and Medicaid Services for multiple-source or generic drugs. If an FUL has not been established, payments must not exceed in the aggregate the lower of the following:

- Estimated acquisition cost plus reasonable dispensing fees
- Providers' usual and customary charges to the general public

Maximum allowable ingredient cost (MAIC) is the price established by Health Services for generic drugs using a reference product that has been determined to be generally equivalent in quality to those products used by physicians throughout the State, and generally available to pharmacies, through usual and customary distribution channels, in sufficient quantities to meet the needs of the Medi-Cal program.

Health Services may be successful in achieving savings that result from changes it developed for one of its three predetermined pharmacy reimbursement rates. Specifically, a trailer bill to the budget act for fiscal year 2002–03, Assembly Bill 442 (AB 442), changes the calculation for the estimated acquisition costs (EACs) that Health Services will use to reimburse pharmacies. Before November 30, 2002, if direct prices for 11 specified manufacturers were not available, Health Services set the EAC at the average wholesale price (AWP) minus 5 percent, using data it obtained from its primary reference source, First DataBank. However, based on AB 442, Health Services eliminated the direct-price option and set the EAC at the AWP minus 10 percent, effective December 1, 2002. As part of cost-saving proposals for the fiscal year 2002–03 budget, Health Services reported in its November 2002 estimate that this change would save $10 million and $20 million in fiscal years 2002–03 and 2003–04, respectively, or a total of $15 million in savings to the State's General Fund for the two years. Health Services implemented the new EAC by first notifying all pharmacies as required and then requesting EDS to update its automated claims processing system. Health Services' analysis of the effect of this change on the month of December 2002 shows that it had net savings of approximately $6 million. If Health Services continues to have the same level of drug utilization for the subsequent six months, it will ultimately achieve savings of $42 million for fiscal year 2002–03 alone yielding a total of $21 million to the State's General Fund instead of $5 million.

With net savings of $6 million in December 2002 alone, Health Services' proposal to change the calculation of one of its predetermined reimbursement rates—the estimated acquisition cost—may prove to be the most successful in achieving savings.

However, Health Services may not be as successful in complying with another change in the trailer bill that requires it to base the maximum allowable ingredient cost (MAIC) on the mean of the wholesale selling price of a generic drug from selected major wholesale distributors. The MAIC is the price set by Health Services for a generic drug. State law defines the wholesale selling price as the price, including discounts and rebates, paid by a pharmacy to a wholesale drug distributor for a drug. Before passage of the recent state law, Health Services chose to base the MAIC on the AWP, and it continues to use this basis until it can fully implement this provision of AB 442.

Over the last several years—and most recently, in September 2002—the Office of the Inspector General (OIG) in the federal Department of Health and Human Services has issued a number of reports analyzing the actual acquisition costs to pharmacies for drugs reimbursed by the Medicaid program. Because most states, including California, use the AWP minus a percentage

discount as the basis for determining their pharmacy reimbursing rates, the OIG compared average wholesale prices with the actual acquisition costs of a sample of pharmacies. The September 2002 report showed that pharmacies purchase drugs costing between 17.2 percent below the AWP for brand name drugs and 72.1 percent below the AWP for generic drugs. As a result, the OIG concluded that the current methods used by states to reimburse pharmacies using a single-percentage discount does not adequately consider the large difference in discounts between brands and generics. By establishing the wholesale selling price, Health Services will pay a pharmacy a price for generic drugs that more closely reflects the pharmacy's actual acquisition cost.

According to Health Services, it plans to ask selected wholesalers in California to report to it their wholesale selling prices for generic drugs. Health Services intends to use the reported wholesale selling price plus an appropriate markup to reimburse pharmacies for each drug ingredient cost. Health Services reported in its November 2002 estimate that, once implemented, this new reimbursement method will provide cost savings of roughly $8 million and $10 million for fiscal years 2002–03 and 2003–04, respectively, or a total of $9 million in savings to the State's General Fund over the two fiscal years. Again, we question whether Health Services will achieve these cost savings for several reasons. First, Health Services' plan for implementing the new reimbursement method points out that it needs to make a key decision as to what constitutes an appropriate markup, and it has not yet done so. Second, the plan does not address what action it will take if wholesalers are unwilling to share their pricing data. Third, state law does not contain any requirement compelling wholesalers to provide their wholesale selling prices to Health Services. Fourth, as discussed in an earlier section of this chapter, EDS has yet to hire a pharmacist to undertake the responsibility for implementing the new method.

Health Services plans to obtain pricing data from wholesalers to develop the new reimbursement rate for generic drugs, but it has not asked wholesalers if they would be willing to share this data, and state law does not require them to do so.

When it developed the new reimbursement method, Health Services did not obtain any written assurances from wholesalers that they would be willing to provide the information. According to Health Services, it did not believe such confirmation was necessary because, given the magnitude of Medi-Cal's market share, there seemed no reason for wholesalers to be unwilling to report their wholesale selling prices. However, to recommend a significant change to existing policy without considering fully all the potential consequences, is imprudent and could delay the State's ability to achieve savings if wholesalers refuse to provide the necessary information.

Pharmacists must take extra steps to justfy reimbursement for drugs neither on the drug list nor the sublist of preferred prior-authorization drugs. However, because it lacks the pharmacists it needs to create the sublist, we question whether it can achieve the $9 million General Fund savings it attributed to the sublist for fiscal years 2002–03 and 2003–04.

Another cost-saving activity that AB 442 requires Health Services to perform is creating a subset of the existing drug list—a preferred prior-authorization drug list (sublist). Health Services' drug list is a list of preferred drugs that a physician can prescribe and for which a pharmacy can seek reimbursement without first obtaining approval from Health Services through its treatment authorization request (TAR) process. Although pharmacists will still have to submit TARs and provide justification for prescribing drugs not included on the drug list, it will require pharmacists to take even greater steps to justify and document reasons for selecting a drug that is not included on the sublist. According to Health Services, the sublist will contain drugs that were deleted from the drug list or were not approved for addition to the drug list. A manufacturer of such a drug would approach Health Services, or Health Services would approach the manufacturer, indicating interest in placing the drug on the sublist. Health Services would then evaluate the drug using the same five criteria it follows when adding a new drug to the list—including the cost of the drug, which is partially driven by the willingness of the manufacturer to negotiate a supplemental rebate contract.

Health Services reported in its November 2002 estimate that implementing the sublist would result in cost savings of roughly $8 million and $10 million for fiscal years 2002–03 and 2003–04, respectively, or a total of $9 million in savings to the State's General Fund for the two fiscal years. However, we question the necessity of a sublist given the additional workload this process would create. Specifically, Health Services' proposal might require it to re-review drugs it has already subjected to the new-drug review process (see pages 23 to 25 for a description of this process). The increased workload to implement the sublist would further overburden a staff already unable to complete their required tasks, as evidenced by the fact that Health Services was unable to complete its review of nine new-drug petitions with priority designations within the required 120 days between October 1999 and November 2002. Finally, according to Health Services, its original cost-saving estimates were based on a cursory review of drug utilization by private third-party payers; however, Health Services was not able to provide us with the documents to support its review. Therefore, we cannot verify the accuracy of the estimate or determine whether the savings exceed the costs associated with the increase in Health Services' workload.

AB 442 also added language that prohibits manufacturers from making retroactive adjustments to federal and state rebates owed as a result of revisions to their best prices or average manufacturer price (AMP)—the average prices paid by wholesalers for drugs distributed to the retail class of trade, which is reported to the federal government by manufacturers. Currently, federal law requires drug manufacturers to pay rebates based on their AMP and best price data, but the federal rebate agreement allows manufacturers to make adjustments to their AMPs or best prices. For Medi-Cal, these adjustments can affect payments manufacturers made in prior quarters for not only the federal rebates but also state supplemental rebates, which are often based on AMPs. Health Services told us that this has resulted in California having to pay back rebates or provide manufacturers with credits toward future rebate payments. By prohibiting manufacturers from retroactively adjusting federal and state rebates owed, Health Services reported in its November 2002 estimate that it could achieve cost savings of about $12 million and $14 million for fiscal years 2002–03 and 2003–04, respectively, or $13 million in savings to the State's General Fund for the two fiscal years.

Health Services has begun the process of incorporating the language from this legislation into its boilerplate contract for supplemental rebates. However, before proposing this legislative change, Health Services should have obtained federal approval to allow it to prohibit manufacturers from making retroactive adjustments to the federal rebates they owe based on revisions to their AMPs or best prices. According to Health Services, it anticipates that when it eventually refuses to make retroactive changes to the federal rebates, manufacturers will protest because their agreements with the federal government allow them to make adjustments. Therefore, Health Services indicated that ultimately it might need to seek a revision to state law to exclude federal rebates. Although state law will protect the State's supplemental rebate portion of the cost savings, if Health Services does not receive or further delays obtaining federal approval, it is unlikely the full savings related to protecting the federal rebates can be achieved.

Health Services is unable to support cost savings of $17.5 million to the State's General Fund relating to its aggressive pursuit of supplemental rebate contracts. Moreover, it does not believe it can generate any additional savings.

Finally, Health Services is unable to support the cost savings it estimated in November 2002, totaling approximately $15 million and $20 million during fiscal years 2002–03 and 2003–04, respectively, by more aggressively pursuing supplemental rebate contracts. This represents cost savings of $17.5 million to the State's General Fund for the two fiscal years. Health Services told us that

these estimates relate to one of its earlier cost-saving proposals that the Legislature did not approve. Specifically, Health Services told us that the Legislature rejected its proposal but did not want to restore the savings associated with the proposal. Instead, the Legislature required Health Services to achieve the savings by more aggressively pursuing supplemental rebate contracts. According to Health Services, it advised the Legislature that it was already aggressive in pursuing supplemental rebate contracts and did not believe it could generate any additional savings.

HEALTH SERVICES JUST RECENTLY BEGAN WORKING WITH MANUFACTURERS TO RECONCILE FEDERAL AND STATE REBATES

As of April 1, 2003, Health Services' records reflect that it received approximately $216 million less in federal and state supplemental rebates than the $3.4 billion it actually invoiced manufacturers between January 1991 and September 30, 2001, and it is just beginning to work with manufacturers to reconcile this difference. Specifically, although it implemented a new invoicing system in February 2002, it was not until February 1, 2003, when it hired four staff members, that it started to work with manufacturers to resolve disputed invoices. Yet, in its proposed budget for fiscal year 2002–03, Health Services estimated that by working with the manufacturers to resolve disputed rebates, it could achieve cost savings of almost $7 million and $14 million for fiscal years 2002–03 and 2003–04, respectively, or a total of $10.5 million in savings to the State's General Fund over two years.

Medi-Cal Utilization Information Submitted Quarterly to Manufacturers

- An 11-digit National Drug Code (NDC) maintained by the federal Food and Drug Administration (FDA).
- Product name registered with the FDA.
- Units paid for by NDC number.
- Rebate amount per unit, total units reimbursed, and rebate amount claimed.
- Number of prescriptions.
- Total amount reimbursed by the State.

EDS submits quarterly invoices to pharmaceutical manufacturers, reflecting Medi-Cal utilization information based on pharmacy claims reimbursed by Health Services. The manufacturers are responsible for calculating the rebate and remitting payments for both federal and state supplemental rebates to Health Services. When a manufacturer does not agree with Health Services' utilization information, it can dispute the amount of the rebate. This places a portion of Health Services' rebate on hold until it can resolve the dispute with the manufacturer.

In a March 1996 audit, we reported that although Health Services prepared invoices specifically for supplemental rebates, the invoices did not specify the amounts the manufacturers owed. Rather, the invoices instructed manufacturers to calculate and submit required supplemental rebates along with the federal rebate payments. We further reported that Health Services had failed to monitor and track supplemental rebate payments. We estimated that Health Services had not collected roughly $40 million in supplemental rebates owed to the State and the federal government. Although Health Services was not convinced of the accuracy of our estimate, deficiencies in its payment tracking system prevented Health Services from providing an alternative amount. Nevertheless, we recommended that Health Services calculate a dollar amount for the supplemental rebate on each invoice it sends a manufacturer, verify the accuracy of the payments, and track manufacturers who owe rebates. Although Health Services has taken some actions to address our earlier recommendations, we found that it is still working toward implementing them. For example, in February 2002, Health Services implemented the Rebate Accounting and Information System (RAIS) through its contract with EDS. Using the RAIS, Health Services can now automatically bill and track the collection of federal and state supplemental rebates due from manufacturers. However, according to Health Services, it is still working toward reconciling long-outstanding rebates that have been disputed by manufacturers and is refining RAIS to provide accurate aging data and calculations for interest on amounts owed by manufacturers. Federal and state laws require manufacturers not only to pay rebates but also to pay any applicable interest on late rebate payments.

In March 1996, we estimated that Health Services had not collected roughly $40 million in supplemental rebates owed to the State and federal governments. As of April 1, 2003, this amount has grown to $216 million.

Before implementation of the RAIS, Health Services' records indicated that it had received roughly $216 million less in federal and state supplemental rebates than the $3.4 billion it invoiced manufacturers between January 1991 and September 30, 2001. Since it began using the RAIS, Health Services has billed manufacturers $1.1 billion as of March 2003, for the five quarters beginning October 1, 2001, through December 31, 2002. Health Services was unable to provide us with information that would allow us to accurately calculate the amounts outstanding because of its inability to obtain timely AMP data from some of the manufacturers and federal rebate data. Similar to the older disputed amounts, these more recent invoices may also include disputed

amounts that Health Services will need to eventually resolve, such as adjustments to AMP and rebate data and the pharmacies overstatement of the quantity of drugs they dispense.

State law requires that Health Services and manufacturers cooperate and make every effort to resolve rebate payment disputes within 90 days of the manufacturers' notifying Health Services of a dispute in the calculation of rebate payments. According to Health Services, it has not met the 90-day requirement because it has never had sufficient staff to do so. Health Services told us that between fiscal years 1996–97 and 2001–02, roughly four staff assigned the task of resolving disputes were redirected to other tasks such as assisting EDS with the implementation of the RAIS. Since our March 1996 audit, we found that Health Services had requested up to six additional staff to resolve drug rebate disputes in almost every subsequent fiscal year. However, Health Services' requests were not approved until recently when, during the fiscal year 2002–03 budget process, it received approval for four additional staff to perform this function. As of February 2003, Health Services had filled all four positions and intends to resolve disputes within 90 days. By working with the manufacturers to resolve rebate disputes, Health Services had expected to achieve estimated cost savings of almost $7 million and $14 million for fiscal years 2002–03 and 2003–04, respectively, or a total of $10.5 million in savings to the State's General Fund over the two years. However, due to the late start in hiring staff caused by the delayed state budget, Health Services' progress has been slow. As of March 2003, staff were still just beginning to work on resolving disputes with manufacturers and had completed only one dispute analysis and have begun to work on completing dispute analyses for other manufacturers. As a result, Health Services does not expect to achieve the budget savings of $3.5 million for the State's General Fund identified for fiscal year 2002–03.

Health Services does not expect to achieve budget savings of $3.5 million for the State's General Fund in fiscal year 2002–03 due to its late start in hiring staff to resolve drug rebate disputes.

HEALTH SERVICES' AIDS DRUG ASSISTANCE PROGRAM HAS NOT TAKEN ADVANTAGE OF THE NEW AUTOMATED BILLING AND TRACKING SYSTEM

Unlike Health Services' Medi-Cal drug program, the AIDS Drug Assistance Program (ADAP) does not have access to certain federal data that would enable it to calculate and bill correctly the federal rebate payments owed by manufacturers. Instead, the ADAP relies on manufacturers to calculate and remit the correct amounts and thus cannot ensure that it has received the full rebate amounts.

In 1998, the federal Health Care Financing Administration, now called the Centers for Medicare and Medicaid Services (center), published a federal register notice that provided the ADAPs in all states with an option to receive the same federal rebates as the Medicaid program and to encourage ADAPs to emulate the Medicaid model. To bill drug manufacturers for federal rebates, the ADAP first has the pharmacy benefit manager with which it has a contract verify and process all claims for drugs dispensed by local participating pharmacies. Then, the ADAP submits the claims to the drug manufacturers and bills them for federal rebates based on estimated unit rebate amounts. The manufacturers send the rebates to the ADAP, usually including the actual unit rebate amounts they used to calculate the federal rebate owed. Without access to actual unit rebate amounts, the ADAP cannot accurately calculate and bill the federal rebates due from manufacturers. Moreover, when the ADAP ultimately receives federal rebates from manufacturers, it cannot verify whether the amounts are correct.

The unit rebate amount is based on confidential pricing information that every participating drug manufacturer is required by law to submit to the center for purposes of administering the federal Medicaid Drug Rebate program. The center, in turn, uses the confidential pricing data to compute the unit rebate amounts that state Medicaid programs, like Medi-Cal, can apply to their utilization data and use in preparing quarterly invoices for the federal rebates that manufacturers owe them. For the Medi-Cal program, the center provides the unit rebate amounts directly to Health Services' fiscal intermediary, EDS, on tapes to update the RAIS on a quarterly basis. The ADAP, however, does not receive unit rebate amount information from the center and must use estimated unit rebate amounts.

ADAP does not have a method to identify whether it receives the correct unit rebate amount. For one drug, we found that the ADAP received a rebate for one quarter that was almost $125,000 less than what it would have received using Medi-Cal's unit rebate amount data.

Our comparison of the federal rebates received by the ADAP with those received by Medi-Cal for nine of 67 drugs we reviewed found that the ADAP's federal rebates were lower, even though the amounts should have been the same. For example, for one drug, the ADAP received a rebate of $436,800 for one quarter, nearly $125,000 less than the $561,700 it would have received using Medi-Cal's unit rebate amount data for that drug for the same quarter. Additionally, we found that one manufacturer did not send the ADAP data identifying the unit rebate amounts for three drugs. As a result, we were unable to compare the unit rebate amounts received by the ADAP for these drugs with Medi-Cal's data.

According to the ADAP, it does not have a method to identify whether it receives the correct unit rebate amounts. The ADAP also does not use an automated system to track the billing and collection of manufacturers' federal rebates. Without an effective accounting system, the ADAP cannot ensure that it submits invoices to manufacturers and receives their federal rebate payments promptly. For example, we found that the ADAP did not send 14 invoices totaling $2.9 million to manufacturers for the first quarter of 2002 (January through March) until October 18, 2002, or more than six months after the completion of the quarter. The ADAP told us that it takes them several months to prepare invoices for a number of reasons, including the desire to wait a sufficient amount of time to incorporate any credits that may result from past invoices. The State Administrative Manual requires state agencies to promptly invoice for amounts due to the State to maximize cash flow and subsequent interest earnings. Because the ADAP does not prepare its invoices promptly, it is delaying the collection of rebates due to the State. Consequently, the State does not have the use of those funds for other commitments and is not maximizing the amount of interest it would otherwise collect by depositing the rebates earlier. Additionally, we suggest that it would be prudent for the ADAP to assess and collect interest from manufacturers that do not remit their rebates promptly as does the Medi-Cal program. This recommendation is in line with federal guidelines that encourage all ADAPs to emulate the Medicaid rebate model, which includes a process to assess and collect interest from manufacturers when they delay submitting federal rebates.

Because the ADAP does not prepare its invoices promptly, it is delaying the collection of rebates due to the State. Consequently, the State does not have use of those funds for other commitments and is not maximizing the amount of interest it could collect.

We believe that it would benefit the ADAP to take advantage of Health Services' RAIS to invoice drug manufacturers and, when the RAIS achieves its projected capability, to calculate interest on amounts owed by manufacturers when they delay in submitting federal rebate payments. In fact, in a letter dated January 2001, the director of the center urged state Medicaid directors to work with the ADAPs in their states to assist in the submission of federal rebate claims to manufacturers within the requirements of the drug pricing confidentiality provisions. The letter suggests that the ADAP send its rebate claim forms with the number of units of each drug dispensed on a quarterly basis to the Medicaid agency to add the unit rebate amounts. The Medicaid agency, on behalf of the ADAP, would submit the claim form to the manufacturer for payment and verify that the ADAP receives the full rebate amount due. Staff in Health Services' contract services unit told us that the RAIS could be modified to handle the ADAP

rebate claims but that the unit would require funds for the changes and the additional workload. However, according to the center, several state Medicaid agencies already provide this assistance to their ADAPs and do not find that it increases their workloads significantly. For its part, the ADAP stated that it does not have the resources to cover the cost of converting to the RAIS, but the ADAP could use the savings that would result from its staff no longer having to track its rebates manually to cover these costs.

The ADAP expressed concern that using the RAIS could cause the manufacturers to confuse its rebate data with Medi-Cal's data and delay the receipt of its rebates. To address this concern, the ADAP could consult with its peers in other states to discover how they avoid the problem. One approach might be to use special designs or colors to distinguish the ADAP invoices from Medi-Cal's. The ADAP also believes that it can accomplish the same goal by providing its rebate data to Medi-Cal quarterly for verification. Then ADAP staff could calculate any additional rebate amounts due from manufacturers, determine if it has received these amounts, and send new invoices to manufacturers that have outstanding rebates due. However, this approach does not address our concern about the ADAP's inability to promptly invoice and collect amounts due to maximize the State's cash flow and subsequent interest earnings.

RECOMMENDATIONS

To improve its ability to realize potential cost savings for Medi-Cal, Health Services should do the following:

- Broaden its recruitment efforts beyond the counties of Sacramento and San Joaquin to all of California and advertise in pharmacy periodicals. If necessary, it should seek the appropriate approvals to expand its recruitment efforts beyond California.

- Perform an analysis to identify the number of staff it needs to meet its federal and state obligations. The analysis should include a reevaluation of the duties assigned to the pharmacist' classifications to identify those that could be performed by nonpharmacist classifications. Further, it should quantify the effect that using nonpharmacist staff has on its federal reimbursements for personnel costs.

- Research its ability to use the services of interns.

- Revise its procedures for performing new-drug reviews to include a timeline for completing reviews and specific steps on how staff should address manufacturers' nonresponsiveness.

- Conduct the therapeutic category reviews specified in its budget proposal for fiscal year 2002–03. Further, it should develop and adhere to annual schedules for future reviews.

- Negotiate state supplemental rebate contracts with manufacturers of generic drugs, as the Legislature intended.

- Obtain written assurance from drug wholesalers that they will provide their wholesale selling prices so that it can compute the new MAIC for generic drugs. If the wholesalers are not willing to provide this information, Health Services should seek legislation to compel them to do so.

- Perform an analysis to support its proposal to create a preferred prior-authorization list. The analysis should include an evaluation of the impact this proposal has on its workload and adequate documentation to support its estimated savings.

- Seek federal approval from the center to prohibit manufacturers from making retroactive adjustments to federal rebates owed as a result of revisions to their AMPs or best prices.

- Evaluate periodically the number of staff needed to resolve disputed rebates within 90 days.

It should also follow the center's guidance and ensure that the ADAP and Medi-Cal staff coordinate their activities for obtaining federal rebates by using the RAIS for invoicing its manufacturers. Furthermore, it should ensure that its ADAP emulates the Medicaid model by seeking legislation to assess and collect interest from manufacturers when they delay submitting federal rebates. ■

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CHAPTER 2

Health Services Generally Incurs Lower Net Costs for Brand Name Drugs but Pays Pharmacies More Than Do Some Other Entities

CHAPTER SUMMARY

The Medical Assistance Program (Medi-Cal), under the Department of Health Services (Health Services), offers pharmacy benefits to beneficiaries and uses a complex method to reimburse its network of pharmacies. Although Medicaid programs in some states either encourage or require the substitution of generic drugs for brand name drugs, Health Services restricts its reimbursement to the brand names for eight drugs, without requiring treatment authorization requests (TARs). Health Services allows Medi-Cal beneficiaries to use these eight brand name drugs because it can obtain lower net costs[6] for these drugs than for their generic counterparts, after applying the federal and state supplemental rebates it receives from the manufacturers.[7] In fact for six of these eight drugs, we estimate that Medi-Cal saved more than $20 million in calendar year 2002 by restricting utilization to the brand name drug. However, for the other two drugs we found that the net costs of the brand names were higher than those of the generics because Health Services failed either to renegotiate the contracts or to secure critical contract terms from the manufacturer—errors that we estimate cost Medi-Cal roughly $57,000 in calendar year 2002.

Generally, we also found that Health Services' net costs for drugs available through Medi-Cal were less than the net costs of drugs available through the AIDS Drug Assistance Program (ADAP) and the Department of General Services (General Services), which procures drugs on behalf of other state departments such as the departments of Corrections, Developmental Services, Mental Health, and the Youth Authority. In both cases, the primary factor that yields lower net costs for Medi-Cal is Health Services' ability to obtain federal and state supplemental rebates.

[6] For purposes of our report, net cost refers to the cost after reducing the drug ingredient cost by any applicable rebates.

[7] Definitions of brand and generic drugs can be found on page 44.

Additionally, when we compared Health Services' pharmacy reimbursement rates with those of the states responding to our survey, we found that Health Services' rates were generally higher. However, few of these states have actually negotiated supplemental rebate contracts with manufacturers. Thus, Health Services' net costs for drugs may be lower. Additionally, at least one state has taken an aggressive approach in collecting copayments for services from beneficiaries by subtracting copayments from the pharmacies' reimbursements and placing the responsibility on pharmacies to recover copayments. If Health Services implemented a similar approach, it could save Medi-Cal at least $20 million annually.

HEALTH SERVICES CONSIDERS THREE PREDETERMINED RATES WHEN REIMBURSING PHARMACIES UNDER MEDI-CAL

Health Services offers pharmacy benefits to beneficiaries in its Medi-Cal program and uses a complex method to reimburse its network of pharmacies. The amount it pays pharmacies includes three components—reimbursement for each drug's ingredient cost, a dispensing fee, and a state-mandated charge. For the drug's ingredient cost, Health Services, through its fiscal intermediary, Electronic Data Systems Federal Corporation (EDS), reimburses pharmacies at one of the three predetermined reimbursement rates: estimated acquisition cost (EAC), federal upper limit (FUL), or maximum allowable ingredient cost (MAIC). After evaluating the three predetermined rates, Health Services compares the lowest of the three rates to the usual and customary rate the pharmacies charge the general public as required by state regulations, and it reimburses the pharmacy whichever is lower. For detailed descriptions of the predetermined rates, see the text box on page 28. EDS periodically updates the predetermined rates in its claims processing system, using information provided by Health Services and its primary price reference source, First DataBank.

Although all drugs have an EAC, not all have an FUL or MAIC. For example, during December 2002, Health Services reimbursed for 17,937 drugs; 5,261 (29 percent) of these drugs had an FUL and only 979 (5 percent) had an MAIC. Most often, the EAC represented the lowest cost of the three predetermined rates. Of the 17,937 drugs, 72 percent were reimbursed at the lowest cost using the EAC, while only 1.5 percent of the drugs were reimbursed at the lowest cost using the MAIC.

In addition to receiving reimbursement for the drug's ingredient costs, the pharmacy receives a professional fee, more commonly known as a dispensing fee, and is assessed a charge for each prescription. Health Services reimburses the pharmacy a dispensing fee of $4.05 for each prescription it fills for Medi-Cal beneficiaries. Effective October 1, 2002, state law requires Health Services to deduct an additional 50 cents per prescription from all pharmacy reimbursement claims except for claims of beneficiaries residing in nursing facilities, which are subject to a deduction of only 10 cents per prescription.

HEALTH SERVICES HAS USED THE LIST OF CONTRACT DRUGS AND DRUG REBATES FOR 10 YEARS TO CONTAIN COSTS

Since 1992, state law has authorized Health Services to contract with drug manufacturers for state supplemental rebates and to maintain a list of these preferred drugs. By establishing the List of Contract Drugs (drug list), the Legislature intended Health Services to negotiate with drug manufacturers as aggressively as necessary to achieve cost savings for Medi-Cal beneficiaries. The drug list is a list of preferred drugs that a physician can prescribe and for which a pharmacy can dispense and seek reimbursement without first obtaining approval from Health Services through the TAR process.

Health Services must balance its responsibilities of ensuring beneficiaries access to a comprehensive range of prescription drugs and containing costs. Specifically, federal law allows a state to establish a formulary or, in California's case, a drug list, as long as it contains the covered outpatient drugs of manufacturers that have entered agreements with the federal government to provide rebates. Federal law also requires the state to establish a prior-authorization program, which allows beneficiaries to obtain drugs that have been excluded from the drug list. To dispense and be reimbursed for a drug excluded from the drug list, a pharmacist must obtain TAR approval from Health Services. Additionally, state law requires Health Services to use the drug list and contract negotiations with drug manufacturers to ensure that Medi-Cal beneficiaries receive prescription drugs that are both therapeutic and cost-effective.

Of the 17 states responding to our survey, it appears that California was one of the first states to use a drug list and drug rebates to contain prescription drug costs.

Of the 17 states responding to our survey, only four indicated that they have a preferred-drug list. However, one of the four states, Kansas, stated it just implemented its preferred-drug list

in December 2002, and Minnesota admitted to having only one preferred drug on its list but planned to include preferred drugs in four more categories by March 2003. Additionally, only four states indicated that they receive rebates other than the federal rebates received by all states, and three of the four states implemented their supplemental rebate programs since December 2002. Thus, of the 17 states responding to our survey, it appears that California was one of the first states to use these two techniques—a drug list and drug rebates—to contain prescription drug costs.

HEALTH SERVICES PAYS LESS FOR CERTAIN BRAND NAME DRUGS THAN IT DOES FOR THEIR GENERIC COUNTERPARTS, BUT IT CAN IMPROVE ITS CONTRACTING PROCESS

States use a variety of techniques to encourage the use of generic drugs, which are typically cheaper than brand name drugs. Two of the 17 states responding to our survey provide an incentive to pharmacies to substitute generic drugs by awarding the pharmacies a higher dispensing fee for filling prescriptions with generic drugs. Additionally, five states have enacted legislation that prohibits the use of a brand name drug when a generic substitute is available, and eight states indicated that they work with physicians to explain the advantages of using generic products. For example, Texas contracts with a third party to educate providers through letters and on-site visits.

Federal Definitions of the Brand Name and Generic Drug Classifications

The federal Food and Drug Administration (FDA) has two application processes for the approval of prescription drugs.

Brand Name Drugs

The FDA uses its New Drug Application (NDA) process as a vehicle through which drug sponsors can formally propose their new pharmaceuticals for sale and marketing in the United States. The FDA refers to prescription drugs approved under its NDA process as innovator, pioneer, or brand name drugs.

Generic Drugs

The FDA uses its Abbreviated New Drug Application process to expedite the availability of less costly generic drugs. The sponsor of a generic drug generally does not have to establish the safety and effectiveness of the drug. Instead, the sponsor must demonstrate that its drug is comparable to a brand name drug in dosage form, strength, route of administration, quality, performance characteristics, and intended use.

Although Health Services' drug list contains both generic and brand name drugs, it negotiates supplemental rebates primarily with manufacturers of brand name drugs. In some cases, federal and state rebates Health Services receives are large enough to reduce the net cost of a brand name drug below the cost of a generic drug. When this occurs, Health Services can add a code to the drug list that restricts utilization to the brand name drug and makes the generic drug available only through the TAR process.

As of September 30, 2002, Health Services had restricted the utilization of 12 drugs on the drug list to the brand names. For four of these drugs,

there had either been no utilization of the generic drugs or generics were not available during calendar year 2002. Table 2 shows that our review of the remaining eight drugs revealed that for six drugs, the net costs paid by Health Services were actually lower for the brand names than for the generics.

TABLE 2

Net Costs for Brand Name Drugs With Restricted Utilization Were Generally Less Than the Net Costs for the Generic Drugs

Generic Name*	Therapeutic Description	Drug With Lower Net Cost	
		Brand Name	Generic
Buspirone HCL, 5 mg	Antianxiety	✓	
Fluoxitine HCL, 20 mg	Psychotherapeutic	✓	
Hydrochlorothiazide, 12.5 mg capsule	Diuretic	✓	
Lisinopril, 5 mg	Cardiovascular		✓
Loxapine succinate, 25 mg	Psychotherapeutic		✓
Metformin HCL, 500 mg	Hypoglycemic	✓	
Quinidine gluconate, 324 mg	Cardiac	✓	
Sotalol HCL, 120 mg tabs	Autonomic	✓	

Source: Department of Health Services' Rebate Accounting and Information System.

✓ Indicates the Bureau of State Audits' confirmation that the product has the lower net cost after applying rebates.

* Health Services' drug list refers to all drugs, whether brand names or generics, by their generic name. When restricting utilization to a particular manufacturer, it identifies the labeler by its unique five-digit labeler code.

For the items we reviewed, the State was generally able to achieve substantial savings by restricting utilization to the brand name drug. For example, for one of the drugs shown in Table 2, the generic drug cost was $2.53 per unit, and the manufacturer paid a federal rebate of .86 cents per unit, but Health Services did not negotiate a state supplemental rebate.[8] As a result, Health Services' net cost per unit was $2.52. However, for the same drug, the brand name was $2.96 per unit and the manufacturer paid both federal and state supplemental rebates of $1.019 and 67.1 cents per unit, respectively. Therefore, Health Services' net cost was $1.27 per unit for the brand name drug, $1.25 less than the unit price of the generic drug. In fact for six of the eight drugs, we estimate that Medi-Cal saved more than $20 million in calendar year 2002 by restricting utilization to the brand name drug.

[8] Federal law prohibits us from disclosing data in a form that reveals the manufacturer or prices charged by the manufacturer.

For calendar year 2002 Health Services saved more than $20 million by restricting utilization to brand names for six of eight drugs we reviewed.

For two of the eight brand name drugs we reviewed, Health Services did not restrict its beneficiaries' utilization to the lower-cost drugs. The contract negotiated with the manufacturer for one of the two brand name drugs expired on December 31, 2001; however, between January 1, 2002, and March 12, 2003, Health Services had not renegotiated or renewed the contract. Consequently, Health Services continued to restrict utilization to the brand name drug without the benefit of receiving the state supplemental rebate. By failing to renegotiate or renew the state supplemental contract before the expiration date, Health Services incurred a net cost of 55 cents per unit for the brand name, receiving no offsetting state rebate, when it could have paid a net cost of 42 cents per unit for the generic drug. Originally, Health Services told us it was negotiating with the drug manufacturer and would attempt to obtain repayment of the rebates for the period between the expiration of the original contract and the establishment of the new contract. However, effective April 1, 2003, the federal Centers for Medicare and Medicaid Services (center) established an FUL for this drug. Health Services believes that with the implementation of the FUL the manufacturer will stop its negotiations. Health Services removed the restriction on this drug on March 12, 2003. However, Health Services should have suspended the drug's utilization restrictions when the contract expired until it could renegotiate the contract with the manufacturer.

According to Health Services, the restriction requiring reimbursement of a brand name drug over a generic is a policy decision that does not require a public hearing or notification period. To lift the restriction, Health Services merely has to instruct EDS to do so. Thus, we fail to understand why Health Services did not suspend the restriction and allow the pharmacies to dispense and be reimbursed for the lower-cost generic drug without requiring TAR approval. Fortunately, in this case the cost to Medi-Cal was minimal, totaling roughly $1,000 in calendar year 2002, because of low utilization.

For the second drug, Health Services said it restricted use to the brand name because it believed that the manufacturer, who produces both the brand name and generic versions of the drug, was going to discontinue the generic drug. Although the State expects each agency to ensure that its contracts are written in a manner that safeguards the State's interests, Health Services did not secure written confirmation from the manufacturer that its generic drug would be taken off the market. In fact, as of November 30, 2002, the manufacturer's generic drug was still

available at $1.57 per unit, but Health Services continued to pay a net cost of $1.93 per unit for the brand name drug. We estimate this restriction cost Medi-Cal up to $56,000 in calendar year 2002 alone.

Health Services' Medi-Cal drug rebate agreement allows either it or the manufacturer to terminate the agreement at least 90 days before the contract expiration date. As of January 1, 2003, Health Services has 245 active supplemental contracts with 74 manufacturers and employs six staff to monitor and negotiate contracts. Currently, Health Services maintains a database that lists each contract's terms, effective date, and expiration date. However, Health Services does not have a review process in place to ensure staff have entered all contracts appropriately into this database or its Rebate Accounting and Information System (RAIS) used for invoicing purposes. Further, although Health Services can run ad hoc reports to determine when its contracts will expire, it does not have a process to ensure that it follows up on and renegotiates contracts before the expiration dates. Until Health Services establishes such processes, it cannot ensure that it invoices all manufacturers at the correct amount. Moreover, it cannot ensure that it renegotiates or renews contracts before the expiration dates and runs the risk of continuing to allow pharmacies to dispense more costly drugs.

Eligibility Requirements for ADAP

- Must be a California resident
- HIV-infected
- 18 years of age or older
- Must have a federal adjusted gross income below $50,000 per year*
- Have a valid prescription from a licensed California physician
- Must lack private insurance or not qualify for Medi-Cal

* An individual is subject to a copayment obligation if his or her annual federal adjusted gross income is between 400 percent of federal poverty level ($33,400 in 2000) and $50,000.

HEALTH SERVICES' NET COSTS FOR MEDI-CAL DRUGS WERE GENERALLY LESS THAN THE NET COSTS OF DRUGS FOR THE ADAP

In addition to the Medi-Cal drug program, Health Services provides reimbursement for drugs under the ADAP—a program for individuals suffering from the acquired immune deficiency syndrome who are not covered by Medi-Cal and otherwise could not afford the drugs they need. The ADAP reports that it spent roughly $182 million on drugs in calendar year 2002. The eligibility requirements for the ADAP differ significantly from the Medi-Cal program. Specifically, the purpose of the ADAP is to provide drugs to individuals infected with human immunodeficiency virus (HIV) who could not otherwise afford them. These include people with low or moderate incomes who lack adequate private health insurance or do not qualify for

Medi-Cal. Nevertheless, many of the 200 drugs for which Medi-Cal spent the most money (top 200 drugs) for its beneficiaries are also used to treat the ADAP's beneficiaries. The top 200 drugs are listed in Appendix B. However, the reimbursement methods used by the two programs are quite different. Medi-Cal reimburses pharmacies at one of three predetermined rates or the usual and customary rate the pharmacies charge the general public, whichever is lowest. The ADAP, however, contracts with a pharmacy benefit manager (PBM) to provide pharmacy services such as claims processing, reimbursement coordination, and data reporting. The PBM, either directly or through its contracts with participating pharmacies, obtains and dispenses prescription drugs to beneficiaries according to the ADAP's formulary. The ADAP uses the average wholesale price (AWP) minus a percentage to reimburse its PBM and adds a dispensing fee of $4.05.[9] AWP is the price assigned to the drug by its manufacturer and is compiled by commercial organizations such as First DataBank.

During the first quarter of calendar year 2002, the ADAP provided reimbursement for 88 of the same drugs we identified as Medi-Cal's top 200 drugs. We were unable to calculate net costs for 21 of these drugs because the manufacturers had not yet submitted rebate information. Of the remaining 67 drugs, Medi-Cal incurred lower net costs than did the ADAP for 51 drugs because of Medi-Cal's more flexible reimbursement structure and the supplemental rebates Health Services received from drug manufacturers. For 27 drugs, Medi-Cal's reimbursement rate was lower than the ADAP's rate. Even when Medi-Cal's reimbursement rate was higher than the ADAP's, its net costs for 24 drugs were lower after applying the supplemental rebates. For the 51 drugs for which the ADAP's net costs were higher than Medi-Cal's, the ADAP spent $711,000 more during the first quarter of 2002 than Medi-Cal would have for the same number of units of the drugs. However, for 16 drugs, the ADAP's net costs were lower than Medi-Cal's. For these 16 drugs, the ADAP spent $697,000 less than Medi-Cal would have for the same number of units of the drugs for the first quarter of 2002. Almost $500,000 of the $697,000 was attributable to supplemental rebates the ADAP received from the manufacturer of two drugs. Health Services told us that it plans to meet with this manufacturer to negotiate an acceptable contract for Medi-Cal.

Although it has no supplemental rebate contracts, the ADAP received such rebates for certain drugs. For two drugs, the supplemental rebates reduced ADAP's net costs below Medi-Cal's net costs by $500,000.

[9] The ADAP's reimbursement rate for branded products was the AWP minus 9 percent, the AWP minus 9.5 percent, and the AWP minus 10 percent for fiscal years 2000–01, 2001–02, and 2002–03, respectively. For generic products for all three fiscal years, the ADAP's reimbursement rate was the AWP minus 20 percent.

Although it has no supplemental rebate contracts, the ADAP has received such rebates for certain drugs. In fact, similar to Medi-Cal, California's ADAP has also been at the forefront of obtaining rebates. For example, according to the ADAP, in 1996, California received a voluntary rebate from one manufacturer in the amount of $2.8 million. However, the ADAP is unable to provide us with the amount it annually collects for these supplemental rebates because it does not track them. According to the ADAP, California and New York have joined a national organization, the Fair Pricing Coalition, which for several years has lobbied drug manufacturers for pricing restraints before placing new HIV treatments on the market. As a result, price concessions were successfully obtained from four drug manufacturers. The ADAP also told us that it had verbal agreements with certain manufacturers to freeze prices on some of the more expensive AIDS drugs, three of which we included in our sample. Further, it has a letter from one manufacturer agreeing to provide a supplemental rebate for a growth hormone used in the treatment of HIV.

However, effective September 30, 2002, state law requires Health Services to negotiate supplemental rebates for the ADAP. According to the ADAP, in December 2002, it convened a meeting of ADAPs from other states—Illinois, Florida, Maryland, Massachusetts, New Jersey, and New York—and it was agreed that these states and California would work together to obtain price concessions from manufacturers that would benefit all ADAPs nationally. In March 2003, the states (including North Carolina and Texas, but excluding Illinois) conducted price negotiations in Washington, D.C. with eight manufacturers of HIV drugs, and a settlement was achieved with one manufacturer. The ADAP continues to negotiate with the other manufacturers and anticipates other settlements by the end of April 2003. However, the ADAP plans to continue its negotiating efforts without requiring manufacturers to sign rebate agreements.

Without a valid agreement, the ADAP has no legal recourse against manufacturers if they choose to discontinue their price freezes or rebates.

In negotiating its rebates with manufacturers, Medi-Cal requires the manufacturers to enter agreements that specify, among other things, their obligations for remitting rebates and the methods used to calculate the rebates. Moreover, Medi-Cal's rebate agreements must be signed by the director as an authorized representative of the State. The ADAP has verbal assurances from certain manufacturers that they will freeze prices, in some instances through August 2004. Yet without valid agreements that identify

the parties and authorized representatives, terms, and conditions, the ADAP has no legal recourse against the manufacturers if they choose to discontinue their price freezes or rebates.

We believe that it would be beneficial for ADAP staff to work with Medi-Cal's contract services unit, which has been negotiating supplemental rebates for more than 10 years and has established practices in negotiating with drug manufacturers. However, the ADAP told us this would be problematic for two reasons. First, several manufacturers have expressed concern that their contract negotiations with the ADAP be held confidential for fear of weakening their contracting negotiations with Medicaid programs. Second, the ADAP also stated that leadership in Medi-Cal has indicated that the current lack of pharmacist staff to negotiate supplemental rebate contracts precludes Medi-Cal from taking on this additional responsibility.

HEALTH SERVICES' NET COSTS FOR BRAND NAME DRUGS WERE GENERALLY LOWER THAN THE NET COSTS FOR DRUGS PURCHASED BY GENERAL SERVICES

State law establishes General Services as the purchaser of drugs for state agencies such as the departments of Corrections, Developmental Services, Mental Health, and the Youth Authority. General Services negotiates contracts with drug manufacturers and has a contract with the Massachusetts Alliance for State Pharmaceutical Buying so that state agencies can purchase drugs at lower prices. State agencies must purchase drugs in accordance with these contracts unless they receive exemptions from General Services. However, state law also establishes Health Services as the purchaser, but not dispenser or distributor, of prescription drugs for Medi-Cal. Thus, Health Services does not require an exemption. In our limited review comparing Health Services' net drug costs to those of General Services, we found that for brand name drugs, Health Services generally was able to obtain lower net costs for Medi-Cal, while for a few generic drugs, its net costs were higher. The primary factor keeping Medi-Cal's net costs lower was Health Services' ability to obtain federal and state supplemental rebates. For example, after applying both rebates, Health Services' costs were reduced, on average, by 37.3 percent.

After applying federal and state supplemental rebates, Health Services' costs were reduced, on average, by 37.3 percent.

General Services has three purchasing options it can use so that state agencies can purchase drugs at lower prices. First, General Services negotiates contracts with drug manufacturers

to obtain drugs at less than the wholesale acquisition costs—the standard prices wholesalers pay manufacturers for drugs, not including special deals such as rebates or discounts. Second, General Services contracts with the Massachusetts Alliance for State Pharmaceutical Buying, which contracts with a group-purchasing organization to take advantage of most of the wholesale acquisition prices of drug manufacturers. Third, General Services has an agreement with a wholesaler (prime vendor) to distribute drugs purchased under the first two options to state agencies and, if necessary, to provide them with drugs at the prime vendor's wholesale acquisition costs plus a service fee.

The net costs paid by Medi-Cal for brand name drugs were typically lower then the net costs General Services paid for the same drugs. Our review focused on comparing the prices Health Services paid for Medi-Cal's top 200 drugs with the prices General Services paid for the same drugs during September 2002, if data were available. Of the 157 drugs we reviewed,[10] after applying federal and state rebates, Health Services had higher net costs for only 14 drugs, primarily because it did not have contracts with manufacturers for supplemental rebates. Of these 14 drugs, nine were generics and five were brand names. Further, General Services purchased seven of the 14 drugs through its contract with the prime vendor, five through its contract with the Massachusetts Alliance, and two through its own contracts with manufacturers. Thus, these 14 drugs demonstrate that Health Services' ability to obtain federal and state rebates is a significant factor in reducing Medi-Cal drug costs.

HEALTH SERVICES GENERALLY REIMBURSES PHARMACIES AT HIGHER RATES COMPARED WITH OTHER STATES, BUT MOST STATES DO NOT RECEIVE SUPPLEMENTAL REBATES

Most of the 17 states that responded to our survey pay their pharmacies at lower reimbursement rates than does California. However, only four of these states receive supplemental rebates from manufacturers as California does. By contracting for supplemental rebates, Health Services' net drug costs may be lower than those of the surveyed states.

[10] We could not compare 34 of the drugs because General Services reported that it did not purchase the drugs. Additionally, we excluded nine drugs because Health Services' rebate data was not available.

Although federal law does not require states to offer pharmacy benefits to beneficiaries, every state provides these benefits, and all but Arizona receive federal rebates from drug manufacturers.[11] Additionally, federal law allows each state to develop its own pharmacy reimbursement rates for generic drugs, as long as its rates do not exceed the FUL. Further, federal law allowed states that already had rebate agreements in effect with manufacturers in November 1990 to continue receiving supplemental rebates. On September 18, 2002, the center issued a letter to all state Medicaid directors clarifying that they must seek its approval to enter into supplemental rebate agreements with drug manufacturers and ensure that such agreements achieve rebates that are at least equal to the federal rebates. Consequently, states' pharmacy reimbursement rates, use of supplemental rebates, and dispensing fees vary.

Similar to California, most of the 17 states responding to our survey use more than one reimbursement rate, but the specific rates used vary. For example, while every state uses the FUL, not all states use an AWP, and among those that do, estimated reimbursement rates range from the AWP minus 5 percent to the AWP minus 50 percent, as shown in Appendix A.

Before December 1, 2002, California's estimated acquisition cost included a reimbursement rate of AWP minus 5 percent, which is higher than all but one of the other states using the AWP. However, as discussed in Chapter 1, recent legislation has lowered this rate to the AWP minus 10 percent effective December 1, 2002. Furthermore, although California paid higher reimbursements when using the AWP minus 5 percent, if it has a contract with a drug manufacturer for a supplemental rebate, the net cost for that drug could be lower than it is in other states. Many states do not receive supplemental rebates. Only four of the states responding to our survey have actually negotiated supplemental rebate contracts. Three of the four states implemented their supplemental rebate programs since December 2002. For example, Kansas reported that it began negotiating supplemental rebates in January 2003, and as of April 2003, had four contracts for drugs. Because rebate information is confidential, we were unable to compare California's net costs with those of other states.

[11] Arizona has a waiver for which special rules apply. That state provides medical services to its indigent population in a managed care system rather than in a Fee-for-Service system.

Federal law allows states to establish reasonable dispensing fees for their Medicaid pharmacy programs. Similar to the reimbursement rates, the dispensing fees established by California and the 17 states responding to our survey also vary, as shown in Table 3.

TABLE 3

Dispensing Fees Vary Among the States Responding to Our Survey

State	Dispensing Fee
California	$4.05
Alaska	$3.45 to 11.46
Colorado	$4.00
Connecticut	$3.60
Idaho	$4.94 to 5.54
Illinois	$0.00
Kansas	$3.40
Kentucky	$4.51
Minnesota	$3.65
Mississippi	$3.91
New Jersey	$3.73 to 4.07
North Carolina	$4.00 to 5.60
Oklahoma	$4.15
Pennsylvania	$4.00
South Carolina	$4.05
Texas	$5.27
Washington	$4.20 to 5.20
West Virginia	$3.90 to 4.90

California recently commissioned a study to determine the adequacy of its pharmacy reimbursement rates (rate study), including whether its dispensing fee actually covers the providers' costs of dispensing drugs. The rate study incorporated the results of a separate study of the actual acquisition costs of pharmaceuticals in California and found that for a "typical" prescription, Health Services was reimbursing pharmacies' drug ingredient cost at a rate that yields a $10 margin. According to the results of the rate study, the actual cost of dispensing drugs

is about $7, almost $3 more than the dispensing fee of $4.05 Health Services pays. Although the rate study found that Health Services' dispensing fee was below the average cost incurred by pharmacies to dispense prescriptions, it recommended that any changes to the dispensing fee be considered in tandem with drug ingredient reimbursement rates. As we discuss on page 29, a health trailer bill to the fiscal year 2002–03 budget act—Assembly Bill 442 (AB 442)—reduced pharmacy reimbursement rates by eliminating the direct price option and setting the estimated acquisition cost at AWP minus 10 percent, effective December 1, 2002. Additionally, as reflected in the 2003–04 Governor's Budget, Health Services has proposed reducing reimbursement rates for providers including pharmacies by 15 percent. Although Health Services believes that further reducing the pharmacy reimbursement rates by 15 percent will bring its payments below the costs identified in the study, we are unable to substantiate its claim. Apparently, Health Services has chosen not to move forward with the study's recommendations.

Federal law allows states to establish copayments; however, it does not allow states to assess charges for certain services, such as emergency services and services provided to any beneficiary under age 18. Additionally, it does not allow states to deny care to any beneficiary unable to afford the copayment. State law allows each participating pharmacy to retain the $1 copayment it collects from each Medi-Cal beneficiary filling a prescription. Further, the beneficiary remains liable to the pharmacy for any unpaid copayments. Health Services could not provide us with an analysis of the pharmacies' collection rates for copayments, but it believes their collection rates are low. At least one state has taken a more aggressive approach toward collecting copayments from beneficiaries. For example, Montana instituted copayments so that beneficiaries could share in the cost of their medical care, thus allowing it to reduce the cost to the state. Montana deducts the copayments from the pharmacies' reimbursements, placing the responsibility of collecting copayments on the providers. State law does not allow Health Services to reduce its pharmacy reimbursements by the copayment. Health Services believes that deducting the copayment from the pharmacy reimbursement rate is effectively reducing the rate. Health Services also believes that given the pending proposal to reduce provider reimbursement rates by 15 percent, deducting the copayment would be a very large cut for pharmacies to absorb. Finally, Health Services believes that deducting the copayment would not generate as much savings to the State as the proposed 15 percent rate reduction because the copayment applies only

Montana deducts the copayments from pharmacies' reimbursements, placing the responsibility of collecting copayments on providers. If Health Services implements this approach, it estimates that Medi-Cal would save more than $20 million annually.

to adults. Health Services estimates that if implemented, by deducting the copayment from the pharmacy reimbursement rate, it would save Medi-Cal more than $20 million annually, after adjusting for beneficiaries who are exempt.

RECOMMENDATIONS

To improve its ability to obtain lower net costs for drugs, Health Services should do the following:

- Establish policies and procedures to ensure that it follows up on and renegotiates supplemental contracts before their expiration dates. Further, it should establish a review process to ensure supplemental rebate contracts are appropriately entered into its contract tracking database and RAIS.

- If it is unable to complete negotiations for state supplemental rebates before contracts expire, it should immediately instruct EDS to remove the restriction on brand name drugs to allow pharmacies to dispense less expensive generic drugs without requiring TAR approval.

- Ensure that it secures written assurance from the drug manufacturer for all agreements made during a negotiation and includes this information in the terms and conditions of the contract.

- Require the ADAP to capitalize on the expertise of Medi-Cal's contract services unit and work with it to negotiate supplemental rebates with drug manufacturers. If it chooses not to work with Medi-Cal, the ADAP needs to ensure that it requires manufacturers to enter rebate agreements.

- Evaluate the pros and cons of deducting copayments from its reimbursement rate and having pharmacies collect these payments from beneficiaries. The evaluation should include, at a minimum, an analysis of costs, benefits, and pharmacies' collection rates. ■

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CHAPTER 3

Health Services Has Not Aggressively Pursued Some Drug Utilization Review and Other Measures That Could Further Control Costs

CHAPTER SUMMARY

Although the Department of Health Services (Health Services) has implemented some cost control strategies for the Medical Assistance Program (Medi-Cal), such as the List of Contract Drugs (drug list), it has been slower than other states to implement some cost-saving techniques. Medi-Cal's drug utilization review (DUR) program—a mechanism to ensure that prescriptions for covered outpatient drugs are appropriate, medically necessary, and not likely to have adverse medical effects—has more alerts than required under federal law, which means that pharmacists can readily receive up-to-date information about potential drug therapy problems. However, unlike seven of the states responding to our survey, Health Services has not adopted step therapy protocols. Under a step therapy protocol, a physician is required to prescribe a less expensive but therapeutically equivalent drug during the early stages of a patient's medical condition and move on to a more expensive drug only if the patient is not responding positively to the first drug.

Health Services' retrospective DUR process monitors drug use and cost trends to identify misuses and educational needs. Through this process, Health Services has identified and developed responses to costly Medi-Cal drug patterns. Currently, Health Services' educational program disseminates information only to general audiences periodically and comprises a small number of active and proposed projects that are heavily dependent on the expertise and resources of its DUR board members. Consequently, efforts to educate providers about inappropriate or medically unnecessary drug therapies, and the potential to capture cost savings that may result from changes in drug prescribing and dispensing behavior, are limited.

In addition, although many states have implemented disease management programs, which are designed to improve the quality of care for Medicaid populations and ultimately contain

costs for both prescription drugs and Medicaid overall, Health Services' progress toward a comprehensive disease management program is minimal. Recently, Health Services has collaborated with the California Pharmacists Association (CPhA) to develop Medi-Cal–specific pilot projects for disease management relating to asthma, diabetes, and hypertension. However, Health Services lacks the funding it needs to begin the proposed pilot projects because it has relied on its nonprofit partners to secure funds. Consequently, until Health Services seeks funding to move forward on these pilot projects, the potential benefits of disease management programs and their applicability to the Medi-Cal population will remain unrealized.

Finally, Health Services includes five optional classes of drugs as part of its pharmacy benefit. If Health Services had excluded these classes of drugs from its benefit, it could have saved nearly $80 million during 2001. Health Services indicated that excluding the five drug classes would likely increase drug costs but could not provide us with an analysis to support its assertions.

Required Elements of a Drug Utilization Review Program

The DUR program is a federal Medicaid requirement to ensure that prescriptions for covered outpatient drugs are appropriate, medically necessary, and not likely to cause adverse medical effects. A state's Medicaid DUR program must contain four components:

Prospective DUR: a review of drug therapy before each prescription is filled and delivered to an eligible beneficiary.

Retrospective DUR: ongoing examination of drug claims and other data to identify patterns of fraud and abuse and of inappropriate drug therapy.

Application of Standards: assessment of data on drug use against explicit predetermined standards to improve the quality of care and conserve program funds.

Education: ongoing and active programs to educate practitioners on common drug therapy problems to improve drug-prescribing practices. DUR educational programs should include at least four elements:

- Information dissemination.
- Written, oral, or electronic reminders suggesting changes in drug prescribing or dispensing practices.
- Use of face-to-face discussions between health care professionals who are experts in drug therapy and selected prescribers and pharmacists targeted for educational intervention, including follow-up discussions.
- Intensified review or monitoring of selected physicians or pharmacists.

Each state must also establish a DUR board composed of licensed, actively practicing physicians and pharmacists to undertake or oversee the DUR program.

Source: Title 42, United States Code, Section 1396r-8 (g)

HEALTH SERVICES' DUR ALERTS EXCEED FEDERAL REQUIREMENTS BUT CAN BE REFINED

Because Health Services' DUR program has more alerts than federal law requires, Medi-Cal pharmacists have ready access to information about potential drug therapy problems, such as harmful drug interactions or inappropriate drug dosages. However, Health Services enables a pharmacist dispensing a drug to a Medi-Cal beneficiary to override all of its prospective DUR alerts rather than requiring the pharmacist to obtain Health Services' approval before dispensing a drug. Health Services said that pharmacists are allowed to override the prospective alerts because the alerts are designed to assist the provider in the proper care of a beneficiary. While the alert system gives information about a beneficiary's medical situation, the provider reviewing the information ultimately determines whether there is a potential

problem. Nonetheless, by refining its DUR program to increase its use of prior authorization and include step therapy protocols, Health Services could achieve greater opportunities to control pharmacy costs.

Federal law requires state Medicaid programs to have a prospective DUR process, which occurs before a pharmacist dispenses a drug to a beneficiary, typically at a pharmacy. A prospective DUR process must include screening for potential drug therapy problems, such as drug interactions, incorrect drug dosage or duration of drug treatment, and clinical abuse and misuse.

Health Services uses a computerized system for its prospective DUR process. When a Medi-Cal beneficiary presents a drug prescription to a pharmacy, the pharmacist inputs the prescription into an on-line claims processing system that, for selected drugs, reviews whether the drug has the potential to cause problems for the beneficiary, among other things. The potential problems appear as warnings, or alerts, on the pharmacist's computer screen. There are two types of alerts that require two different courses of action from the pharmacist. If the alert is a "soft edit," the pharmacist can override it after consulting with the beneficiary or the beneficiary's physician or based on the pharmacist's discretion. On the other hand, if the alert is a "hard edit," the pharmacist cannot override it and must submit a treatment authorization request (TAR) for Health Services' approval before dispensing the prescription. First DataBank, Health Services' primary source for DUR criteria, creates and maintains databases for use in drug screening processes. The DUR board is also involved in evaluating and recommending to Health Services which alerts to activate as part of the prospective DUR process and to which drugs the alerts should apply. Health Services' pharmaceutical unit develops the hard edits, also called utilization restrictions, based on cost considerations and other factors.

We obtained information from 10 of the 17 states responding to our survey on the number of prospective DUR alerts they use and found that, except for Washington, California employs more alerts than these states do. As Table 4 on the following page illustrates, California uses 13 alerts, whereas other states use between four and 14 alerts. During a 2002 quarterly meeting, Health Services' DUR board voiced its concern that a large number of alerts may be counterproductive and lead to pharmacists automatically overriding them. However, Health Services believes that a more comprehensive set of alerts

TABLE 4

Health Services Employs More Alerts in its Prospective Drug Utilization Review Process Compared to Other States

Alert Definition	Federal Law Requirements*	California	Alaska	Connecticut	Idaho	Minnesota	New Jersey	North Carolina	South Carolina	Texas	Washington	West Virginia
Drug allergy	✓	✓					✓				✓	
Drug disease	✓	✓	✓	✓		✓	✓	✓	✓		✓	
Drug-to-drug interaction	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓
Therapeutic duplication	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓
High dose	✓	✓†	✓	✓		✓	✓‡	✓	✓†	✓§	✓	✓
Low dose	✓	✓†	✓	✓		✓		✓	✓†		✓	✓
Incorrect duration	✓	✓		✓						✓	✓	
Duration of therapy				✓							✓	✓‖
Additive toxicity		✓		✓							✓	
Drug pregnancy		✓	✓	✓					✓		✓	
Ingredient duplication		✓								✓	✓	✓
Drug gender conflict							✓				✓	✓
Drug age conflict		✓		✓	✓		✓		✓		✓	✓
Early refill and/or overutilization		✓		✓	✓	✓		✓	✓	✓	✓	✓
Late refill and/or underutilization		✓		✓	✓	✓		✓	✓			
Totals		**13**	**5**	**12**	**4**	**7**	**7**	**7**	**9**	**6**	**14**	**9**

Sources: Responses to Bureau of State Audits' survey and accompanying correspondence.

✓ Indicates state uses alert.

* Federal law includes a requirement for a clinical abuse/misuse screen, but no state reports using such an alert.

† California's high dose and low dose alerts both include adult and pediatric subcategories. South Carolina's high dose alert includes underage and overage subcategories. South Carolina's low dose alert includes an overage subcategory.

‡ Information obtained from New Jersey did not distinguish whether separate alerts exist for high and/or low dose.

§ Texas indicates the use of maximum dose, which is the equivalent of high dose.

‖ West Virginia indicates the use of maximum duration, which is the equivalent of duration of therapy.

provides more information to pharmacists and generates data it can use in other components of the DUR program for greater opportunities to track utilization of certain drugs or classes of drugs. Our review of the available DUR literature, along with a review of state responses to our survey, found no indication or guidance as to the appropriate number of alerts that should be used in a DUR process.

Health Services has established a target list of 115 drugs that are subject to the prospective DUR process. According to Health Services, these drugs were initially placed on the target list because of their high cost. However, Health Services is currently in the process of organizing the target drug list by therapeutic category. Health Services believes that changing the focus of the target drug list will improve the interrelationship between the different components of the DUR program and establish a better approach to ensuring the well-being of Medi-Cal beneficiaries.

Health Services uses a hard edit, which requires pharmacists to seek its approval before dispensing and seeking reimbursement, for four drugs because of their potential for misuse and fraud.

Twelve states responding to our survey indicated that they use a combination of hard and soft edits in their prospective DUR systems. For example, South Carolina employs nine alerts, one of which, the early-refill alert, is a hard edit that cannot be overridden by a pharmacist without approval. Only one state, Oklahoma, indicated that it uses only hard edits. The prospective DUR process used by the former pharmacy benefit manager that contracted with the California Public Employees' Retirement System (CalPERS) used hard edits for specific drugs within therapeutic classes. For example, several drugs within the classification of central nervous system stimulant therapeutics are subject to prior authorization. Although Health Services' prospective DUR process employs soft edits, as previously described, it does use hard edits in its claims adjudication system for four drugs not included on the DUR target drug list: nicotine (used for smoking cessation), serostim (a growth hormone used in the treatment of acquired immune deficiency syndrome, or AIDS), and ribavirin and PEG-interferon (two drugs used to treat hepatitis C). Health Services requires that pharmacists submit TARs for these four drugs because of the drugs' potential for misuse and fraud. However, Health Services should consider using hard edits in its prospective DUR process to realize additional cost savings.

Drug Alerts Requiring TAR Approval May Prove to Be an Effective Cost Control

Two steps Health Services could take to possibly realize cost savings are adopting "duration of therapy" and "step therapy protocol" edits in its prospective DUR process. In 2000, the secretary of the Health and Human Services Agency established a task force to explore drug use and cost control strategies in the Medi-Cal program. One issue discussed by the task force was the possibility of having Health Services reestablish a hard edit for duration of therapy to control the use of certain drugs that become unnecessary or inappropriate after a specified period—for example, drugs prescribed for specific medical conditions such as ulcers. In the past, Health Services used a hard edit for duration of therapy but decided to discontinue its use because of the substantial increase in the volume of TARs that its staff had to process as a result of the edit. Task force participants supporting the reestablishment of the edit believed that it would prevent unnecessary prescription refills, reduce inappropriate therapies for certain medical conditions, and possibly reduce costs. Task force participants opposed to reestablishing the duration-of-therapy edit believed that any cost savings gained by using it would be nullified by a large increase in Health Services' workload and higher administrative costs. Another issue of concern was Health Services' ability to meet the federal government's mandated 24-hour turnaround time for processing TARs resulting from the edit. Health Services said it discontinued the hard edit for duration of therapy in the late 1990s but could not provide us with data to support its claim that the volume of TARs that staff had to process increased substantially because of that particular hard edit. Although it does not use the duration of therapy edit in its prospective DUR process, Health Services told us that, beginning in March 2001, it reestablished the hard edit for duration of therapy in its claims adjudication system for the drug serostim and subsequently added the drugs ribavirin, nicotine, and PEG-interferon. According to Health Services, it uses the hard edit for duration of therapy on a selective basis because it is concerned with how the edit will affect the TAR approval workload.

Step therapy protocols, which recommend starting treatment of a condition with a less expensive drug that has a verified equivalent effect and moving on to a more expensive drug only if the patient is not responding to the first drug, are another type of hard edit that may control drug costs.

Another hard edit that may be useful in controlling drug costs would require a physician to prescribe a less expensive but therapeutically equivalent drug for a beneficiary who is in the early stages of a particular medical condition. This type of hard edit, called step therapy protocols or accepted treatment guidelines, would recommend starting treatment of a condition with a less expensive drug that has a verified

equivalent effect and moving on to a more expensive drug only if the patient is not responding to the first drug. For example, a recent study of the effect of blood pressure therapy compared the results of using older, less expensive drugs with the results of using newer, more expensive drugs. The study found that the older drugs were superior in a number of ways, including lowering blood pressure, and should be the preferred first step in treating high blood pressure. Building these types of study results into the prospective DUR process would encourage the use of less expensive medications, unless a physician requests and receives authorization to prescribe a more expensive drug to treat a condition.

Based on a decrease in the average prescription cost for calendar year 2001, West Virginia reported savings of more than $3.1 million related to one of its step therapy protocols.

Seven of the 17 states responding to our survey reported that they use step therapy protocols in their prospective DUR processes. West Virginia's Rational Drug Therapy Program, for example, requires its beneficiaries to use two two-week trials of generic anti-inflammatory medications, commonly used to treat arthritis, before it will cover the brand name drugs. The cost savings, based on a decrease in the average prescription cost for calendar year 2001, totaled more than $3.1 million for 9,600 claims. South Carolina beneficiaries are required to use two different generic antiulcer medications for up to eight weeks of therapy before they can receive the more expensive brand name products. The information provided by South Carolina, however, did not report the costs of the generic drugs used in place of the brand names; therefore, determining cost savings, if any, was not possible.

Health Services does not have step therapy protocols in place, although staff told us they have considered the use of this technique. Health Services told us that there is a need to ensure that step therapy protocols are based on scientific analysis and nationally recognized treatment guidelines, as well as the cooperation of the physicians who treat Medi-Cal beneficiaries. In addition, Health Services believes that it would need to make significant changes to include such protocols in its prospective DUR process. Despite Health Services' previous considerations of implementing step therapy protocols, however, it was unable to provide us with data or an analysis evaluating the costs and benefits of altering its process to include step therapy protocols. Consequently, we cannot determine the feasibility of this approach, but as previously discussed, at least one state responding to our survey reported that it has achieved cost savings by implementing step therapy protocols.

HEALTH SERVICES' RETROSPECTIVE DUR PROGRAM TRACKS DRUG TRENDS, BUT ITS EDUCATIONAL PROJECTS ARE IN EARLY STAGES OF DEVELOPMENT

Health Services' retrospective DUR process monitors drug use and cost trends to identify misuse and educational needs. Through this process, Health Services has identified and developed responses to costly patterns of fraud and inappropriate drug prescribing practices. Currently, implementations of Health Services' DUR educational projects are in early stages, with one major project under way and others in development.

Health Services Monitors Drug Use Trends to Identify Misuse and Educational Needs

Health Services' retrospective DUR process includes the ongoing, periodic examination of claims data and other records to identify patterns of Medi-Cal fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and Medi-Cal beneficiaries for specific drugs or groups of drugs. It also includes an ongoing, periodic examination of medical and pharmacy claims data to assess the clinical quality of how select Medi-Cal–covered drugs are prescribed and dispensed. Health Services' ability to monitor and respond to drug utilization trends in the Fee-for-Service population is increasingly important because Medi-Cal data indicate that the number of pharmacy prescriptions per beneficiary increased by 33 percent between 1998 and 2001. This increase occurred despite a decrease in the average number of Fee-for-Service beneficiaries from 3.3 million to 2.7 million over the same period. Two units within Health Services are responsible for performing reviews for the retrospective DUR program: the audits and investigations unit (audits unit) and the pharmaceutical unit.

Capabilities of Health Services' Management Information System

- A data warehouse containing records of all Medi-Cal services to beneficiaries.
- An on-line management information application for summary data reporting.
- A decision support component for specialized health care reporting.
- A geographic information system for access and utilization analysis.
- Episodic analysis for disease and provider profiling.
- Ad-hoc report writing for all specialized analyses.

According to Health Services, it accesses claims data and other records from three systems to conduct its retrospective DUR process: First, the Scenario database is an Electronic Data Systems Federal Corporation (EDS) owned system that includes paid claims of every type, except managed care, for a rolling 15-month period. Second, the Management Information System/Decision Support System (MIS) contains 30 months of paid claims data and archived data, including managed care, going back to fiscal year 1996–97

and specific analytical tools for more detailed data analyses. Third, the Rebate and Accounting Information System (RAIS) contains more than 10 years of pharmacy claims data, four years of rolling denied claims data, and drug rebate data. Both the MIS and the RAIS are directly accessible by Health Services' staff for DUR-related activities, and reports generated by the Scenario system are available from EDS.

The audits unit examines claims data from the EDS system and develops trend analyses for evidence of possible fraudulent activity among Medi-Cal providers and beneficiaries rather than drug therapeutic issues. It employs a variety of criteria to develop audits or investigative cases, including looking for unusual patterns in billing and prescribing. The audits unit also examines data to develop comparative analyses of provider behavior.

Health Services' pharmaceutical unit identified that the utilization rate for one drug had grown much faster than anticipated, which eventually led its audits unit to uncover a prescription forgery ring.

The importance of Health Services' efforts in monitoring drug use and cost trends was evident in a recent case involving the growth hormone serostim, used in the treatment of AIDS. During the summer of 2000, Health Services' pharmaceutical unit identified that the utilization of serostim had increased significantly during the previous three years, increasing from approximately $8.8 million in 1997 to more than $38 million in 1999. The audits unit investigated counterfeit prescriptions and eventually uncovered a prescription forgery ring. During its yearlong investigation, the audits unit determined that the growth hormone was being used for cosmetic purposes instead of AIDS therapy.

The pharmaceutical unit designs and implements computer edits and audits used in processing Medi-Cal pharmacy claims and in the DUR programs. Additionally, the pharmaceutical unit monitors medical and pharmacy claims data to assess the clinical quality of the prescribing and dispensing of select Medi-Cal–covered drugs, suggesting appropriate interventions to address the problems it or others identify. For example, after serostim was linked to misuse, the pharmaceutical unit added a hard edit requiring a pharmacist to seek TAR approval before dispensing the drug.

The pharmaceutical unit also reviews some DUR retrospective data to identify the educational needs of drug providers. Pharmaceutical unit staff and the DUR board typically review these data during quarterly meetings. The DUR board makes recommendations to Health Services about educational

interventions warranted by utilization trends or about emerging topics in the medical community. The first major review that led to an educational project began in early 1998 when Health Services examined the increasing utilization and cost of atypical antipsychotic drugs. According to its chief, the pharmaceutical unit analyzed the data over the next several months and ultimately chose to develop an educational project to address the increasing cost and utilization of atypical antipsychotic drugs. Because the pharmaceutical unit has only recently been engaged in retrospective DUR, however, the educational component of the DUR program has been limited in its ability to educate health care practitioners to improve drug prescribing or dispensing practices, and possibly to save costs.

Health Services' Educational Methods Related to DUR Are Indirect and Project Oriented

In contrast to Medicaid programs in some other states we surveyed, Health Services does not promote education that emerges from the retrospective DUR program by sending letters to physicians and pharmacists (providers). Instead, Health Services uses educational methods such as a monthly bulletin and a Web site to affect physicians' prescribing behavior. Although these educational efforts benefit from the expertise of Health Services' DUR board, the activities are not as specifically targeted as letters and depend on providers to seek them out.

Types of DUR Educational Intervention Activities Nationwide

- 88 percent send letters to physicians about individual patients with drug therapy problems.
- 78.5 percent send letters to pharmacists about individual patients with drug therapy problems.
- 54.8 percent profile physicians with prescribing problems.
- 16.7 percent conduct telephone interventions with physicians and pharmacists.
- 11.9 percent conduct face-to-face interventions with physicians and pharmacists.
- 7.1 percent write journal or newsletter articles.
- 4.8 percent give continuing education programs or presentations at hospitals and other institutions.

Source: *Medicaid Drug Utilization Review and Managed Care,* Journal of Managed Care Pharmacy, March/April 2000 (vol. 6, no. 2, p. 131)

Federal law gives state Medicaid DUR boards the authority to select both the subject matter of educational activities and the mechanisms to implement those activities. State programs employ various approaches to implement educational programs, as indicated in an independent survey of state Medicaid program directors published in April 2000.

Similar to the results shown in the text box, our survey found that some of the 17 responding states send letters to providers. In general, the methods states use to identify providers for educational letters are similar. DUR boards typically select criteria for retrospective DUR. The criteria include drug therapy problems, such as overuse or incorrect duration, associated with therapeutic classes or categories, such as antibiotics or pain

Unlike nine of the 17 states responding to our survey, Health Services does not send letters to providers to address inappropriate prescribing or dispensing patterns.

control. Depending on the criteria selected and based on the expert opinion of DUR board members, profiles are created for providers whose prescribing or dispensing behaviors fall outside the predetermined criteria. Profiles of patients' drug use may also be created and sent to providers. Letters describing the criteria and the reason for the profile are then sent to a group of those providers. Nine of the 17 states responding to our survey indicate they use these "Dear Dr." letters. For example, a Dear Dr. letter may include information comparing a doctor's prescribing patterns to his or her peers, suggested treatment guidelines, and materials on educational courses.

The educational method used by CalPERS' former pharmacy benefits manager (PBM) also relied on Dear Dr. letters. According to the PBM, the retrospective DUR process identified providers whose prescribing or dispensing patterns fell outside the set parameters. Providers received messages either electronically or through Dear Dr. letters that contained information comparing their prescribing or dispensing behaviors to those of their professional peers and suggesting how to change their approaches. Finally, the PBM monitored the providers' prescribing or dispensing behaviors to determine whether the patterns had changed and the extent to which cost savings resulted from changes in prescribing.

Unlike some other states, Health Services does not rely on sending letters to providers. The chief of the pharmaceutical unit cited a 1991 study of a sample of counties prepared by SRI International that tested whether a letter-oriented educational effort similar to those just described had an effect on utilization of Medi-Cal–covered services and Medi-Cal costs. The educational effort consisted of sending letters to providers that included complete profiles of the patients' drug use, and in some cases included scientific literature. The SRI analysis concluded that there was no significant decrease in service use or health care costs in the counties involved in the sample. However, the study also suggested that there was limited follow-up with providers who received the letters, that scientific data were not always included with the letters, and that measuring Medi-Cal costs over a longer period might have revealed cost savings. Health Services also told us that the use of Dear Dr. letters to providers for DUR education would be very difficult to implement and administer in California because of the large number of Medi-Cal beneficiaries and providers. However, we question this assertion. Although it may not be feasible to send Dear Dr. letters to all Medi-Cal drug providers, Health Services

can, as do Medicaid programs in other states, use profiling to identify providers whose practices indicate they are most in need of intervention and send letters only to them. In fact, the audits unit is in the early stages of developing a process to identify, send out letters, and follow up on providers who have increased activity in certain service categories or demonstrate patterns that are inconsistent with their peers. Therefore, as Health Services continues to implement its retrospective DUR program, it might reconsider the use of letters in a focused educational program that targets providers whose prescribing or dispensing practices are inappropriate and who are not likely to be involved in other educational projects or affected by less active forms of educational intervention.

Although Health Services does not send Dear Dr. letters, it uses several less direct mechanisms to disseminate education materials on general drug therapy to providers. Health Services publishes the monthly *Medi-Cal Update Pharmacy Bulletin* and supplies the Medi-Cal DUR Manual (manual) to providers in California. Health Services' manual describes the role of its DUR board, lists the drug use criteria and standards used in its DUR program, and provides some general education materials. In addition, articles have been published in professional journals about the educational project on atypical antipsychotic drugs, and presentations have been made at professional conferences. Finally, Health Services' DUR Web site maintains a wide variety of program information and publications. The potential drawback of these methods of affecting drug utilization is that they are either indirect, in that they are available to a general audience rather than a set of identified providers, or they are passive, in that they rely on providers to seek them on their own initiative.

The potential drawback of the methods Health Services uses to affect drug utilization is that they are either indirect, in that they are available to a general audience rather than a set of identified providers, or that they are passive, in that they rely on providers to seek them on their own initiative.

Health Services' DUR board is responsible for identifying drug therapy problems and recommending the types of interventions that will most effectively improve the quality of drug therapy. In this capacity, it has recommended a number of educational projects. Most of the projects will ultimately implement direct educational interaction with prescribers in specific subject areas. For example, several presentations have already been made at facilities throughout California to improve appropriate utilization and to address the high cost of atypical antipsychotic drugs, the therapeutic class of drugs that has been the most costly for Medi-Cal. Table 5 provides an overview of the DUR board's active and proposed educational projects.

TABLE 5

Medi-Cal's DUR Education Projects Focus on High-Cost and Large-Scale Health Issues, but Are at an Early Stage or in Development

Project	Focus/Status
Atypical Antipsychotic Drugs	Program designed to improve appropriate utilization and address high costs of atypical antipsychotic drugs, which was the most expensive therapeutic class of drugs in the Medi-Cal Fee-for-Service system at more than $350 million during 2001. Educational presentations have been made at more than 17 venues in California, including state and county mental health facilities. Continuing education credits are available for physicians who participate in the educational program. Plans are to develop an intensive educational intervention with identified high prescribers of atypical antipsychotic drugs, which will include monitoring and follow-up. Printed programs and CD ROMs of the program have been sent to more than 4,200 health care providers. Articles about the project have been published in professional journals. Health Services is partnering with the University of California, San Diego Graduate Department of Continuing Education, and the Neuroscience Education Institute. Funding is from unrestricted educational grants provided by pharmaceutical manufacturers.
Long-Term Care	A 2001 proposal developed by the California Pharmacists Association (CPhA), in cooperation with the University of Southern California School of Pharmacy, to evaluate appropriate drug therapy and associated costs, and address these issues through education of physicians, pharmacists, and providers who serve the Medi-Cal long-term care community (LTC). The LTC population is responsible for 14 percent of Medi-Cal costs although beneficiaries account for only 1 percent of the total caseload. The original proposal focused on the treatment of congestive heart failure, hypertension, diabetes, and osteoporosis in the LTC population, but was subsequently scaled back to include only the osteoporosis component. Through April 2003, efforts to obtain funding of nearly $109,000 to conduct the study have not been successful.
Antibiotic Resistance	A DUR Board member is serving in a liaison capacity to the Alliance Working for Antibiotic Resistance Education (AWARE), an effort to improve the utilization of antibiotic medication through education about appropriate treatment guidelines. AWARE is focused on the problem of the overuse of antibiotic medication. The Medi-Cal DUR program participates in the AWARE steering committee and subcommittees to address the problem of antibiotic overuse in California. The AWARE network includes the federal Centers for Disease Control and Prevention (CDC) and the California Medical Association.
Asthma	A project in development to use claims data to predict pediatric asthma health status, quality of care, and relationships between quality of care and costs in the Medi-Cal population. An education program will be established after the predictive model is completed. According to Health Services data, the total net cost of asthma among the Medi-Cal Fee-for-Service population was more than $51 million during 2001.
Arthritis	A project in development designed to identify practice patterns, treatment outcomes, and costs of chronic rheumatoid arthritis in the Medi-Cal population. The project is designed to identify health care provider patterns and use those findings for future guidance of arthritis care and policy through an educational program.
Influenza	During federal fiscal year 2001, Health Services and the DUR board collaborated with the CPhA and the CDC to profile influenza outbreaks by location. The profiling resulted in a cooperative data sharing effort among the organizations.
Diabetes and Pain Management	Health Services and the DUR board are in an exploratory stage of developing projects to address the treatment of diabetes and the management of chronic pain in the Medi-Cal population. No project proposals or documents have been drafted for diabetes or pain management. According to Health Services' data, the total net cost of diabetes was more than $234 million during 2001.

The advantage of Health Services' approach is that it can rely on the expertise and resources of its voluntary DUR board members. However, Health Services' heavy reliance on the DUR board can also prove to be a potential weakness of DUR education. Health Services devotes only minimal resources to the board and the projects selected for development. Specifically,

Because Health Services lacks a formal plan outlining the goals, anticipated outcomes, and resource needs of its DUR education program, we could not assess the adequacy of the resources it devotes to this program.

Health Services develops the retrospective DUR data used to select projects, attends the quarterly board meetings, and performs some limited oversight of the projects. However, it relies heavily on board members to develop and implement the projects and obtain funding for the projects. As a result, if a board member is unwilling or unable to direct a project or to raise the necessary funding, the project may never get off the ground, missing an opportunity to educate physicians about appropriate drug therapy. Although Health Services says this is not a problem at present, as noted in Table 5, its LTC project still lacks funding. However, because it lacks a formal plan outlining the goals, anticipated outcomes, and resource needs of the DUR educational program, we could not assess the adequacy of the resources it devotes to the DUR educational program or what its future needs may be.

Although the DUR board may have the resources it needs to carry out most of the current education projects, it is questionable whether Health Services would be able to provide additional resources to the DUR educational program if needed. As we discuss in Chapter 1, Health Services is already having difficulty hiring the pharmacists it needs. If it needs to expand its involvement in the DUR educational program, one approach it might consider is outsourcing some of those functions to a pharmacy school, as is done in other states, such as Oregon and Idaho. According to a representative of the Oregon State University College of Pharmacy (college), the college's role in the Oregon DUR program is to administer the DUR board, including recruiting members, and to provide general pharmacist consulting services, such as analyzing drug utilization and drug policy and providing drug information and educational interventions, on behalf of the Oregon Department of Human Services. Health Services told us that it has considered contracting out some of its retrospective DUR and educational activities to a school of pharmacy; however, it has not conducted an evaluation of the costs and benefits of outsourcing these functions.

HEALTH SERVICES HAS NOT KEPT PACE WITH SOME OTHER STATES IN IMPLEMENTING DISEASE MANAGEMENT PROGRAMS

Health Services has yet to establish comprehensive programs in disease management for the Medi-Cal population. The number of states that are implementing disease management programs

has increased dramatically within the past two years, and although these states' programs vary in their design and most are in their early phases, patient health outcomes are generally positive. In some cases, however, disease management programs have caused pharmacy costs to increase. Although Health Services supports disease management—particularly considering the health demographics of the Medi-Cal population, which includes mostly aged, blind, and disabled beneficiaries—it says it currently does not have the resources to develop in-house disease management programs and is wary of putting them in the hands of an outside contractor. Instead, Health Services has chosen to collaborate with nonprofit organizations to develop disease management pilot projects, which could lead to widespread applicability to the Medi-Cal population. However, implementation of the pilot projects is in doubt because rather than securing funding itself, Health Services has relied on its nonprofit partners.

Common Components of a Disease Management Program

- Patient identification.
- Use of evidence-based practice guidelines.
- Supporting adherence to evidence-based medical practice guidelines by providing medical treatment guidelines to physicians and other providers, reporting patient progress in compliance with protocols, and providing support services to assist the physician in monitoring the patient.
- Services designed to enhance patient self-management and adherence to the treatment plan for the patient's disease.
- Routine reporting and feedback mechanisms.
- Communication and collaboration among providers and between the patient and his or her providers.
- Collection and analysis of process and outcomes measures.

Source: Federal Centers for Medicare and Medicaid Services

Disease Management Programs Have Been Increasing Throughout the Country

As a means of coping with rising health care costs, the use of disease management has expanded across state Medicaid programs. *Disease management* is defined as an approach to delivering health care services to persons with chronic illnesses that aims to improve patient outcomes while containing health care costs. The text box identifies the most common components of a disease management program.

The growing popularity of disease management is illustrated in a report by the Kaiser Commission on Medicaid and the Uninsured, which identifies 21 states as having or planning to implement Medicaid disease management or case management programs in fiscal year 2002–03. This number is up from 11 states with such programs in fiscal year 2001–02.

The disease management programs developed by states vary widely in several respects. States have targeted different diseases or groups of diseases for their programs, rely in varying degrees on outsourcing to disease management organizations or administer programs in-house, and use various

types of medical services and medical professionals. According to the National Pharmaceutical Council, the diseases most state programs focus on are diabetes and asthma.

In reviewing research literature and other publications, we found that although the number of states with disease management programs has increased, there are limited quantitative analyses assessing the programs' impact on health care quality and cost savings. The analyses that have been conducted to date indicate that disease management programs have raised the quality of care in Medicaid, but have not produced significant cost savings in the short term. Moreover, some states have reported an increase in drug utilization as a result of patient adherence to drug therapy. Part of the challenge in evaluating disease management outcomes is that, like health management organizations, states vary in the program performance indicators they select. For example, some programs have used clinical outcomes such as improvements in glycemic control or cholesterol levels, while others measure hospital admission rates or visits to emergency rooms. Still others measure patient participation in educational programs and adoption of techniques to self-manage their diseases.

Disease management does not appear to be prevalent among the 17 states responding to our survey. Specifically, only five of the responding states indicated that they have disease management programs, and none provided data on cost savings or other outcome information. Nonetheless, our additional research of other state programs provides some information about the outcomes of their disease management programs. As Table 6 shows, states use a variety of outcome measures, reductions have been measured in health care service utilization, improvements in patient knowledge and self-management have been noted, and for the few states that provided them, cost-effectiveness outcomes were positive.

Although Health Services has yet to implement a comprehensive disease management program, it does have a Medical Case Management Program (case management) that coordinates medical care and ensures the continuity of care for Medi-Cal beneficiaries suffering from chronic and/or catastrophic illness and/or requiring medically complex services. Case management is voluntary on the part of participating physicians, hospitals, and beneficiaries. The goals of the case management program are to improve beneficiary health outcomes and reduce health care costs through more efficient delivery and authorization

TABLE 6

Outcome Information for State Disease Management Programs in Other States Is Limited

State	Disease(s)	Outcomes and Issues	Cost Savings
Colorado[1]	Asthma, Diabetes, Cancer, High Risk Newborns, Schizophrenia	Demonstration project began July 2002 and will be complete December 2003.	Cost savings not reported.
Florida[2]	Asthma, Congestive Heart Failure (CHF), Depression, Diabetes, HIV/AIDS, Hypertension	A 2001 evaluation of its disease management program criticized the Florida Agency for Health Care Administration for its slow implementation and assessment of the program, for not adequately addressing barriers that could hinder program success, and for deficiencies in the program design.	Cost savings not determined.
Idaho[3]	Asthma, Diabetes	New program	Cost savings not reported.
Mississippi[4]	Asthma, Diabetes, Coagulation Disorders, Hyperlipidemia	Although the initial outcomes of Mississippi's approach were promising, the program encountered a hurdle: low pharmacist participations. Mississippi has yet to determine the cause of the low pharmacist participation since its overall evaluation of the program will not be complete until late 2003.	Results based on 11 patients included a 96 percent reduction in hospital costs, and a 58 percent reduction in emergency room costs. Savings in hyperlipidemia and coagulation disorders were not available.
North Carolina[5]	Asthma, Diabetes	A 2001 report indicated that patients in the asthma study population had the highest overall appropriate asthma medication use rate compared to other study populations. A 2002 evaluation of the managed care diabetes project reported improvements in five of six quality indicators related to improved patient outcomes.	The average asthma episode cost for children under 18 was 19 percent less than for children not enrolled in the program. The managed care diabetes project study did not compute cost savings.
Texas[6]	Diabetes	A 2001 study of the managed care diabetes pilot project reported that 96 percent of participants responding attended diabetes self-management classes; 91 percent of participants that received education indicated changes and improvements in food preparation to assist with control of their diabetes, while 90 percent stated they had started or changed the way in which they exercised.	Cost savings not reported; low patient participation prevented valid cost-benefit analysis.
Virginia[7]	Asthma	A 1999 study reported a reduction in emergency room visits by 41 percent for patients of participating physicians who received feedback compared to only 18 percent for comparison physicians; 25 percent increase in dispensation of some drugs recommended for asthma.	A cost effectiveness analysis found direct savings to Medicaid of between $3 and $4 for every incremental dollar spent providing disease management support to participating physicians. Drug costs were not reported.
Washington[3]	Asthma, CHF, Diabetes, End-stage Renal Disease	Contract guarantees a net savings rate of .61 percent for asthma patients; a guarantee net savings rate of 1.48 percent for both CHF and diabetes patients; and a guarantee net savings rate of 5 percent for patients with end stage renal disease.	Annual cost savings are projected to be $2 million for fiscal year 2003.
West Virginia[3]	Diabetes	Not reported	Cost savings not reported.

Sources:

[1]Colorado Medicaid, Department of Health Care Policy and Financing, Medical Assistance Office, State of Colorado, www.chcpf.state.co.us.

[2]Office of Program Policy Analysis and Government Accountability, Florida Legislature, Justification Review: *Medicaid Disease Management Initiative Sluggish, Cost Savings Not Determined, Design Changes Needed,* May 2001.

[3]Response to Bureau of State Audits' survey.

[4]*Mississippi DSM Program is Model for Nation,* L. Michael Posey, Pharmacy Today, 6 (6) 2000 ; telephone interview with Dr. Joseph Byrd, Chair, Department of Pharmacy Practice, University of Mississippi School of Pharmacy.

[5]North Carolina Community Care Program, *Frequently Asked Questions,* May 2001; Medical Review of North Carolina, Inc., *Managed Care Diabetes Project,* June 2002.

[6]Final report submitted by the Health and Human Services Commission, *Texas Medicaid Managed Care Diabetes Pilot,* December 2001.

[7]*Impact of Disease Management on Outcomes and Cost of Care: A Study of Low-Income Asthma Patients,* Louis F. Rossiter et. al., Inquiry, 2000, Summer, 37 (2).

of medical services. The program is designed to avoid high-cost medical services and prevent acute care hospitalization or institutionalization by maintaining beneficiaries in a home care environment. Case management is similar to disease management in that it focuses on those beneficiaries with chronic and/or catastrophic illnesses, but it differs from disease management in that case managers manage medical services rather than a specific disease.

One approach to disease management that may be feasible in California is currently used in Mississippi. The Mississippi program allows pharmacists to evaluate patients, review and assess drug therapy compliance, and provide education to patients suffering from asthma, diabetes, coagulation disorders, and hyperlipidemia (the presence of excess fat in the blood). Mississippi obtained approval from the federal government to allow participating pharmacists to receive a reimbursement of $20 per claim. Subsequent Mississippi state regulations established several program requirements designed to foster collaboration between pharmacists and physicians, use of professional expertise, and use of nationally recognized practice guidelines.

Requirements of Mississippi's Pharmacist-Coordinated Disease Management Program

- A physician must refer the patient for pharmacist services.
- The physician and pharmacist cooperatively develop a disease management protocol for each patient.
- A pharmacist must be either a doctor of pharmacy or a registered pharmacist and complete disease-specific certification programs.
- Each pharmacist must complete a State Pharmacy Board-approved recertification course every two years.
- Patient treatment protocols must incorporate nationally accepted practice guidelines.
- The number of patients per pharmacist is not restricted, but visits are limited to 12 per recipient per year for all diseases.
- The pharmacist must consult with patients in a distinct area conducive to privacy.

Although the initial outcomes of the Mississippi approach were promising, the program has encountered a hurdle: low pharmacist participation. Discussions with an official of the Mississippi program indicated that it has yet to determine the cause of the low pharmacist participation since its overall evaluation of the program will not be complete until late 2003.

CalPERS recently contracted with Blue Cross of California (Blue Cross) to implement disease management programs for its members who suffer from asthma, congestive heart failure (CHF), cardiovascular disease, diabetes, and depression. The disease management programs of Blue Cross use a multidisciplinary team that includes not only a pharmacist but also physicians, nurses, and other health care providers to help patients manage their diseases. In addition, the Blue Cross CHF and asthma disease management programs are expected to decrease medical utilization, such as emergency room visits, and promote beneficiaries' measured adherence to medications. We were able

Some disease management programs have been shown to improve the quality of care, but we found little evidence that they yield short-term cost savings. Nonetheless, with some programs reporting a reduction in hospital stays following their implementation, the possibility of long-term savings exists.

to obtain outcome data for Blue Cross' CHF program, and the results indicate decreases in hospital admissions, emergency room visits, and the average hospital stay for CalPERS members participating in the program. The data also indicated an increase in medications supplied to beneficiaries, positive results in quality of life measures, and mixed conclusions regarding beneficiaries' satisfaction with their health plan. Specific cost savings resulting from the CHF program were not included in the data.

Like the CalPERS disease management program, many other programs have been shown to improve the quality of care, but we found little evidence that they yield short-term cost savings, and in fact, sometimes drug use has increased. However, we did find that some programs have reported a reduction in hospital stays and emergency room visits following the implementation of disease management programs, indicating that the possibility of long-term savings exists. With the promise of improved patient care and the potential for long-term cost savings, disease management programs could benefit Medi-Cal, with its high proportion of chronically ill patients.

Despite Working With Other Organizations on Disease Management, Health Services Has Not Sought Funding for the Pilot Projects

Health Services has not yet implemented a comprehensive disease management program, but it has been collaborating with the CPhA to develop disease management pilot projects that parallel the approach used in Mississippi. The Medi-Cal Pharmacist Care Project was initially proposed in 2000 by the University of Southern California (USC) School of Pharmacy, in cooperation with the CPhA and Health Services, as an effort to establish a framework wherein qualified pharmacists would serve as coordinators of disease management for high-risk Medi-Cal beneficiaries suffering from asthma and diabetes. A second proposal focusing on pharmacist services for hypertension was developed in 2002. The objectives of the proposals are to determine whether a pharmacist-coordinated model of disease management, applied to the Medi-Cal population, can improve health outcomes for beneficiaries. A feature of the asthma-diabetes proposal is a reimbursement system for disease management services. According to the CPhA's associate vice president for clinical affairs, the absence of a financial incentive for pharmacists is a major barrier to the implementation of a pharmacist-coordinated disease management model in

California. Our discussions with Health Services' staff revealed a continuing interest in the pharmacist-coordinated model and a perception that the Medi-Cal environment would likely make it a feasible approach to disease management. However, Health Services has not been successful in its attempts to find funding for the pilot projects, despite the possibility that the projects could establish disease management programs that would produce long-term savings for Medi-Cal.

One of the proposed pilot projects establishes a budget of approximately $315,000 to operate an asthma and diabetes study for three years. Faculty from the USC School of Pharmacy estimate that, on average, an annual 10 percent overall savings could be achieved for high-risk asthma and diabetes beneficiaries in the study population. The asthma-diabetes proposal is not expected to produce any net change in drug costs to the Medi-Cal program. Additionally, the budget for the two-year hypertension project is approximately $707,000. The CPhA has been able to secure nearly $367,000 and is seeking unrestricted grants of $40,000 from pharmaceutical companies, with the remaining $300,000 being requested from the California HealthCare Foundation. The hypertension proposal does not provide an estimate of cost savings for the study population but does state that if pharmacist services improve patient adherence to drug therapy and reduce blood pressure, estimates of the long-term savings in health care costs will be provided.

Despite Health Services' interest in the disease management pilot projects, it has chosen to rely on the CPhA and other organizations to secure funding. Proceeding with the pilot projects would allow Health Services to test the feasibility of a pharmacist-coordinated approach to disease management and its potential for improving Medi-Cal beneficiary health outcomes and cost savings. However, the potential benefits of the disease management pilot projects, and their applicability to the Medi-Cal population, will remain unrealized until Health Services moves forward on funding these pilot projects.

HEALTH SERVICES MAY BE ABLE TO ACHIEVE ADDITIONAL SAVINGS BY REEVALUATING ITS POLICY REGARDING OPTIONAL PHARMACY BENEFITS

Under federal law, states are allowed to exclude several therapeutic classifications from reimbursement in their pharmacy benefit programs. As shown in Table 7 on the following page, all states responding to our survey include at least two of the optional categories listed in their benefit programs.

Had it excluded the five optional classes of drugs from its pharmacy benefits in calendar year 2001, the State might have saved nearly $80 million.

Health Services made a policy decision to include five of these optional classes of drugs as part of its pharmacy benefit: anorexia, weight loss, or weight gain drugs; cough and cold drugs; smoking-cessation drugs; barbiturates; and benzodiazepines, which include antianxiety drugs. Health Services' data show that, had it excluded these classes of drugs from its pharmacy benefit, it might have saved the State nearly $80 million during calendar year 2001. The bulk of this cost, $70 million, represents Health Services' reimbursement for cough and cold drugs. According to Health Services, this category contains antihistamines—a group with many new drugs on the market that cost much more than the earlier generation of drugs—as well as eye, ear, and throat preparations used to treat cold and cough symptoms. However, Health Services warns that prescription antihistamines are used extensively by asthma patients to reduce asthma attacks brought on by allergies; thus, it may not be feasible to exclude these drugs from coverage. Yet Health Services was unable to provide us with the proportion of beneficiaries that use antihistamines for this purpose.

Health Services justifies its spending of almost $80 million for these optional services with its belief that these drugs are keeping overall drug costs down. According to Health Services, if it did not cover these drug classes—in particular, the cough and cold drugs—its beneficiaries would demand prescription drugs from their physicians to relieve their symptoms, thereby creating a shift to higher-priced drugs that are not optional. Additionally, Health Services told us that other costs, such as Medi-Cal hospitalization costs, might increase because without the optional drugs, some beneficiaries might ultimately require hospitalization. However, Health Services could not provide us with an analysis to support the net effect that discontinuing to offer the optional drug class would have on increasing drug and hospitalization costs for certain beneficiaries. An analysis is particularly important since Alaska, Oklahoma, and Pennsylvania are able to exclude all cough and cold drugs from

TABLE 7

Coverage of Optional Services Varies Among the States Responding to Our Survey

State	Anorexia, Weight Loss, or Weight Gain Drugs	Fertility Drugs	Cosmetic or Hair Growth Drugs	Drugs for Symptomatic Relief of Cough and Colds	Smoking-Cessation Drugs	Prescription Vitamins and Mineral Products, Except Prenatal Vitamins and Fluoride Preparations	Barbiturates	Benzodiazepines
California	✓*			✓	✓		✓	✓
Alaska							✓	✓
Colorado				✓§	✓*	✓*	✓	✓
Connecticut				✓		✓	✓	✓
Idaho				✓		✓	✓	✓
Illinois				✓	✓	✓*	✓*	✓
Kansas	✓*			✓†	✓			✓*
Kentucky	✓			✓		✓	✓	✓
Minnesota	✓			✓	✓	✓	✓	✓
Mississippi				✓	✓		✓	✓
New Jersey				✓†	✓‖	✓†	✓	✓
North Carolina	✓			✓	✓	✓	✓	✓
Oklahoma	✓*				✓*		✓*	✓*
Pennsylvania					✓	✓†	✓	✓
South Carolina				✓		✓	✓	✓
Texas				✓	✓		✓	✓
Washington				✓		✓	✓	✓
West Virginia				✓‡	✓	✓	✓‡	✓

Source: Results of survey conducted by the Bureau of State Audits.

✓ Indicates the state covers this optional classification of drugs.

* State survey indicated drugs were available only with prior authorization.

† State survey indicated drugs were available only to children. For Pennsylvania children are defined as those under 3 years of age.

‡ State survey indicated that coverage was limited.

§ State survey indicated individuals over 21 need prior authorization.

‖ State survey indicated that the state only covers legend drugs, which are any drugs whose labeling states "Caution: Federal law prohibits dispensing without prescription" or similar words.

coverage. After conducting such an analysis, Health Services might be able to limit cough and cold drugs to beneficiaries who have asthma or are elderly, and similarly limit or eliminate other categories.

RECOMMENDATIONS

To achieve additional savings in its Medi-Cal pharmacy program, Health Services should do the following:

- Measure the effect that the use of the duration-of-therapy hard edit has on its workload. If feasible, consider reestablishing this edit for additional drugs.

- Evaluate its ability to adapt its prospective DUR program by using other types of hard edits, including step therapy protocols for specific drugs or classes of drugs. The evaluation should include an analysis of the costs and benefits associated with these approaches.

- Reevaluate the cost-effectiveness of using Dear Dr. letters in a focused educational program that targets physicians and pharmacists, whose prescribing or dispensing practices are inappropriate.

- Work with the DUR board to develop a formal plan for its educational activities that includes at a minimum, the goals, anticipated outcomes, and resource needs. Further, Health Services should update the plan annually.

- If, in the future, it determines that it lacks adequate resources for its retrospective DUR and educational activities, it should evaluate the cost-effectiveness of outsourcing some of these functions.

- Consider seeking funds to continue its collaboration with the CPhA and USC for the proposed pharmacist-coordinated disease management pilot projects. Then evaluate the results of the pilot projects and, if feasible, implement the models on a more widespread basis.

- Conduct a study to identify the effect of discontinuing all or a portion of the optional drug therapeutic classifications from its benefits on Medi-Cal beneficiaries and Medi-Cal's drug costs. If it determines it is cost-effective to do so, discontinue some or all of the optional drug classifications.

We conducted this review under the authority vested in the California State Auditor by Section 8543 et seq. of the California Government Code and according to generally accepted government auditing standards. We limited our review to those areas specified in the audit scope section of this report.

Respectfully submitted,

ELAINE M. HOWLE
State Auditor

Date: April 30, 2003

Staff: Joanne Quarles, CPA, Audit Principal
Denise L. Vose, CPA
Aveena DeMesa
Kyle D. Gardner, Ph.D.
Matt Taylor

APPENDIX A

Reimbursement Rates and Rebate Practices Vary Among the States Responding to Our Survey

The Joint Legislative Audit Committee requested that the Bureau of State Audits conduct a survey of selected states' Medicaid program practices aimed at containing costs. The survey we designed asked states to respond to a series of questions such as whether they provide reimbursement for prescription drugs using methods such as a federal upper limit, estimated acquisition costs, or maximum allowable ingredient costs, and whether they receive rebates other than federal rebates. Table A.1 presents this information as it relates to California as well as a summary of the responses from the 17 states that completed our survey.

TABLE A.1

Reimbursement Rates and Rebate Practices Vary Among the States Responding to Our Survey

State	Federal Upper Limit	Estimated Acquisition Cost (EAC)	Maximum Allowable Ingredient Cost (MAIC) or (MAC)	Supplemental Rebate
California	Yes	Before December 1, 2002, the average wholesale price (AWP) minus 5 percent After December 1, 2002, AWP minus 10 percent	Traditionally, the MAC was calculated using a reference generic product's AWP minus 5 percent. On October 1, 2002, a new law went into effect that allows the program to use the wholesale selling price of a drug to set the MAC.	Yes
Alaska	Yes	AWP minus 5 percent	Not Applicable	No
Colorado	Yes	Rate charged by the provider	One drug, Clozapine, on state MAC, price calculated as generic.	No
Connecticut	Yes	AWP minus 12 percent	Yes, but no details provided.	No
Idaho	Yes	An approximation of the net cost of the drug and a reasonable operating margin	Yes, but no details provided.	No
Illinois	Yes	AWP minus 12 percent for brand name drugs AWP minus 25 percent for generic drugs	AWP minus 25 percent of the least expensive product generally available	Yes

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State	Federal Upper Limit	Estimated Acquisition Cost (EAC)	Maximum Allowable Ingredient Cost (MAIC) or (MAC)	Supplemental Rebate
Kansas	Yes	AWP minus 13 percent for brand name drugs AWP minus 27 percent for generic drugs	MACs are set by the state with input from an independent consulting pharmacist to help ensure that payment is fair and equitable.	Yes
Kentucky	Yes	AWP minus 12 percent	State MAC program began on 04/01/03	No
Minnesota	Yes	AWP minus 14 percent	The state uses a variety of sources to determine MACs. There are pharmacy benefit managers willing to share their MACs and pharmacy contacts willing to share actual acquisition costs. Also, the state reviews the MACs established by other states, and monitors professional literature for new generics.	Yes
Mississippi	Yes	Not available	Not applicable	No
New Jersey	Yes	AWP minus 10 percent	Not applicable	No
North Carolina	Yes	AWP minus 10 percent	The MAC is established between the actual acquisition cost and the AWP of the generic drug.	No
Oklahoma	Yes	AWP minus 12 percent	The MAC is based on the average of two pricing formulas: • The Oklahoma State and Education Employees Group Insurance Board's MAC value. • The lower of AWP minus 15 percent or wholesale selling price plus 12 percent.	No
Pennsylvania	Yes	AWP minus 10 percent	The state uses First Databank baseline prices for some multisource over-the-counter drugs.	No
South Carolina	Yes	AWP minus 10 percent	The state contracts with First Health to develop and maintain a state-specific MAC list.	No
Texas	Yes	Before December 16, 2002, the lower of AWP minus 15 percent or the wholesale acquisition cost (WAC) plus 12 percent After December 16, 2002, the lower of the AWP minus 16 percent or the WAC plus one percent for single-and multi-source drugs not subject to the MAC	MAC set on the median price and determined by the WAC minus 12 percent for drugs subject to MAC.	No
Washington	Yes	AWP minus 14 percent and AWP minus 50 percent for drugs with five or more manufacturers	Automated MAC list includes drugs with two or more manufacturers/labelers. Additional MAC list manually developed and maintained by the state.	Yes
West Virginia	Yes	AWP minus 12 percent	Not applicable	No

APPENDIX B

Health Services Incurred More Than 60 Percent of Its Total Drug Costs on 200 Drugs

Table B.1 presents the 200 drugs that represented the largest share of the Department of Health Services' (Health Services) drug expenditures (top 200 drugs) for the period of January 1 through December 31, 2001. The federal Food and Drug Administration identifies each drug on this top 200 drug list as a unique drug with its own National Drug Code (NDC). The NDC is specific to a manufacturer and product, which includes specific strength, dosage, and package size. The top 200 drugs represent more than 60 percent of Health Services' total drug costs for calendar year 2001. Health Services provided us with a data file that contained a summary of the total amount Health Services reimbursed pharmacies for each drug listed by NDC for calendar year 2001. Because these amounts represent payments to pharmacies, they have not been reduced by any federal or state supplemental rebates Health Services received from manufacturers.

TABLE B.1

Health Services Incurred More Than 60 Percent of Its Total Drug Costs on 200 Drugs for the Period January Through December 2001

Rank	Label Name	Dosage	Amount Paid	Number of Claims
1	Zyprexa	10mg tablet	$122,688,103	262,780
2	Celebrex	200mg capsule	60,289,675	466,077
3	Prilosec	20mg capsule	56,681,812	326,609
4	Prevacid	30mg capsule	55,416,137	348,078
5	Serostim	6mg vial	45,434,011	7,176
6	Zyprexa	5mg tablet	40,605,826	150,013
7	Prozac	20mg pulvule	33,964,522	227,115
8	Compounded drug		31,478,271	82,706
9	Vioxx	25mg tablet	30,341,386	319,548
10	Lipitor	10mg tablet	28,240,820	315,057
11	Claritin	10mg redi-tabs	26,573,154	275,821
12	Risperdal	3mg tablet	26,108,769	89,198

continued on next page

Rank	Label Name	Dosage	Amount Paid	Number of Claims
13	Seroquel	200mg tablet	$25,238,376	65,423
14	Paxil	20mg tablet	25,108,143	237,178
15	Lipitor	20mg tablet	24,947,925	178,791
16	Neurontin	300mg capsule	24,241,802	171,142
17	Risperdal	2mg tablet	21,794,450	90,453
18	Glucophage	500mg tablet	21,666,113	308,837
19	Combivir	tablet	19,769,011	34,132
20	Clozaril	100mg tablet	19,181,231	120,750
21	Depakote	500mg tablet	17,493,361	127,674
22	Zocor	20mg tablet	17,138,471	108,609
23	Zyprexa	7.5mg tablet	17,059,915	54,559
24	Seroquel	100mg tablet	16,668,936	80,782
25	Zyprexa	2.5mg tablet	16,078,851	80,583
26	Risperdal	1mg tablet	15,428,683	102,705
27	Levaquin	500mg tablet	15,223,225	194,122
28	Norvasc	10mg tablet	14,276,810	166,038
29	Risperdal	4mg tablet	14,262,611	42,925
30	Pravachol	20mg tablet	14,158,336	137,542
31	Viracept	250mg tablet	13,816,624	21,798
32	Ultram	50mg tablet	13,682,825	194,144
33	Aciphex	20mg tablet	13,573,969	93,848
34	Epivir	150mg tablet	13,435,500	49,807
35	Ambien	10mg tablet	13,119,587	172,823
36	Prevacid	15mg capsule	13,117,609	77,466
37	Pravachol	40mg tablet	13,093,475	77,441
38	Norvasc	5mg tablet	11,975,952	194,979
39	Prilosec	20mg capsule	11,951,321	67,235
40	Celebrex	100mg capsule	11,775,988	131,479
41	Kaletra	softgel capsule	11,277,675	19,324
42	Oxycontin	80mg tablet	10,203,594	8,740
43	Zerit	40mg capsule	9,840,063	38,708
44	Azmacort	inhaler	9,555,667	122,859
45	Paxil	10mg tablet	9,455,701	103,549
46	Procrit	40000u/ml vial	9,393,707	4,504
47	Nasonex	50mcg nasal spray	9,380,663	153,107
48	Plavix	75mg tablet	9,255,864	76,122
49	Cipro	500mg tablet	9,229,067	106,987
50	Glucophage	850mg tablet	9,215,911	80,682
51	Sustiva	200mg capsule	9,079,404	24,286
52	Ziagen	300mg tablet	8,946,288	24,801

Rank	Label Name	Dosage	Amount Paid	Number of Claims
53	Xalatan	0.005% eye drops	$8,887,560	157,540
54	Glucophage	1000mg tablet	8,736,306	70,086
55	Zocor	40mg tablet	8,690,261	55,835
56	Enbrel	25mg kit	8,658,094	7,938
57	Albuterol	90mcg inhaler	8,643,683	291,513
58	Depakote	250mg tablet	8,629,288	99,817
59	Lipitor	40mg tablet	8,499,702	50,373
60	Actos	45mg tablet	8,393,796	38,085
61	Avandia	8mg tablet	8,342,475	39,946
62	Trizivir	tablet	8,340,929	8,920
63	Actos	30mg tablet	8,339,884	42,432
64	Clozapine	100mg tablet	8,134,983	50,778
65	Buspar	15mg tablet	8,002,021	46,229
66	Buspar	10mg tablet	7,888,224	56,711
67	Avandia	4mg tablet	7,865,469	56,078
68	Megace	40mg/ml oral suspension	7,865,234	44,215
69	Oxycontin	40mg tablet	7,731,935	16,394
70	Humulin	70/30 vial	7,729,012	103,076
71	Zyrtec	10mg tablet	7,687,557	127,251
72	Serevent	21mcg inhaler	7,485,310	84,277
73	Pepcid	20mg tablet	7,438,313	85,598
74	Wellbutrin SR	150mg tablet	7,381,772	75,026
75	Lotensin	20mg tablet	7,288,916	141,076
76	Depakote	500mg tablet	7,267,489	58,618
77	Neurontin	400mg capsule	7,160,097	38,548
78	Atrovent	inhaler	7,114,637	119,837
79	Norvasc	5mg tablet	7,010,114	125,420
80	Effexor XR	75mg capsule	6,982,781	59,848
81	Fosamax	10mg tablet	6,840,268	80,377
82	Seroquel	25mg tablet	6,736,253	56,910
83	Prozac	10mg pulvule	6,714,070	56,214
84	Singulair	10mg tablet	6,706,839	71,514
85	Patanol	0.1% eye drops	6,698,677	92,487
86	Humulin N	100u/ml vial	6,602,540	103,526
87	Lotensin	10mg tablet	6,583,676	141,048
88	Allegra	60mg capsule	6,554,545	100,473
89	Risperdal	0.5mg tablet	6,540,086	48,399
90	Procrit	10000u/ml vial	6,513,860	7,583

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Rank	Label Name	Dosage	Amount Paid	Number of Claims
91	Celexa	20mg tablet	$6,417,984	77,119
92	Lotrel	5/20mg capsule	6,218,965	58,997
93	Risperdal	3mg tablet	6,055,074	20,865
94	Ambien	5mg tablet	5,934,353	96,834
95	Fosamax	10mg tablet	5,745,467	69,276
96	Risperdal	2mg tablet	5,656,238	25,025
97	Risperdal	1mg tablet	5,640,324	42,753
98	Diflucan	200mg tablet	5,605,239	14,275
99	Zoloft	50mg tablet	5,552,053	65,292
100	Celebrex	200mg capsule	5,511,940	41,443
101	Diovan	80mg capsule	5,424,253	76,718
102	Zoloft	100mg tablet	5,414,622	56,862
103	Paxil	30mg tablet	5,299,256	52,819
104	Isosorbide MN	60mg tablet	5,270,702	99,839
105	Aricept	5mg tablet	5,268,470	32,708
106	Renagel	800mg tablet	5,070,862	15,352
107	Miacalcin	200u nasal spray	4,965,922	76,265
108	Paxil	40mg tablet	4,921,238	48,745
109	Remeron	15mg tablet	4,772,733	53,182
110	Oxycontin	20mg tablet	4,762,942	20,704
111	Biaxin	500mg tablet	4,741,711	56,349
112	Remeron	30mg tablet	4,711,109	47,119
113	Flomax	0.4mg capsule	4,637,721	60,473
114	Duragesic	100mcg/hr patch	4,600,638	8,142
115	Rebetron	1200 therapy pak	4,569,080	3,890
116	Cozaar	50mg tablet	4,554,126	68,412
117	Evista	60mg tablet	4,551,837	67,698
118	Topamax	100mg tablet	4,522,111	15,566
119	Glyburide	5mg tablet	4,521,830	70,731
120	Neurontin	600mg tablet	4,499,438	21,696
121	Avonex admin pack	30mcg vial	4,448,504	4,883
122	Norvir	100mg softgel capsule	4,446,108	18,230
123	Acetaminophen/codeine	3 tablet	4,422,115	478,604
124	Crixivan	400mg capsule	4,235,418	12,266
125	Detrol	2mg tablet	4,226,376	56,384
126	Vioxx	12.5mg tablet	4,200,462	44,397
127	Avandia	8mg tablet	4,156,623	19,171
128	Premarin	0.625mg tablet	4,152,885	99,585
129	Subdue liquid		4,135,688	1,337
130	Prempro	0.625/2.5mg tablet	4,131,507	59,093

Rank	Label Name	Dosage	Amount Paid	Number of Claims
131	Lotrel	5/10mg capsule	$4,079,673	44,524
132	Epogen	10000u/ml vial	4,074,110	3,727
133	Accolate	20mg tablet	4,057,465	53,140
134	Prevacid	30mg capsule	4,047,996	29,301
135	Neupogen	300mcg/ml vial	4,020,823	2,678
136	Novolin	70/30 100u/ml vial	4,013,639	65,696
137	Prograf	1mg capsule	4,000,622	7,337
138	Agenerase	150mg capsule	3,954,113	8,995
139	Paxil	20mg tablet	3,917,720	40,070
140	Glucophage	500mg tablet	3,852,210	57,110
141	Lamictal	100mg tablet	3,826,463	16,347
142	Avandia	4mg tablet	3,789,337	28,789
143	Procrit	20000u/ml vial	3,744,114	4,358
144	Synagis	100mg vial	3,730,178	2,780
145	Viramune	200mg tablet	3,677,116	12,485
146	Plavix	75mg tablet	3,614,560	28,602
147	Videx	400mg capsule	3,590,152	12,745
148	Effexor XR	150mg capsule	3,568,354	33,121
149	Atenolol	50mg tablet	3,556,017	131,355
150	Diovan	160mg capsule	3,507,842	44,731
151	Zestril	10mg tablet	3,474,589	71,097
152	Albuterol	90mcg inhaler	3,442,207	96,665
153	Combivent	inhaler	3,412,032	56,583
154	Nifedipine ER	60mg tab	3,404,021	29,772
155	Oxandrin	2.5mg tablet	3,386,130	4,468
156	Depakote	250mg tablet	3,367,288	45,127
157	Protonix	40mg tablet	3,347,351	34,859
158	Lamictal	25mg tablet	3,343,260	12,269
159	Ultram	50mg tablet	3,335,990	48,967
160	Amaryl	4mg tablet	3,335,241	60,505
161	Aricept	10mg tablet	3,322,844	22,680
162	Lotensin	40mg tablet	3,311,654	65,078
163	Neoral	100mg gelatin capsule	3,309,513	6,316
164	Risperdal	1mg/ml solution	3,251,338	16,441
165	Diovan HCT	160/12.5mg tablet	3,199,559	38,846
166	Ipratropium BR	0.02% solution	3,191,323	36,174
167	Cerezyme	400u vial	3,166,213	325
168	Neurontin	100mg capsule	3,152,385	61,535

continued on next page

Rank	Label Name	Dosage	Amount Paid	Number of Claims
169	Ditropan XL	5mg tablet	$3,141,461	28,799
170	Arthrotec	75 tablet	3,136,993	29,830
171	Fortovase	200mg softgel capsule	3,127,937	9,875
172	Zestril	20mg tablet	3,115,190	56,009
173	Zithromax	250mg z-pak tablet	3,031,303	81,303
174	Dilantin	100mg capsule	2,992,341	87,023
175	Prilosec	40mg capsule	2,985,575	13,016
176	Ortho Tri-cyclen	28 tablet	2,971,571	36,289
177	Famotidine	20mg tablet	2,937,418	33,978
178	Vanceril	inhaler	2,930,395	50,427
179	Risperdal	0.5mg tablet	2,923,940	23,848
180	Pepcid	20mg tablet	2,898,266	33,416
181	Casodex	50mg tablet	2,865,031	6,295
182	Nifedipine ER	30MG tablet	2,864,947	53,140
183	Actiq	1600mcg lozenge	2,859,461	716
184	Prozac	20mg pulvule	2,842,029	19,374
185	Aerobid	aerosol w/adapter	2,832,571	31,902
186	MS Contin	100mg tablet	2,832,010	2,790
187	Humulin R	100u/ml vial	2,828,244	53,461
188	Hyzaar	50-12.5 tablet	2,774,450	42,874
189	Actos	15mg tablet	2,766,989	21,631
190	Famotidine	20mg tablet	2,730,191	29,000
191	Rebetron	1000 therapy pak	2,730,165	2,531
192	Viramune	200mg tablet	2,693,773	9,007
193	Pediasure (vanilla)	—	2,657,705	10,385
194	Wellbutrin SR	100mg tablet	2,655,282	26,984
195	Altace	10mg capsule	2,652,407	32,502
196	Imitrex	50mg tablet	2,633,659	17,713
197	Catapres-TTS	3 patch	2,614,981	21,299
198	Serzone	100mg tablet	2,595,997	26,348
199	Singulair	10mg tablet	2,588,579	27,077
200	Diflucan	100mg tablet	2,577,877	17,812

Top 200 Drugs	**$1,855,759,950**	**14,458,459**
All Medi-Cal Drugs	**$2,881,386,693**	**42,277,462**
Top 200 as a Percentage of All Medi-Cal Drugs	**64.41%**	**34.20%**

State of California
Health and Human Services Agency

GRAY DAVIS
GOVERNOR

GRANTLAND JOHNSON
SECRETARY

Agency Departments & Boards:

Aging

Alcohol and Drug Programs

Child Support Services

Community Services and Development

Developmental Services

Emergency Medical Services Authority

Employment Development Department

Health Services

Health and Human Services Data Center

Managed Risk Medical Insurance

Mental Health

Rehabilitation

Social Services

Statewide Health Planning and Development

Workforce Investment

April 17, 2003

Ms. Elaine M. Howle*
State Auditor
Bureau of State Audits
555 Capitol Mall, Suite 300
Sacramento, CA 95814

Dear Ms. Howle:

Thank you for forwarding for review and comment the draft Bureau of State Audits' report entitled, "Its Efforts to Further Reduce Prescription Drug Costs for the Medical Assistance Program Have Been Hindered by Its Inability to Hire More Pharmacists and Its Lack of Aggressiveness in Pursuing Available Cost Saving Measures." Enclosed is the Department of Health Services' response to the review findings and recommendations.

The Davis Administration is committed to continuing to provide high-quality services to Medi-Cal beneficiaries while protecting taxpayer dollars. In fact, the draft report validates the Administration's many successes as a trustee of the Medi-Cal drug program, including that Medi-Cal has led the nation in obtaining prescription drugs at the lowest net cost (Chapter 2). With the insight provided by the draft report and the ongoing efforts by the Department of Health Services, I am certain that the Davis Administration will maintain California's Medi-Cal program as a national leader in the nation in managing drug cost.

If you require further information concerning the Department's activities in the Medi-Cal prescription drug program, please contact Assistant Secretary Peter Harbage at 654-3301.

Sincerely,

GRANTLAND JOHNSON

Enclosure

* California State Auditor's comments begin on page 103.

1600 Ninth Street • Room 460 • Sacramento, CA 95814 • Telephone (916) 654-3454 • Fax (916) 654-3343
Internet Address: www.chhs.ca.gov

Agency's comments provided as text only.

State of California—Health and Human Services Agency
Department of Health Services
714 P Street, Room 1253
Sacramento, California 95814

April 17, 2003

Ms. Elaine M. Howle
State Auditor
Bureau of State Audits
555 Capitol Mall, Suite 300
Sacramento, CA 95814

Dear Ms. Howle:

The Department of Health Services (Department) appreciates your review of Medi-Cal's drug rebate program and your sharing of the Bureau of State Audits' draft report entitled, *"Department of Health Services: Its Efforts to Further Reduce Prescription Drug Costs for the Medical Assistance Program Have Been Hindered by Its Inability to Hire More Pharmacists and Its Lack of Aggressiveness in Pursuing Available Cost Saving Measures."* Generally, the Department agrees with the report's recommendations. Attached, please find the Department's detailed response.

The Davis Administration is committed to continuing to provide high-quality services to Medi-Cal beneficiaries while protecting taxpayer dollars. Medical inflation has far outpaced the overall rate of inflation, and the cost of prescription drugs has been one of the leading reasons for this. As a result, many states have struggled to find ways to obtain critical prescription drugs in an affordable manner. Medi-Cal California has been a national leader in the nation in managing drug cost.

The draft report validates the Administration's many successes in the drug rebate program, including that Medi-Cal has led the nation in obtaining prescription drugs at the lowest net cost (Chapter 2). But, California can --and must-- do even more to reduce drug costs. By implementing both the Davis Administration's budget proposals from last year and the valuable recommendations in the draft report, the Medi-Cal program will continue to be the national leader. Medi-Cal's past success provides a strong foundation on which to move forward. These efforts are vital given the importance of these medications to Medi-Cal beneficiaries and the need to control state costs.

Medi-Cal's Successful History of Cost Effective Drug Purchasing

Medi-Cal has been recognized as one of, if not the most, cost effective Medicaid health care delivery systems in the nation. In fact, while Medi-Cal covers all of the 34 optional Medicaid benefits, it has one of the lowest per capita expenditures in the nation. According to reports by the federal government and the Kaiser Family Health Foundation, for federal fiscal year 2001, the average cost per Medicaid beneficiary was $5,475 per year. California's average cost was $4,607 per year, $868 below the average. The average cost in Texas was $5,343, New York $6,487, and Florida $4,857. New York, which pays $1,880 more per beneficiary than California, is only able to purchase 26 optional services at this high cost. The ability to provide such a wide range of services to Medi-Cal beneficiaries at a low cost is evidence of the Department's successful efforts to purchase a range of services at lower prices, especially hospital services and prescription drugs, strong utilization control programs, an effective claims processing system, and a strong anti-fraud program.

With reference to drugs specifically, your report indicates that the Medi-Cal program receives the lowest drug prices of any of the 17 states you surveyed and lower drug prices than the AIDS Drug Assistance Program and California's Department of General Services. The Medi-Cal program now effectively operates the program that other states now strive to implement. In fact, during fiscal year 2002/03, the Medi-Cal program will reduce its overall budget by obtaining $312 million of additional rebates beyond what the federal Medicaid program obtains. Half of these additional rebates go to the State general fund. While drug specific data is held confidential by state and Federal law, California receives substantial drug rebates –with discounts ranging anywhere from 30% to over 70%.

Strong Utilization Controls Protect Taxpayer Dollars, Provide Quality Care

In addition to the most effective drug rebate program in the nation, the Medi-Cal program has strong utilization controls on drug expenditures, which include:

- Six Prescription Limit – Pursuant to state law, Medi-Cal limits beneficiaries to six-prescriptions per month without State prior authorization of a prescription. This limit reduces fraudulent, and duplicative prescription dispensing. Beneficiaries can exceed the limit through prior authorization.
- Code I limits – Code I limits are various utilization control parameters established on the use of a prescription drug, that are used alone or in combination. These limitations include restrictions quantity, gender, age, frequency of billing, duration of therapy, days supply, and diagnostic or other requirements.
- Drug Utilization Review (DUR), which adds another layer of utilization control. Medi-Cal's computerized billing program (through a process known as "edits") alert the pharmacist to potential therapeutic or over-utilization problems.

The Davis Administration is Committed to Ongoing Program Improvement

Even with this past success, the Administration understands that prescription drug services are an area in which the State could increase program savings while protecting the health of Medi-Cal beneficiaries. In the fiscal year (FY) 2002-2003 Governor's Budget, the Department proposed a number of programmatic changes in an attempt to further reduce costs in the pharmaceutical program while protecting patient care. The Legislature adopted these proposals, which included funding for additional staff to develop, implement, and monitor these changes.

The Department has already implemented many of the proposals contained in the budget as well as additional changes in the Medi-Cal drug program. This includes:

- Reductions in the reimbursement rates for pharmacy providers.
- Increased supplemental drug rebates for some of the most expensive classes of drugs (including antipsychotics and non-steroidal anti-inflammatory drugs).
- Increased utilization controls for the drugs shown to have a high potential for abuse or misuse (Oxandralone, Serostim, and Fuzeon).
- Implementation of a new Rebate Accounting Information System (RAIS) in 2002. RAIS is a computerized invoicing, accounts receivable and data storage system that gives Medi-Cal better control of the rebate program and allow for additional monitoring of drug misuse. The Department has recently hired four staff to work on the resolution of outstanding uncollected drug rebates. These rebate staff have just completed a resolution with a manufacturer for uncollected rebates dating back to 1991.
- Implementation of aggressive zero tolerance anti-fraud activities that identify provider fraud or abuse, including a moratorium on the enrollment of new non-chain pharmacies and the re-enrollment of existing non-chain pharmacies due to fraud problems encountered within this provider type.

For the Administration to reach its goal of having control over Medi-Cal drug prices, more work remains to be done. The Department is working on the following program changes to further increase state savings (some of which are recommended in the report). Steps include:

- Expanded use of drug contracting to obtain additional rebates on Medi-Cal drugs that in the past have not had supplemental rebates paid on them.
- More therapeutic category reviews (TCR). TCRs have the State, compare drugs within a class of drugs against each other and obtain the best drugs and prices in that class. For example, the Department recently completed a TCR on Proton Pump Inhibitors, a class of drugs for the treatment esophageal reflux and ulcers. This TCR reduced approximately $120 million of annual Medi-Cal expenditures in this class of drugs by more than $20 million while adding all drugs in this category to the Medi-Cal list of contract drugs. As recommended in your audit, this successful program can be expanded to additional categories of drugs.

- Additional utilization controls and disease management controls that would produce savings while still providing quality services to Medi-Cal beneficiaries.
- Contracting for generic drugs and reducing payments to generic drugs by establishing a new Maximum Allowable Ingredient Cost for these drugs.
- Exploration of additional disease management in the Medi-Cal program, including funding and implementation of a drug disease management program, development of step therapy protocols that are designed to require providers to use more cost effective therapies before moving to newer and potentially higher cost therapies, and expansion of the Department's post-service drug utilization review program.

Further evidence of the Department's commitment to controlling costs is the significant progress of late towards obtaining qualified pharmacy staff. As noted in the audit, the Department has difficulty in obtaining the staff necessary to implement cost-saving measures. Program improvements include the following:

- Most critical, the Department of Personnel Administration recently approved a request to provide a $2,000 per month recruitment and retention payment to senior level pharmacists, which will enable the Department to recruit pharmacists in a highly competitive job market. With the additional staff, the Department can implement various cost saving measures.
- Pursuant to the budget trailer bill adopted last year, the Department is contracting with our fiscal intermediary, EDS, to hire additional pharmaceutical staff to assist the Department in its efforts. With the ability to hire staff at the salary established by the State with the added recruitment and retention payment, EDS has already begun hiring and should be able to rapidly meet its staffing capacity.
- The Department is reclassifying pharmacy positions to other classifications to do work that does not require a pharmacist. For example, the Department has recently hired a nutritionist to work on savings reductions for nutritional products covered by Medi-Cal.

The Department is committed to the goal of building upon our successful Medi-Cal drug program to continue to lead the nation in obtaining vital drugs for Medi-Cal beneficiaries at the lowest possible cost to the State. The Department is grateful for the assistance rendered by your report. If you require further information concerning the Department's Medi-Cal drug program, please contact Stan Rosenstein, Deputy Director for Medical Care Services, at (916) 654-0391.

Sincerely,

(Signed by: Diana M. Bontá, R.N., Dr. P.H.)

Diana M. Bontá, R.N., Dr. P.H.
Director

Enclosure

CALIFORNIA DEPARTMENT OF HEALTH SERVICES (DHS)
RESPONSE TO BUREAU OF STATE AUDITS REPORT:

"Department of Health Services: Its Efforts to Further Reduce Prescription Drug Costs for the Medical Assistance Program Have Been Hindered by Its Inability to Hire More Pharmacists and Its Lack of Aggressiveness in Pursuing Available Cost Saving Measures."

The following are responses to recommendations beginning on Page 50 of the draft report.

- *Broaden its recruitment efforts beyond the counties of Sacramento and San Joaquin to all of California, expand beyond California, and advertise in pharmacy periodicals.*

The Department agrees with the recommendation to broaden its recruitment efforts statewide and use pharmacy periodical advertising, if necessary. In fact, in a recent pharmacy recruitment, EDS sent flyers to every pharmacist in the state as well as ran advertisements in a number of pharmacy publications. With the Department of Personnel Administration's approval of a new recruitment and retention payment for Department pharmacists, the Department can now be successful in its recruitment efforts, which will also be conducted statewide. We do not believe recruitment outside of California will likely significantly increase the number of viable candidates as a California pharmacist license is required and most non-California pharmacists are not registered in California. To obtain a license in California, the pharmacist would have to pass the California Board of Pharmacy licensing exam.

- *Perform an analysis to identify the number of staff it needs to meet its federal and state obligations. The analysis should include a reevaluation of the duties assigned to the pharmacists' classifications to identify those that could be performed by nonpharmacist classifications. Further, it should quantify the effect that the use of nonpharmacist staff has on its federal reimbursements for personnel costs.*

The Department agrees with the recommendation to analyze the number and mix of staff needed to meet federal and state mandates. Currently, the Department is attempting to identify duties that it can re-direct to non-pharmacist staff. The Department has recently done this by hiring a nutritionist to do required work on the nutritional formulae benefit. The Department has been able to identify some duties, such as the development of fiscal calculations related to drug rebates, database development and maintenance, and responding to surveys (such as that used in this audit) as duties that an analyst can perform under the general direction of a pharmacist. Therefore, the Department will reclassify a vacant pharmacist position into an analyst position. The Department will also analyze the overall fiscal impact of moving from 75 percent federal funding for pharmacists to 50 percent federal funding for non-pharmacist staff.

- *Research its ability to use the services of an intern.*

While pharmacy interns could assist Department staff in lower level work on the Medi-Cal drug program, interns cannot provide the expertise to address the complex financial and drug coverage issues that the Department faces. Determining which drugs are of the best benefit to Medi-Cal beneficiaries at the best price requires pharmacists with extensive experience and expertise. The Department only uses experienced pharmacists in this process. The Department cannot entrust these benefit decisions to graduate interns. But, interns could learn a lot about drug coverage and assist the Department in routine work.

Therefore, the Department has already reinitiated its discussions with the University of the Pacific and will be seeking a proposal from the University regarding the structure of the internship. Additionally, Department staff have been approached by representatives of other universities. The Department continues to work on this concept.

- *Revise its procedures for performing new-drug reviews to include a timeline for completing reviews and specific steps on how staff should address manufacturers' nonresponsiveness.*

The Department agrees with the recommendation that it revise the procedures for reviewing new petitions to contain additional guidance to staff and manufacturers on the ramifications of prolonged delays in negotiating a supplemental rebate contract. However, the guidelines for action must allow the Department and manufacturers leeway of action. Each contract negotiation is unique and each manufacturer has varying levels of expertise within its contracting groups; therefore, establishing highly specific procedures that force the Department into taking inappropriate action is ill advised. The Department will establish new procedures that clearly delineate the response time for a manufacturer.

In the past, the Department has placed a priority on processing drugs, which the FDA designated as priority drugs. According to the FDA, priority drugs provide a therapeutic gain over other available drugs. These priority drugs were processed in specific timeframes, which were sometimes exceeded if the drug manufacturer did not provide needed information. The Department did not place a priority on adding new drugs to the Medi-Cal program that were found by the FDA to not provide a therapeutic gain. The Department's procedures will continue to emphasize that first priority must go to new drugs found by the FDA to have a therapeutic gain.

- *Conduct the therapeutic category reviews specified in its budget proposal for fiscal year 2002-03. Further, it should develop and adhere to an annual schedule for future reviews.*

The Department agrees that it should take all necessary steps to reduce drug costs. As was discussed with the auditors, the intent of the Department was to either renegotiate the contracts for antipsychotic drugs and non-steroidal anti-inflammatory drugs (NSAID) or perform a TCR. Statute mandates that a TCR take 150 days to complete negotiations, therefore, implementation of new contracts due to the TCR would be delayed at least that long. The Department thought it prudent to pursue renegotiated contracts as soon as possible in order to obtain enhanced rebates immediately.

As was pointed out to the auditors, the intent of the Department in the antipsychotic drugs and NSAID categories was to either renegotiate the contracts for these drugs or perform a TCR so that the State could obtain program savings. In fact, when the Department presented the antipsychotic and NSAID proposal to the Legislature, the TCR was presented as the failsafe tool that would be used only if renegotiations did not generate the required savings. The Department's approach already has achieved $19.5 million GF savings on these classes.

The Department is committed to considering TCRs for additional classes of drugs that it believes would result in cost savings.

- *Negotiate state supplemental rebate contracts with manufacturers of generic drugs, as state law requires.*

The Department agrees with the recommendation that it should attempt to negotiate contracts for multiple-source drugs. Contracting for multi-source drugs was included as a proposal in the Governor's 2002/03 budget and was approved the Legislature. The Department, as reported in the audit, obtained pharmacist positions in the 2002-03 budget to perform multiple-source drug contracting. However, the Department's ability to contract for multiple-source drugs, as the audit points out, has been hampered by a lack of trained pharmacist staff. With the Department of Personnel Administration's approval of the Department's request for a recruitment and retention payment for pharmacists, we believe that we will be able to hire the necessary staff to implement this new contracting program.

Also noted in this audit, often the Department can realize a lower overall net cost by negotiating a supplemental rebate with the manufacturer of the innovator (brand name) multisource drug, instead of the non-innovator multisource (generic) drug. However, as discussed with the auditors in interviews, the savings potential of multisource contracting is reduced by the establishment of upper payment limits such as Maximum Allowable Ingredient Cost (MAIC) or a Federal Allowable Cost (FAC). These payment limits reduce the amount of reimbursement to the pharmacy and eliminate the ability of the pharmacy to dispense the innovator drug. The establishment of upper payment limits shifts the burden of cost reduction from the drug manufacturer to the pharmacy provider. The Department will strive to obtain the best mix of savings in the most rapid way possible using both of these tools.[1]

[1] The law is ambiguous as to whether the Department is required to contract with multi-source manufacturers. The subdivision of law the auditor is basing this mandate on is in Welfare and Institutions (W&I) Code section 14105.3(d), which states:

> "The department shall contract with manufacturers of single-source drugs on a negotiated basis, and with manufacturers of multisource drugs on a bid or negotiated basis."

The Department interprets this to mean that the method of contracting allowed for multi-source drugs is "on" either a bid or negotiation basis. The Department arrives at the conclusion that contracting for generic drugs is optional based on a subsequent section of statute 14105.33(a) which states:

> "The department may enter into contracts with manufacturers of single-source and multiple-source drugs, on a bid or nonbid basis, for drugs from each major therapeutic category, and shall maintain a list of those drugs for which contracts have been executed."

This section is clearly permissive ("may") and does not mandate the contracting "for" multisource drugs.

- *Obtain written assurance from drug wholesalers that they will provide their wholesale selling prices. If the wholesalers are not willing to provide this information, Health Services should seek legislation to compel them to do so.*

The Department's fiscal intermediary, as part of the implementation plan, will be obtaining written agreements with drug wholesalers to supply the needed information. The Department continues to believe that the wholesalers will be cooperative with this effort. However, if the Department encounters barriers to obtaining the needed information, it will seek authority to legally compel the drug wholesalers to provide the needed information.

- *Perform an analysis to support its proposal to create a preferred prior authorization list. The analysis should include an evaluation of the impact this proposal has on its workload and adequate documentation to support its estimated savings.*

As part of this preferred prior authorization budget proposal, the Department requested an additional pharmacist to perform the drug contract negotiations that would be necessary for drugs that the Department had previously reviewed for addition to the drug list. The Department also believes that some of the workload can and should be absorbed into the current petition review process for new drugs denied addition to the drug list.

- *Seek federal approval from the center to prohibit manufacturers from making retroactive adjustments to federal rebates owed as a result of revisions to their AMP or best price.*

The Department will notify the Centers for Medicare and Medicaid Services (CMS) of the state statute that prohibits a reduction in rebate due to the Medi-Cal program due to manufacturer adjustments in AMP or best price. We do not believe that federal approval is necessary. Further, we believe that this is an issue that CMS should address on a national level as it affects the budgets of every state in the nation.

- *Evaluate periodically the number of staff needed to resolve disputed rebates within the 90-day deadline established by state law.*

The Department agrees with the recommendation that it should assess the progress of disputes periodically and if needed, reassign staff or take other steps necessary to complete required tasks.. The Department believes that it should resolve these disputes as quickly as possible. To do this the Department has recently implemented the new Rebate Accounting Information System (RAIS), which has significantly improved our rebate billing and collection process. Further the Department has expanded the dispute resolution staff. The Department anticipates that it will make significant progress toward resolving disputes within the 90-day timeframe.[2] The Department also anticipates resolving the backlog of disputes by the end of fiscal year 2004-05.

- *Follow the center's guidance and ensure that the ADAP and Medi-Cal staff coordinate their activities for obtaining federal rebates by using the RAIS for invoicing its manufacturers.*

The Department will ensure that the ADAP and Medi-Cal programs work together in the most efficient way to improve the invoicing and collection of rebates, either through the use of the RAIS or other process, for the ADAP program. The Department must ensure that the use of the RAIS for ADAP rebates does not jeopardize any supplemental rebate agreements that ADAP or Medi-Cal have with drug manufacturers.

The following are responses to recommendations beginning on Page 69 of the draft report.

- *Establish policies and procedures to ensure that it follows up on and renegotiates supplemental contracts before their expiration dates.*

The Department agrees with the recommendation that it should establish contract renegotiation policies and procedures and will do so. The Department is currently making every effort to renew contracts at the current contract terms. Renewing the contracts at their current level will maintain the supplemental rebates. Once the Department is able to fully staff the pharmaceutical unit, extensive renegotiation of contracts, which might result in additional rebates, can occur.

[2] It is worth clarifying that the law does not require the dispute be resolved within 90-days of notification, but states the Legislatures intent that the Department work with manufactures to resolve disputes as quickly as possible. W&I Code section 14105.33(u) which states:

> "It is the intent of the Legislature in enacting subdivisions (k) to (t), inclusive, that the department and manufacturers shall cooperate and make every effort to resolve rebate payment disputes within 90 days of notification by the manufacturer to the department of a dispute in the calculation of rebate payments."

- *If it is unable to complete negotiations for state supplemental rebates before the contract expiration date, it should immediately instruct EDS to remove the restriction on brand name drugs to allow pharmacies to dispense less expensive generic drugs without requiring TAR approval.*

The Department agrees that if it is unable to renegotiate a state supplemental rebate on a labeler-restricted drug, it should analyze the net cost and remove the restriction to allow the use of generic drugs when there is a net savings to the state. The Department would do this only if the net cost, with federal rebate alone, is less than that of the brand name drugs. The Department has identified the monitoring of these net costs as a duty that can be performed by an analyst.

- *Ensure that it secures written assurance for all agreements made during negotiations, and includes this information in the terms and conditions of the contract.*

The Department agrees with this recommendation, and will ensure that all terms and conditions are delineated within its supplemental rebate contracts with manufacturers.

- *Require the ADAP to capitalize on the expertise of Medi-Cal's contract services unit and work with it to negotiate supplemental rebates with the manufacturers. If it chooses not to work with Medi-Cal, the ADAP needs to ensure that it requires manufacturers to enter into rebate agreements.*

The Medi-Cal and ADAP programs will seek each other's expertise, to the extent possible, regarding drug contracting. Again, the Department must ensure that the sharing of expertise between the programs does not jeopardize any supplemental rebate agreements that ADAP or Medi-Cal have with drug manufacturers.

- *Evaluate the pros and cons of deducting co-payments from its reimbursement rate and having pharmacies collect these payments from beneficiaries. The evaluation should include, at a minimum, an analysis of costs, benefits, and pharmacies' collection rates.*

Currently, with certain federal required exceptions, the Medi-Cal program has a $1 copay on prescription drugs provided to adults. Federal Medicaid law prevents Medi-Cal from requiring a copay on drugs provided to children and on certain classes of drugs, and it prohibits a provider from denying treatment to a Medi-Cal beneficiary due to that person's inability to pay for this copay. Currently, pharmacies can request a one-dollar copay from beneficiaries per prescription dispensed in addition to the Medi-Cal reimbursement. According to the California Pharmacist Association (CPhA), most pharmacies do not even attempt to collect this dollar and beneficiaries typically tell the pharmacy that they cannot afford the copayment. To the extent that the pharmacy is not able to collect the copay, reducing the copay from the providers' rate is a $1 rate reduction. Because federal law

prevents pharmacies from enforcing the collection of the copay, increasing the copayment effectively makes this proposal a cut in provider reimbursement.

The Governor's Budget for 2002-03 proposed the copay methodology described in the audit as being done by one state and this proposal was rejected by the Legislature. Instead the Legislature adopted another proposal in the Governor's May Revise and reduced payments to pharmacies in the Medi-Cal program by changing how drug ingredient costs are priced and restoring a full 50 cent reduction from every pharmacy claim. These changes were more of a broad-based cut that applied to all pharmacy services without the limits prescribed for co-payments.

The Governor's Budget for 2003-04 proposes an additional 15% rate cut for pharmacies, which is again a broad-based cut that generates more savings to the State.

An analysis of the costs, benefits, and pharmacy collection rates would require the Department to conduct a survey of pharmacies. A contractor would likely conduct such a survey, which would require a budget augmentation to pay for the contract.

The following are responses to recommendations beginning on Page 94 of the draft report.

- *Measure the effect that the use of duration therapy hard edit has on its workload. If feasible consider reestablishment of this edit for additional drugs.*

The Department agrees with this recommendation. The Department identified the savings potential of expanded duration of therapy and frequency of billing audits in the 2002-03 budget. The Department plans to use recently hired contract pharmacists to begin comparing Medi-Cal drug utilization patterns with standards of practice to determine the appropriateness of various audits.

- *Evaluate its ability to adapt its prospective DUR program by using other types of hard edits, including step therapy protocols for specific drugs or classes of drugs. The evaluation should include an analysis of the costs and benefits associated with these approaches.*

The Department agrees with the recommendation that it analyze the costs and benefits of using step therapy protocols. This type of analysis would require an augmentation to the fiscal intermediary's DUR support staff to conduct this review. Development and implementation of step protocols will require an augmentation to Department staff. The enforcement of step protocols would have to be through the claims processing system and the Treatment Authorization Request (TAR) process. This clearly would lead to an increase in the volume of TAR requests and require and augmentation of pharmacist staff to review those requests.

Any additional protocols or "hard edits" must be based in sound therapeutic principles and ensure that beneficiary access to medical necessary treatment is not prohibited. The Department must assess the overall impact on the entire Medi-Cal program, not just the drug program.

- *Reevaluate the cost-effectiveness of using Dear Dr. Letters to educate physicians and pharmacist.*

The Department agrees with this recommendation. Department staff will work with the DUR Board to develop a "Dear Dr." letter campaign for a small number of issues. The Department will then assess the effect the letters have on the prescribing patterns.

- *Work with the DUR board to develop a formal plan for its education activities, including the resources needed to implement the plan. Further, Health Services should update the plan annually.*

The Department agrees with the recommendation to work with the DUR to develop a formal education plan. The Department has the desire to expand its education of both providers and beneficiaries; however, the implementation and ongoing support of educational programs are labor intensive. Therefore, the increase in workload would require augmentation of Department and/or fiscal intermediary staff.

- *If, in the future, it determines that it lacks adequate resources to perform its retrospective DUR and education activities, it should evaluate the cost effectiveness of outsourcing some of these functions.*

The Department agrees with this recommendation. As a note, the Department currently outsources most of its retrospective DUR work to the Medi-Cal fiscal intermediary who performs much of the technical support for the DUR program.

- *Consider seeking funds to continue its collaboration with the CPhA and USC for the proposed pharmacist-coordinated disease management pilot projects. Then evaluate the results of the pilot projects and if feasible, implement the model on a more widespread basis.*

The Department has been in close contact with CPhA regarding the pharmacist-based disease management programs. According to CPhA staff, they have recently received significant monetary commitments from drug manufacturers and the CPhA Educational Foundation to fund this project. CPhA has also identified an active, local disease management program to serve as a model for the study.

The intent of the pilot study is to prove the feasibility and cost effectiveness of a pharmacist-based disease management program. The Department is exploring whether obtaining additional State funding for this pilot would be cost effective.

- *Conduct a study to identify the effect of discontinuing all or a portion of the optional drug therapeutic classifications from its benefits on Medi-Cal beneficiaries and Medi-Cal's drug costs. If it determines it is cost effective to do so, discontinue some or all of the optional drug classifications.*

Before dropping these optional drug classifications as benefits in the Medi-Cal program, consideration must be given to the health care consequences and costs in other parts of the Medi-Cal program that could occur with the removal of these drugs. These categories contain some medically necessary drugs that can prevent incidence of serious disease, improve the health of beneficiaries and reduce spending for expensive health care services. While many of these drugs already have strong utilization controls, it may be more appropriate to establish additional utilization controls on these drugs rather than eliminate them. For example, the Department can explore establishing a utilization control that would limit the use of antihistamines to people with asthma or the use of weight loss drugs to individuals diagnosed with morbid obesity.

Elimination of this optional category could have significant impacts on the health of Medi-Cal patients. For example, if Medi-Cal were to discontinue over-the-counter drugs as benefits, most insulin products would no longer be available to beneficiaries.

The drugs that would be eliminated include:

- *Smoking cessation drugs, which are highly cost effective and allow Medi-Cal beneficiaries the ability to stop smoking, which is a major health benefit.*
- *Drugs for the symptomatic relief of cough and colds includes antihistamines, whose use by people with asthma prevents unnecessary emergency care.*
- *Certain mental health drugs, which are critical for the treatment of mental illness.*
- *Weight loss drugs, whose use by obese patients, aid in reducing the risk of heart disease and other costly complications of obesity.*
- *Drugs used for weight gain by increasing the appetite in individuals suffering from debilitating illnesses such as cancer and AIDS.*

Review of the figures that appear in Appendix A

- *Table A.1 presents the 200 drugs that represented the largest share of Health Service' drug expenditures (top 200 drugs for the period of January 1 through December 31, 2001. The top 200 drugs represent more than 60 percent of Health Services' total drug costs for calendar year 2001. Health Services provided us a data file that contained summary of the total amount Health Services reimbursed pharmacies for each drug listed by National Drug Code for calendar year 2001.*

The Department would like to emphasize that this table represents the amount the Department reimbursed pharmacy providers for providing the listed drugs to Medi-Cal beneficiaries. Missing from this table are the substantial rebates, discounts ranging anywhere from 30% to 70%, that significantly reduce these drug costs (drug specific rebate data is held confidential by state and Federal law). Given these substantial discounts, we recommend that BSA make this point clear within Appendix A.

COMMENTS

California State Auditor's Comments on the Response From the Department of Health Services

To provide clarity and perspective, we are commenting on the response by the Department of Health Services (Health Services) to our audit report. The numbers below correspond to the numbers placed in the margins of Health Services' response.

1. Health Services is mischaracterizing our report. Although we found that Health Services' net costs for drugs available through the Medical Assistance Program (Medi-Cal) were less than the net costs of drugs available through the AIDS Drug Assistance Program and those purchased by the Department of General Services (General Services), as we state on page 13 we were unable to compare California's net costs of drugs with other state's net drug costs. Further, we point out on page 52 that prior to December 1, 2002, California's pharmacy reimbursement rate was higher than all but one of the 17 states responding to our survey. However, we also state that if Health Services has a contract with a manufacturer for a supplemental rebate, it is possible that the net cost for that drug would be lower than it would be in other states. Thus, Health Services' statement that our report validates that Medi-Cal has led the nation in obtaining prescription dugs at the lowest net cost is incorrect.

2. Although we are pleased to learn that Health Services is working on these changes to its program, we are disappointed that it did not indicate the progress it has made to date. When we completed our fieldwork, Health Services had made little or no progress and had obstacles to overcome before it could do so. For example, it was not conducting any therapeutic category reviews (TCRs), and had not completed one since 2001. In fact, as we state on page 25, Health Services told us it lacked the staff to complete these labor-intensive reviews.

   Similarly, we have questions regarding the progress Health Services has made in contracting for generic drugs and establishing a new maximum allowable ingredient cost (MAIC) for these drugs. As we note on page 28, Health Services told us that its ability to negotiate rebates with manufacturers of generic drugs was hindered

by its inability to hire pharmacists and by the manufacturers' reluctance to negotiate lower prices for such drugs. Finally, on pages 29 and 30 of our report we enumerate several obstacles it must overcome before implementing a new MAIC.

- Our primary concern is that Health Services broaden its recruitment efforts so that it can meet its federal and state obligations. If Health Services finds that it is unable to hire pharmacists from within the State, we believe that expanding its recruitment efforts outside of the State is a viable option. In doing so, we would expect Health Services to demonstrate that its efforts within the State were unsuccessful and to seek the appropriate approvals. Finally, to clarify, we have modified our recommendation on page 38 as follows: Broaden its recruitment efforts beyond the counties of Sacramento and San Joaquin to all of California and advertise in pharmacy periodicals. **If necessary,** it should **seek the appropriate approvals** to expand its recruitment efforts beyond California.

- Health Services is incorrect in stating that it has achieved $19.5 million in savings to the State's General Fund. Rather, this amount is an estimate prepared by Health Services of the savings it anticipates for fiscal year 2002–03 as a result of renegotiating these contracts. To prepare its estimate, Health Services first assumed that the utilization of these drugs for prior quarters is representative of fiscal year 2002–03 and it also used an estimated per unit rebate amount in its calculation because manufacturers do not provide this data until after the completion of a quarter. Further, as indicated on page 26, Health Services recognizes that TCRs would generate a greater level of cost savings than renegotiating the supplemental rebate contracts of a few drugs. Thus, it is missing opportunities to generate additional savings for the State.

- Health Services is correct in stating that the establishment of a federal upper limit (FUL) by the federal Centers of Medicare and Medicaid Services (center) reduces its savings potential for generic drugs. However, Health Services is able to negotiate supplemental rebates for those generic drugs that do not have an FUL. For example, as we discuss on page 51, the Department of General Services was able to purchase nine generic drugs at a lower net cost than Health Services because Health Services did not have supplemental rebate agreements with the manufacturers.

- To provide clarification, we have modified page 28 of our report to state the following: Health Services has not routinely established contracts with manufacturers of generic drugs despite having clear authority to do so. In fact, the Legislature has declared its intent that the list of contract drugs contain a mix of brand name and generic drugs. Moreover, Health Services has adopted regulations establishing the mechanism through which it enters contracts for generic drugs in order to obtain refunds, rebates, guaranteed prices, or other forms of preferential prices. We also modified the related recommendation on page 39 to state the following: Negotiate state supplemental rebate contracts with manufacturers of generic drugs, as the Legislature intended. Finally, throughout the report we changed the word "required" to "authorized" when discussing Health Services' legal responsibility for entering into these contracts.

- Health Services' belief that it does not need to seek federal approval causes us concern. Specifically, as we discuss on page 32, the federal Secretary of Health and Human Services and the manufacturers enter into a rebate agreement that allows manufacturers to make adjustments to their average manufacturer price (AMP) and best price. Because the State is not a party to this agreement we question whether Health Services can enforce the state requirement that prohibits manufacturers from making changes to federal rebates owed to the State as a result of revisions to their AMP or best price without federal approval. Nevertheless, we have brought this issue to the attention of an official with the center.

- We would like to point out that our report correctly cites the state law regarding Health Services' dispute resolution process on page 35. However, to provide clarity, we have modified our recommendations on pages 5 and 39 to read as follows: Evaluate periodically the number of staff needed to resolve disputed rebates within 90 days.

- Health Services correctly indicates that in fiscal year 2002–03, it proposed this same approach, but the Legislature rejected its proposal. However, we do not believe that Health Services provided the Legislature with sufficient analysis of the costs, benefits, and pharmacies' collection rates on which to base its decision. Therefore, we are merely recommending that Health Services evaluate the pros and cons of deducting copayments from its reimbursement rate and having pharmacies collect these payments from beneficiaries.

- Appendix B (formerly Appendix A) clearly states that the expenditures included in the table represent the amounts Health Services reimbursed pharmacies for its top 200 drugs. However, to address Health Services' concern we have added a sentence on page 83 explicitly stating that the amounts have not been reduced by any federal or state supplemental rebates Health Services received from manufacturers.

cc: Members of the Legislature
Office of the Lieutenant Governor
Milton Marks Commission on California State Government Organization and Economy
Department of Finance
Attorney General
State Controller
State Treasurer
Legislative Analyst
Senate Office of Research
California Research Bureau
Capitol Press