# 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*

*Audit Highlights . . .*

*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.*

**REPORT NUMBER 2002-118, APRIL 2003**

**Department of Health Services' response as of July 2004**

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 the Department of Health Services' (Health Services) Medi-Cal Fee-for-Service 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. Specifically, we found that:

### Finding #1: 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 years 2001–02 and 2002–03 to meet increases in its workload and to implement several budget reduction proposals. Additionally, although Health Services contracted with its fiscal intermediary, Electronic Data Systems Federal Corporation (EDS), for the services of five more pharmacists, as of March 2003, it had also been unable to hire the

pharmacists. Consequently, Health Services had 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, 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. However, Health Services' efforts to advertise open positions have consisted of sending more than 4,000 notices to licensed pharmacists in the counties surrounding Sacramento.

Health Services agreed that it should pursue other approaches to attempt to meet its staffing needs. For example, Health Services might be able to reassign general pharmacist duties to a nonpharmacist position that requires a lesser level of expertise and might be easier to fill. However, 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 State's General Fund. 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.

To address its difficulties in attracting qualified pharmacists, we recommended that 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 reimbursement for personnel costs.

- Research its ability to use the services of interns.

***Health Services' Action: Partial corrective action taken.***

In its original response to our recommendation, Health Services indicated that it sent flyers to every pharmacist in the State and placed advertisements in a number of pharmacy publications. After receiving approval from the Department of Personnel Administration to offer pharmacists a recruitment and retention payment of $2,000 per month, Health Services stated that it was able to hire four pharmacists in October 2003. However, as of July 2004, Health Services stated that it still has two vacant pharmacist positions it anticipates filling before the end of September 2004. Health Services is considering listing its pharmacist position as hard-to-fill, which it stated will allow the recruitment and retention pay to become part of a pharmacist's base salary and count toward his or her retirement. Health Services believes this will help its future recruitment efforts and reduce pharmacist turnover. Additionally, Health Services stated it has hired three research analysts to perform drug cost analyses formerly performed by the pharmacists. Finally, Health Services also indicated that its development of an internship position with the University of Pacific (UOP) in Stockton is ongoing and there has been a new staff member assigned by UOP to this activity.

**Finding #2: Health Services does not complete many drug reviews promptly.**

Between October 1999 and November 2002, it has taken Health Services as long as, and in a few instances longer than, one year to review new drugs before adding them to its drug list. Health Services has not established a deadline that addresses how long the entire new-drug process should take for drugs without a priority designation. It believes a reasonable time frame to conclude a new-drug review is roughly four to eight months.

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. Health Services attributes many of the delays in completing new-drug reviews to the drug manufacturers' lack of responsiveness and difficulties that arise during negotiations in addition to its inability to hire pharmacists to perform the new-drug reviews.

We recommended that Health Services 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.

***Health Services' Action: Corrective action taken.***

In October 2003, Health Services indicated that it has increased the number of pharmacists who can negotiate contracts and it is making changes so that it can complete new drug reviews more timely. In November 2004, Health Services provided us a copy of its Medi-Cal Drug Review Policies and Procedures and indicated that these new policies are available on its Web site.

### Finding #3: Health Services could further reduce costs by completing more reviews of entire drug categories.

Between 1998 and 2002, Health Services has only performed four therapeutic category reviews (TCRs) for the 113 classes of drugs on the drug list. 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. Yet, in 2002, Health Services did not develop a TCR schedule. In addition, 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. However, it has yet to perform any of these TCRs because under its current staffing situation, it is unable to do so.

We recommended that Health Services conduct the TCRs specified in its budget proposal for fiscal year 2002–03. Further, it should develop and adhere to annual schedules for future reviews.

***Health Services' Action: Corrective action taken.***

In October 2003, Health Services noted that the Legislature revised the law to require it to complete a TCR within 120 days instead of 150 days. Additionally, Health Services plans to complete four TCRs annually. As of November 2004, Health Services stated that it has completed four TCRs including cholesterol-lowering agents, non-sedating antihistamines, angiotensin-converting enzyme (ACE) inhibitors/angiotension

receptor blockers (ARB), and antidepressants. Additionally, Health Services stated that it has two others in progress—proton pump inhibitors and nonsteriodal anti-inflammatory drugs.

### Finding #4: 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. 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. However, it may not fully achieve the added cost savings identified in the November 2002 estimate, or the savings may be delayed. Specifically, we found the following:

- 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 the reluctance of generic drug manufacturers to negotiate lower prices. Yet, Health Services reported that it could achieve cost savings of roughly $40 million to the General Fund for fiscal years 2002–03 and 2003–04, by pursuing supplemental rebate contracts with generic drug manufacturers. However, because of the difficulties Health Services has experienced in filling vacant pharmacist positions, we question whether it will achieve this cost savings.

- Health Services may not be successful in achieving savings that result from a change 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), requires Health Services to base the maximum allowable ingredient cost (MAIC) on the mean of the wholesale selling price (WSP) 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 WSP as the price, including discounts and rebates, paid by a pharmacy to a wholesale drug distributor for a drug. According to Health Services, it plans to ask selected wholesalers in California to report their WSPs for generic drugs and it intends to use the reported WSP plus an appropriate markup to reimburse pharmacies for each

drug ingredient cost. Health Service reported that, once implemented, the new reimbursement method will provide cost savings of roughly $9 million to the General Fund for fiscal years 2002–03 and 2003–04. However, we again question whether Health Services will achieve these cost savings for several reasons that include its difficulties in hiring pharmacists to implement this new reimbursement method and its lack of a plan to address what action it will take if wholesalers are unwilling to share their pricing data.

- 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. It would add drugs to the sublist after evaluating the drug using certain criteria, including the cost of the drug, which is partially driven by the willingness of the manufacturer to negotiate a supplemental rebate contract. 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. The increased workload to implement the sublist would further overburden a staff already unable to complete their required tasks. Health Services reported that implementing the sublist would result in cost savings to the General Fund totaling $9 million for fiscal years 2002–03 and 2003–04. However, according to Health Services, its cost-saving estimate was based on a cursory review of drug utilization by private third-party payers, yet, it could not 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.

- Finally, 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 that it could achieve $13 million in savings to the General Fund for fiscal years 2002–03 and 2003–04.

However, before proposing this legislative change, Health Services should have obtained approval from the federal Centers for Medicare and Medicaid Services (center) 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 agreement 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.

To ensure that it fully achieves the added cost savings identified in the November 2002 estimate, we recommended that Health Services should do the following:

- 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.

***Health Services' Action: Partial corrective action taken.***

Health Services stated that only one manufacturer expressed an interest in negotiating a contract for generic drug rebates and it hopes to finalize the agreement in October 2004.
Health Services stated that it has provided limited technical assistance to the Department of Justice in the development of Senate Bill 1170 (SB 1170) that creates reporting requirements for drug manufacturers, principal drug labelers, and drug wholesalers; however, this legislation has not yet been enacted. Additionally, as of July 2004, Health Services indicated it has drafted trailer bill language that defines the MAIC for generic drugs and imposes penalties on wholesalers failing to report prices.
In October 2003, Health Services stated that it plans to analyze the cost-effectiveness of a preferred prior authorization list on a drug-by-drug or therapeutic drug category basis. As of May 2004, Health Services indicated that it is in the process of conducting a review of certain drugs for preferred prior authorization status. Health Services completed a review of the drugs used for the treatment of erectile dysfunction and is releasing rebate contracts. Health Services also stated that it is in the process of analyzing the drugs used in the treatment of multiple sclerosis and it intends to have rebate contracts effective in several months.
Finally, Health Services indicated that the center has issued a regulation effective January 1, 2004, that allows manufacturers to make retroactive adjustments to their AMPs or best prices for a three-year period. Further, the center informally indicated that state law prohibiting retroactive rebate adjustments would not supercede the federal rule. Therefore, Health Services is seeking agreement from the center that the State's statute prohibiting any retroactive adjustments of the state supplemental rebates can be made effective by incorporating the State's statute in the language included in the supplemental rebate contract with the manufacturer.

**Finding #5: Health Services just recently began working with manufacturers to reconcile federal and state rebates.**

In a March 1996 audit, we reported that although Health Services prepared invoices specifically for supplemental rebates, the invoices did not specify the amount the manufacturers owed. Rather, the invoices instructed manufacturers to calculate and submit required supplemental rebates along with their federal rebate payments. We further reported that Health Service 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. During the fiscal year 2002–03 budget process, Health Services received approval and hired four analysts as of February 2003 to help resolve these issues, although it had requested approval to increase its staff of analysts for almost the past five years. Between January 1991 and September 30, 2001, the amount of unresolved rebates grew to more than $216 million, or 6 percent of the $3.4 billion invoiced. 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 the rebate payments. Health Services estimated that it could achieve a total of $10.5 million in savings to the General Fund for fiscal years 2002–03 and 2003–04 by resolving some of these rebate disputes.

To ensure that it has sufficient staff to work with manufacturers to resolve disputed rebates promptly and achieve cost savings, we recommended that Health Services evaluate periodically the number of staff needed to resolve disputed rebates within 90 days.

***Health Services' Action: Pending.***

In its October 2003 response, Health Services indicated that it expected to expand its staff by filling 10 analyst positions and one manager position by December 2004 in anticipation of resolving the backlog of disputes by the end of fiscal year 2004–05. In its July 2004 response, Health Services stated that it has filled the manager's position and is working on filling two analyst positions.

**Finding #6: 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 a unit rebate amount based on confidential pricing information 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 Health Care Financing Administration, now the Centers for Medicare and Medicaid Services, 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 ADAP's to emulate the Medicaid model.

However, because ADAP does not have access to the unit rebate amount information from the center, it bills manufacturers for its federal rebates using an estimated unit rebate amount that may be inaccurate. Additionally, the manufacturers send the rebates to the ADAP, usually including the actual unit rebate amounts they used to calculate the federal rebate owed; however, ADAP cannot verify whether the amounts are correct. In fact, 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 for one quarter that was nearly $125,000 less than the amount it would have received using Medi-Cal's unit rebate amount data for that drug for the same quarter.

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 receive their federal rebate payments promptly. In fact, we found that the ADAP did not send 14 invoices totaling $2.9 million to manufacturers for the first quarter of 2001 until October 18, 2002, or more than six months after the completion of the quarter. 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.

We believe that it would benefit the ADAP to take advantage of Health Services' Rebate Accounting and Information System (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 state to assist in the submission of federal rebate claims to manufacturers within the requirement of the drug pricing confidentiality provisions.

We recommended that Health Services should 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.

***Health Services' Action: None.***

Health Services indicated that ADAP and the Medi-Cal staff met and discussed the possibility of using RAIS for invoicing ADAP manufacturers. Although both programs agreed that the idea was feasible, they determined that the costs associated with changing systems and adding ADAP to RAIS was prohibitive. However, Health Services stated that ADAP has begun using the most recent unit rebate amount provided by drug manufacturers to more closely estimate rebates owed to it and believes that this has resulted in less than a 1 percent difference between the estimated amount invoiced and the actual rebates owed.

Finally, in its October 2003 response to our recommendations, Health Services stated that it does not plan to seek legislation to assess and collect interest from manufacturers when they delay submitting federal rebates. Specifically, in its July 2004 response, Health Services explained that, based on an analysis of rebates invoiced for calendar year 2003, ADAP continues to be successful in collecting rebate payments due from drug manufacturers in a timely manner. It also indicated that proposing legislation imposing interest penalties on manufacturers for late rebate payments would have limited benefit and implementing the necessary billing system would not be cost-effective.

**Finding #7: Health Services pays less for certain brand name drugs than it does for their generic counterparts, but it can improve its contracting process.**

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 reimbursement to eight brand name drugs because it is generally able to obtain lower net costs for them than for their generic counterparts after applying the supplemental rebates it receives from the manufacturers. 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 estimated cost Medi-Cal roughly $57,000 in 2002.

Currently, Health Services maintains a database that lists each supplemental rebate 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 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.

To ensure it obtains the lowest net cost for drugs, we recommended that 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.

***Health Services' Action: Partial corrective action taken.***

Health Services stated that it has assigned a pharmacist to monitor the status of contracts and bring to the attention of the pharmacy section management those contracts that will be expiring in the upcoming six months. Management then assigns pharmacist staff to renew or renegotiate the contracts. Health Services also indicated that it has established a review process to ensure that supplemental rebate contracts are appropriately entered into its contract tracking database and RAIS.

Additionally, Health Services noted that if it is unable to complete negotiation for state supplemental rebates, it plans to remove the restriction to allow the use of generic drugs when there is a net cost savings to the State. In October 2003, Health Services indicated that it had begun evaluating the net cost impact of removing the restrictions to use brand name drugs on a case-by-case basis and, as of May 2004, it continues to do so.

Finally, Health Services stated it will ensure that all terms and conditions are delineated in the supplemental rebate contracts with manufacturers.

### Finding #8: Health Services could save $20 million annually by placing the responsibility on the pharmacists to recover copayments.

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, however, has taken a more aggressive approach toward collecting copayments from beneficiaries. 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. 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.

We recommended that Health Services 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.

***Health Services' Action: None.***

In October 2003, Health Services indicated that the 2003 Budget Act includes a 5 percent reimbursement reduction for pharmacies effective January 1, 2003. Health Services believes that this reduction will allow for greater annual savings than deducting copayments from its reimbursement rate and having pharmacists collect the payments from beneficiaries. However, as of November 2004, Health Services is under a preliminary injunction and cannot implement the 5 percent rate cut. It has appealed the injunction and was scheduled to provide oral argument in the 9th Circuit Court of Appeals the week of December 6, 2004. Additionally, Health Services stated that it is evaluating various beneficiary cost-sharing proposals as part of the Medi-Cal redesign effort.

### Finding #9: 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 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. 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. However, Health Services 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. Additionally, 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.

Another hard edit that might 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. Health Services told us that it had previously considered 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. However, one state that responded to our survey reported that it has achieved cost savings totaling more than $3.1 million for 9,600 claims by implementing step therapy protocols.

To achieve additional savings in its Medi-Cal pharmacy program, we recommended that 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 savings.

- 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.

***Health Services' Action: Pending.***

Health Services stated that it has begun using the duration of therapy hard edits for one drug only and there is significant concern related to the effect these edits have on its workload. According to Health Services, it is exploring other processes such as step therapy that would reduce workload and make broader implementation of duration of therapy hard edits possible. Finally, Health Services indicated that it is moving forward with the first DUR hard edit for early refills. However, it has not yet established a firm implementation date.

**Finding #10: Health Services' educational methods related to DUR are indirect and project oriented.**

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.

Specifically, 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 "Dear Dr." letters to physicians and pharmacists (providers). Instead, Health Services 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 that are most in need of intervention and send letters only to them.

In addition, 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. 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. 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 education program or what its future needs may be.

As we previously discussed, 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. 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.

To improve its efforts to educate providers about inappropriate or medically unnecessary drug therapies and potentially capture additional cost savings, we recommended that Health Services should do the following:

- 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.

***Health Services' Action: Pending.***

Health Services indicated that it is in the process of filling two research analyst positions created to determine the cost effectiveness of Dear Dr. Letters and any other prescribing education efforts it undertakes as part of its drug expenditure reductions initiatives. Additionally, Health Services stated that it will develop prescriber profiles to create general educational documents for all prescribers and to facilitate its plans to contact prescribers directly to address their prescribing practices. In its May 2004 response, Health Services also indicated that it recently hired research staff and is in the process of hiring a physician to work on this issue.

**Finding #11: Despite working with other organizations on disease management, Health Services has not sought funding for the pilot projects.**

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. 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.

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.

We recommended that Health Services 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.

***Health Services' Action: Pending.***

In October 2003, Health Services indicated that CPhA received significant monetary commitments to fund a pilot project. Thus, CPhA is moving forward on a pilot project in the San Diego area that focuses on diabetes and, according to Health Services, one of its pharmacists is providing feedback to CPhA on the pilot project's design. Health Services stated that, if results are positive, it would take the appropriate steps to incorporate the project in the Medi-Cal program. During April 2004, Health Services indicated it met with CPhA to discuss the next steps of the diabetes pilot project. CPhA is preparing a business proposal for Health Services' review, but has not yet provided Health Services with a timeframe.

### Finding #12: 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. 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 2001.

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

We recommended that Health Services 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, Health Services should discontinue some or all of the optional drug classifications.

***Health Services' Action: Pending.***

Health Services stated that it analyzed the effect of discontinuing all or a portion of the optional drug categories on Medi-Cal beneficiaries and on drug expenditures. Health Services concluded that the savings would be minimal and the potential for detrimental impact on beneficiaries could be significant. However, the analysis Health Services provided did not calculate the amount of the net savings or loss. Health Services indicated that to perform this type of analysis would require a long-term or a very large retrospective study.