PHARMACEUTICALS

State Departments That Purchase Prescription Drugs Can Further Refine Their Cost Savings Strategies

Audit Highlights . . .

Our review of the State's procurement and reimbursement practices as they relate to the purchase of drugs for or by state departments revealed the following:

- ☑ *Although the Department of General Services (General Services) generally got the best prices for the drug ingredient cost because of up-front discounts, it had the highest state cost after considering rebates, dispensing fees, co-payments, and third-party payments.*
- ☑ *The Department of Health Services' net drug ingredient cost and state cost are lower than General Services and the California Public Employees' Retirement System's (CalPERS) because it receives substantial federal Medicaid program and state supplemental rebates.*
- ☑ *Although CalPERS receives rebates through entities it contracts with to provide pharmacy services to its members, it cannot directly verify it is receiving all of the rebates to which it is entitled.*

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REPORT NUMBER 2004-033, MAY 2005

California Public Employees' Retirement System and the Department of General Services' responses from the State and Consumer Services Agency, and the Department of Health Services' response from the Health and Human Services Agency as of May 2006

Chapter 938, Statutes of 2004, required the Bureau of State Audits (bureau) to report to the Legislature on the State's procurement and reimbursement practices as they relate to the purchase of drugs for or by state departments, including, but not limited to, the departments of Mental Health, Corrections and Rehabilitation, the Youth Authority (Youth Authority), Developmental Services, Health Services (Health Services), and the California Public Employees' Retirement System (CalPERS). Specifically, the statutes required the bureau to review a representative sample of the State's procurement and reimbursement of drugs to determine whether it is receiving the best value for the drugs it purchases. The statutes also required the bureau to compare, to the extent possible, the State's cost to those of other appropriate entities such as the federal government, Canadian government, and private payers. Finally, the bureau was required to determine whether the State's procurement and reimbursement practices result in savings from strategies such as negotiated discounts, rebates, and contracts with multistate purchasing organizations, and whether the State's strategies result in the lowest possible costs. The bureau examined the purchasing strategies of the three primary departments that contract for prescription drugs—the Department of General Services (General Services), Health Services, and CalPERS. We found that:

Finding #1: In some instances, CalPERS cannot directly verify that it is receiving all of the rebates to which it is entitled.

Negotiating drug rebates is one tool available to reduce drug expenditures. Drug manufacturers typically offer rebates based on the extent to which health care plans influence their products' market share. Although CalPERS does not directly contract with drug manufacturers, it receives rebates from some entities it contracts with

☑ *In our comparison of 57 prescription drug costs across the three state departments and select U.S. and Canadian governmental entities, the Canadian entities got the lowest prices about 58 percent of the time. However, federal law strictly limits the importation of prescription drugs through the Food, Drug, and Cosmetic Act whose stringent requirements generally exclude any drugs made for foreign markets.*

for pharmaceutical services. In some instances CalPERS receives rebates under a pass-through method. In the pass-through method, the entity negotiates rebates and contracts with pharmaceutical manufacturers so that rebate payments between the manufacturer and the entity are based on historical and prospective pharmacy utilization data for all of the members of the health care plan that the entity administers. The entity then collects and passes through to plan sponsors, such as CalPERS, either a percentage or the entire amount of the rebates earned by the sponsors based on their member utilization.

Typically, these entities prohibit CalPERS from having access to any information that would cause them to breach the terms of any contract with the pharmaceutical manufacturers to which they are a party. Because CalPERS does not have access to the entities' rebate contracts with the manufacturers, CalPERS cannot directly verify that it is receiving all of the rebates to which it is entitled. According to CalPERS, this rebate practice between the entity and the manufacturer is an industry practice and is not unique to it. CalPERS intends to continue to pursue greater disclosure requirements in future contracts with its contracting entities.

We recommended that the Legislature consider enacting legislation that would allow CalPERS to obtain relevant documentation to ensure that it is receiving all rebates to which it is entitled to lower the prescription drug cost of the health benefits program established by the Public Employees' Medical and Hospital Care Act. Additonally, CalPERS should continue to explore various contract negotiation methods that would yield more rebates for the drugs it purchases and that would allow it to achieve greater disclosure requirements to verify that it is receiving all of the rebates to which it is entitled.

Legislative Action: Unknown.

CalPERS' Action: Corrective action taken.

CalPERS reports that the providers for two of its HMO plans will furnish rebate information as part of the financial statements that they regularly provide. CalPERS also stated the provider of another of its HMOs considers rebates proprietary and confidential, and the provider does not identify rebates in its financial statements. However, a pharmacy carve-out analysis, conducted by a consultant for pharmacy claims from May 2003 through April 2004, confirmed that this HMO's management of the pharmacy benefit is the most cost-effective of CalPERS' health plans. CalPERS stated that it will continue to assess this HMO's performance and management as part of its recurring rate analysis.

CalPERS also reports that it entered into a three-year contract with a new pharmacy benefits manager (PBM) for its self-funded PPO plans. The term of the contract is from July 2006 through June 2009. According to CalPERS, this contract contains extensive provisions regarding guarantees, rebates, transparency, disclosure, and cost accountability. Because CalPERS has only received the first quarterly payment of rebates and guarantees under the new contract, it cannot yet quantify the additional savings the contract will generate. However, CalPERS expects that the total rebate payment will be twice what it received under its contract with the prior PBM based on its first quarterly payment. CalPERS stated that its new contract also requires the PBM to provide a profit and loss report specific to the CalPERS account within 30 days of the end of each contract year, and allows a CalPERS representative to audit this report.

Finding #2: General Services is in the early stages of its direct negotiations with manufacturers and aims to increase its ability to reduce the net ingredient cost of prescription drugs.

Although rebates typically decreased the cost of prescription drugs for Health Services and CalPERS, General Services' net ingredient costs, drug ingredient cost minus any rebates or additional discounts, for the drugs in our sample are about the same as its costs for the drugs before any discounts or rebates. General Services says this is because it is still in the early stages of its direct negotiations with manufacturers to achieve reduced drug costs. Currently, departments purchasing drugs through General Services can obtain rebates only for one drug product class, a rebate General Services obtained through contract negotiation efforts. For that one drug product class, state agencies received at least $1.5 million in rebates for their purchases in fiscal year 2003–04.

To ensure that state departments purchasing drugs through General Services' contracts are obtaining the lowest possible drug prices, we recommended that General Services seek more opportunities for departments to receive rebates by securing more rebate contracts with manufacturers.

General Services' Action: Partial corrective action taken.

General Services reports that to obtain the best and lowest drug price, its primary strategy continues to be to negotiate price discounts upfront with the manufacturer. However, General Services notes that if rebates result in the State obtaining the best and lowest prices, they have been and will continue to be pursued.

Finding #3: Although General Services has made progress, it still needs to negotiate more contracts with drug manufacturers.

In a January 2002 report, *State of California: Its Containment of Drug Costs and Management of Medications for Adult Inmates Continue to Require Significant Improvements*, the bureau recommended that General Services increase its efforts to solicit bids from drug manufacturers to obtain more drug prices on contract. At that time, General Services had about 850 drugs on contract, but during most of fiscal year 2003–04 had only 665 drugs on contract. General Services states

that because of limited resources, it is focusing on negotiating contracts with manufacturers of high-cost drugs. However, opportunities still exist for General Services to increase the amount of purchases made under contract with drug companies.

We recommended that General Services continue its efforts to obtain more drug prices on contract by working with its contractor to negotiate new and renegotiate existing contracts with certain manufacturers.

General Services' Action: Partial corrective action taken.

General Services reports that its strategic sourcing contractor and its partners are providing support to General Services in its efforts to negotiate and renegotiate contracts with drug manufacturers. Specifically, the contractor has assisted General Services, as needed, in the negotiation of new and renegotiation of existing contracts within the atypical antipsychotic category of drugs, which make up approximately 30 percent of annual drug costs. In addition, General Services entered into two pharmaceutical contracts using its strategic sourcing methodology that should result in significant savings to the State. Namely, General Services implemented a contract with a new prime vendor responsible for distributing drugs purchased under the State's drug procurement program that it estimates will save the State $1.3 million annually. General Services also contracted with a PBM for the Department of Corrections and Rehabilitation to use to provide prescription drugs to parolees that General Services estimates will save the State an additional $3.8 million annually. However, General Services reports that its recent efforts to contract with manufacturers of gastrointestinal and anticonvulsant classes of drugs were not successful in delivering cost savings contracts.

Finding #4: General Services was not able to demonstrate that it fully analyzed how to improve its procurement process.

General Services was unable to provide documentation demonstrating that it addressed another recommendation in our January 2002 report: that it fully analyze measures to improve its procurement process, such as joining the Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP) or contracting directly with a group-purchasing organization. General Services does contract with the alliance, but that contract covers only 16 percent of the drug purchases state departments made. With state departments purchasing almost half their prescription drugs at the prime vendor's price, General Services stands to reap benefits for the State by figuring out additional ways to procure prescription drugs.

General Services recognizes that it can do more to ensure that its strategies result in the lowest possible cost to the State. In September 2004, General Services hired a contractor to analyze state spending and identify opportunities to generate savings. General Services stated that, as resources become available, it intends to solicit bids to contract directly with a group-purchasing organization to determine if additional savings can be realized beyond the savings generated by the alliance.

We recommended that General Services follow through on its plan to solicit bids to contract directly with a group-purchasing organization to determine if additional savings can be realized. However, in doing so it should thoroughly analyze its ability to secure broader coverage of the drugs state departments purchase by joining MMCAP. The analysis should include the availability of current noncontract drugs from each organization being considered and the savings that could result from spending less administrative time trying to secure additional contracts directly with drug manufacturers.

General Services' Action: Partial corrective action taken.

General Services determined that an alternative method of accessing a group-purchasing organization should be assessed. It reports that this assessment will include an analysis of the benefits of joining the cooperative purchasing arrangement used by MMCAP. As part of this process, General Services is working with the alliance to identify ways of increasing value from a group-purchasing organization through enhanced reporting and formulary management activities. General Services is also working with the University of California and CalPERS to develop strategies and methods for using a group-purchasing organization. Finally, General Services plans to send a request for information to large and medium size group-purchasing organizations by early January 2007 to gather information to assist it in evaluating the pricing and services available through the alliance. If the information received indicates that additional savings or service benefits can be realized, General Services will promptly prepare and issue a request for proposals for a new method of accessing a group-purchasing organization.

Finding #5: General Services has not fully considered how to identify and mitigate obstacles to enforcing its statewide formulary.

In our January 2002 report, the bureau recommended that General Services fully consider and try to mitigate all obstacles that could prevent the successful development of a statewide formulary, such as departments not strictly enforcing such a formulary at their institutions. A drug formulary is a list of drugs and other information representing the clinical judgment of physicians, pharmacists, and other experts in the diagnosis and treatment of specific conditions. A main purpose of a formulary is to create competition among manufacturers of similar drugs when the clinical uses are roughly equal. However, the success of a statewide formulary and the State's ability to create enough competition to negotiate lower drug prices for certain products depends on how well state departments adhere to the formulary when they prescribe drugs. Although General Services has developed a statewide formulary, it has not identified the obstacles to enforcing it. General Services has not required departments to adopt a policy requiring strict adherence to the statewide formulary and does not monitor departments' adherence to the formulary. General Services does not believe its role is to enforce the formulary, but the goals of a statewide formulary in reducing drug costs cannot be realized without such enforcement.

We recommended that General Services facilitate the Common Drug Formulary Committee and Pharmacy Advisory Board's development of guidelines, policies, and procedures relating to the departments' adherence to the statewide formulary and ensure that departments formalize their plans for compliance.

General Services' Action: Corrective action taken.

General Services reports that at the Common Drug Formulary Committee's October 2005 meeting, and the Pharmacy Advisory Board's January 2006 meeting the formulary was approved. In addition, the departments of Corrections and Rehabilitation, Mental Health, and Developmental Services have provided General Services with implementation plans for the statewide formulary. Now that the statewide formulary has been implemented, General Services and the committee will begin to focus additional resources on the administrative and enforcement concerns raised in our report.

Finding #6: General Services does not have information concerning non-prime vendor drug purchases made by departments required to participate in its bulk purchasing program.

Although state law requires specific state departments to purchase drugs through General Services, our survey of various departments indicates they are not always doing so. Specifically, California Government Code requires the departments of Corrections and Rehabilitation, Developmental Services, Youth Authority, and Mental Health to participate in General Services' bulk purchasing program. In addition, California Public Contract Code requires that all state departments purchasing drugs totaling more than $100 must purchase them through General Services. California State University, the University of California, and some entities within the California Department of Veterans' Affairs are exempt from this requirement. Although we found that departments generally purchase most drugs through General Services' contract with its prime vendor, they also purchase drugs through other vendors.

Nine state entities purchased prescription drugs using General Services' prime vendor, but each of these entities also purchased drugs from non-prime vendor sources during fiscal year 2003–04. For example, although the Youth Authority purchased drugs from the prime vendor costing roughly $1.8 million, it also purchased drugs costing almost $451,000 through other vendors. Seven of the nine entities we surveyed purchased 20 percent to 100 percent of their drugs through non-prime vendor sources. General Services stated that it did not have insight into the amounts and kinds of drugs that entities were purchasing through other sources and therefore has not analyzed these purchases.

In order to make more informed decisions concerning the operation of its prescription drugs bulk-purchasing program and to be able to expand the program to include those prescription drugs that best serve the needs of state departments, we recommended that General Services ask those departments that are otherwise required to participate in the bulk purchasing program to notify General Services of the volume, type, and price of prescription drugs they purchase outside of the bulk purchasing program.

General Services' Action: Corrective action taken.

General Services reports that it now requires those departments that must participate in the bulk-purchasing program to provide it with quarterly reports on drugs purchased outside of the program. This information will aid General Services' pharmaceutical and acquisitions staff in making decisions about the bulk-purchasing program.

Finding #7: Health Services needs to improve the accuracy of its pharmacy reimbursement claim data.

Our review found that Health Services sometimes uses incorrect information when paying pharmacies. In several instances Health Services' payments to pharmacies were based on outdated or incorrect information. Health Services receives updates from a pricing clearinghouse and changes its prices monthly. One factor that Health Services uses to determine the appropriate drug price for a claim is the date of service. Specifically, Health Services uses this date to query its pricing file and identify the price in effect during the date of service on the claim. However, Health Services holds the price updates it receives from its primary reference source until the subsequent month because its budgetary authority only allows for monthly updates. Additionally, Health Services did not update its prices to reflect the elimination of the direct pricing method, which was the price listed by Health Services' primary or secondary reference source or the principal labeler's catalog for 11 specified pharmaceutical companies. Despite state law eliminating this method as of December 1, 2002, Health Services continued to use it during fiscal year 2003–04 to reimburse pharmacies. Health Services stated that the system change error related to the direct pricing method occurred prior to the July 2003 implementation of its fiscal intermediary's Integrated Testing Unit, which is responsible for performing comprehensive tests of system changes to prevent program errors. Health Services also incorrectly calculated drug prices. Although Health Services began corrective action after we brought the issues to its attention, its analyses to quantify the full extent and dollar impact of these errors was not complete as of April 2005.

To ensure that it reimburses pharmacies the appropriate amounts for prescription drug claims, we recommended that Health Services analyze the cost-effectiveness of increasing the frequency of its pricing updates. If this analysis shows that it would be cost-effective to conduct more frequent updates, Health Services should seek budgetary authority to do so. Health Services should also identify prescription drug claims paid using the direct pricing method, determine the appropriate price for these claims, and make the necessary corrections. In addition, we recommended that Health Services ensure that the fiscal intermediary's Integrated Testing Unit removes future outdated pricing methods promptly. Finally, Health Services should ensure that its fiscal intermediary's Integrated Testing Unit verifies that, in the future, drug prices in the pricing file are calculated correctly before authorizing their use for processing claims.

Health Services' Action: Partial corrective action taken.

Health Services reports that a 2005 budget health trailer bill amended the Welfare and Institutions Code to increase the frequency of drug price updates to weekly instead of monthly. Health Services began processing weekly updates in January 2006. In addition, Health Services determined that using the direct pricing method, which was eliminated by state law effective December 1, 2002, caused it to overpay 457,368 claims for a total of $2.9 million, and to underpay 199,380 claims by more than $450,000. Therefore, Health Services reports that its total net recoupment will be approximately $2.5 million for the period of December 1, 2002, through June 30, 2005. Health Services stated that its assessment of the provider impact and corrections to the pricing file must be implemented before it can move forward on this recoupment. As of early-December 2006, Health Services

was working with its fiscal intermediary to complete the corrections. Finally, Health Services has implemented safeguards within the fiscal intermediary's Integrated Testing Unit to assure that these types of errors in the pricing file will not occur on future system changes.