Department of Health Services:

Has Not Collected $40 Million in Supplemental Rebates From Drug Manufacturers

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Summary

Audit Highlights ...

We found that:

- ☑ ***Evidence does not clearly demonstrate that the department's drug reviews adhere to criteria established by law;***
- ☑ ***$40 million in supplemental rebates owed to the State and the federal government have not been collected;***
- ☑ ***The supplemental rebate program has not limited accessibility to drugs; and***
- ☑ ***Potential program revenue of approximately $70 million far exceeds the program's estimated $5 million annual cost.***

Results in Brief

The Department of Health Services (department) has not collected approximately $40 million in supplemental rebates owed to the State and the federal government by drug manufacturers because it has not adequately administered the California Medical Assistance Program (Medi-Cal) drug rebate program (program). The department does not calculate and bill specific supplemental rebate amounts owed by manufacturers, and it has failed to monitor and track supplemental rebate payments and sanction manufacturers who do not remit the required amounts owed to the State and the federal government. As a result, the State has not received $20 million in supplemental rebates, and the federal government has not received its $20 million share in supplemental rebates.

The department prepares various types of documents related to its reviews of drugs to be added to the Medi-Cal List of Contract Drugs (LCD). Although the department has indicated that it follows the criteria stated in the Welfare and Institutions Code when conducting its reviews, it does not uniformly prepare and retain its documents in a manner that clearly demonstrates that the criteria were the bases for its decisions.

The 1994 legislation authorizing the supplemental rebate program has not significantly reduced the availability of drugs
to Medi-Cal recipients. Because some drug manufacturers were unwilling to participate in the supplemental rebate program, only 16 drugs were suspended from the LCD. In addition, the administrative costs of the supplemental rebate program are far exceeded by the potential revenue from the program. The annual required costs to administer the program are approximately $5 million, but the potential revenue for fiscal year 1994-95 was approximately $70 million.

Recommendations

To properly administer the program, the department should:

- Collect all supplemental rebates owed by:
  - ☑ Calculating a specific dollar amount on the invoice that the department sends to a manufacturer;
  - ☑ Monitoring the accuracy of payments;
  - ☑ Tracking manufacturers who have not paid; and
  - ☑ Sanctioning manufacturers for nonpayment or for late or erroneous payments.
- If needed, seek statutory authority to:
  - ☑ Use ingredient cost or another pricing base it already possesses as the statutorily approved pricing base if using the average manufacturer price for billing is impractical;
  - ☑ Suspend drugs from the LCD that are produced by manufacturers who do not pay the rebate; and
  - ☑ Charge interest on late payments.
- Develop and retain standard evaluation documents demonstrating that the department used the criteria stated in the Welfare and Institutions Code, Section 14105.39(d), when it made its decision to add, not add, remove, or retain drugs on the LCD.

Agency Comments

The department agrees that it has not received rebates from a large number of drug manufacturers and indicated that it intends to seek legislative authority to sanction drug manufacturers who do not pay or consistently make late payments. Although it is not convinced of the accuracy of

the supplemental rebates owed, the department states that it is not in a position to specify a more accurate amount because of deficiencies in its payment tracking system.

Introduction

Background

The Department of Health Services (department) is responsible for administering the California Medical Assistance Program (Medi-Cal). One of the components of Medi-Cal is the Medi-Cal drug rebate program (program). The primary objective of the program is to obtain significant price discounts on pharmaceuticals prescribed for Medi-Cal beneficiaries. Discounts are in the form of manufacturer rebates on drugs purchased through Medi-Cal. To accomplish this, the Welfare and Institutions Code directs the department to contract with manufacturers to provide discount prices at least comparable to those they offer to other high-volume purchasers of drugs. Another significant objective of the program is to ensure that Medi-Cal beneficiaries have access to appropriate drug therapies and a comprehensive range of drug products. Before the program was established, the list of drugs that Medi-Cal would reimburse for could be changed only by regulation. In July 1990, the Welfare and Institutions Code established the Medi-Cal List of Contract Drugs (LCD) and allowed the department to add drugs available to beneficiaries through a negotiation process.

The program was established in July 1990 as the Medi-Cal Drug Discount Program. (See Appendix A for a more complete description of the history of the program.) Under this program, the department entered into contracts with several drug manufacturers and achieved price reductions based on the discount prices provided to other third-party purchasers of drugs. The discounts were in the form of rebates, or equalization payment amounts as defined in Section 14105.31 of the Welfare and Institutions Code, and were based on the difference between the price that the manufacturer charged to wholesalers and the manufacturer's "best price." Best price is the negotiated

price, or the manufacturer's lowest price available to any other customer. Before implementing the drug discount program, the department estimated savings of $50 million for fiscal year 1990-91. The Office of the Auditor General issued a report on the program in June 1991, which concluded that the department did not achieve these estimated savings.

In January 1991, the federal government implemented a nationwide drug rebate program under the Omnibus Budget Reconciliation Act of 1990. Under this federal program, Section 1927 of the Social Security Act requires drug manufacturers to submit quarterly rebates directly to states, as described in the contract between the manufacturer and the federal government. The Social Security Act also required that the rebate be based on the total number or units of a drug paid for under the state Medicaid program and various pricing bases depending on whether the drug was a single-source or generic drug.

In 1992, new state legislation was implemented that significantly amended the policies of the program. This new legislation allowed the department to expand the current contracting activities to include those drug manufacturers without state rebate contracts. The legislation also allowed the department to aggressively negotiate with drug manufacturers to achieve the savings outlined in the Budget Act of 1992. To achieve these savings, the department implemented the provisions of the 1992 legislation in a manner that required manufacturers to negotiate a higher rebate than the federal rebate. If the manufacturer refused to negotiate a higher rebate, the department could counter by removing the manufacturer's product line from the LCD.

The other legislative change required the department to negotiate or renegotiate contracts to ensure that there are as many single-source drugs within each therapeutic category of drugs as the department determined necessary to meet the needs of the Medi-Cal population. The department implemented the therapeutic category review process to accomplish this requirement. This process reviewed a specific category of drugs designed to address a particular symptom or ailment rather than a single drug.

Legislation enacted in 1994 requires manufacturers to submit
a supplemental rebate for all drugs subject to the federal rebate. The supplemental rebate is 10 percent of the average manufacturer's price for all drugs paid through Medi-Cal, except for specific drugs that are exempted by state statutes.

The legislation allowed those manufacturers that had already negotiated contracts with the department based on the 1992 provisions to apply their existing negotiated supplemental percentage against the mandated amount. For example, if the manufacturer was already submitting a negotiated supplemental rebate of 6 percent of average manufacturer price, it would need to remit only an additional 4 percent. However, if a manufacturer did not sign a supplemental rebate contract, the legislation required the department to make its drugs available only through prior authorization. The supplemental rebate law is scheduled to expire on June 30, 1996.

The existing program operates as follows. Providers, usually pharmacists, request reimbursement from the State for the
drugs they provide to Medi-Cal beneficiaries. The department reimburses the providers at the lowest of four predetermined pricing bases. The four bases are average wholesale price less 5 percent, estimated acquisition cost, federal allowable cost, and maximum allowable ingredient cost. The department accumulates utilization data from the Medi-Cal drug claims submitted by the providers. At the end of each quarter, the department invoices the drug manufacturers for the federal rebate and requests that they submit the supplemental rebate.

The department's Medi-Cal contracting section administers the program. The department has budgeted 17 positions for this section, including 8 pharmaceutical consultants. According to a department summary, the main function of the section is to develop policies regarding the scope of the drugs and medical supplies available to Medi-Cal beneficiaries. The contracting section also negotiates contracts with manufacturers to obtain rebates and reviews drug therapies and medical supplies to ensure that the most cost-effective drugs and products are included on the LCD and Medical Supplies List.

Scope and Methodology

The purpose of this audit was to determine whether the program had realized any savings since fiscal year 1990-91 and to assess the accessibility of drugs to Medi-Cal beneficiaries without prior authorization.

To determine whether the department used different methodologies to estimate cost savings for different fiscal years or for changes in the program, we interviewed department staff members to obtain the department's current and previous methodologies for estimating savings. We also evaluated how these methodologies affected the department's presentation of the savings that it reported to the Legislature.

We ascertained the amounts of savings realized since fiscal year 1990-91 and compared the results to the department's estimates. Specifically, we compared the actual rebates collected with the department's estimate of collections by fiscal year. Because rebates are the only portion of the department's estimates of savings that are measurable, we did not have any data to compare to the department's other estimates of savings.
The rebates pertaining to fiscal years 1990-91 through 1994-95 that the department collected through February 29, 1996, were based on data we obtained from the department's accounting records. We did not determine the accuracy of all of this data; however, we corrected for errors that came to our attention, such as supplemental rebate collections recorded as federal rebate collections.

To determine the extent to which quantifiable offsetting costs are included in the department's cost-benefit analysis of adding drugs to or deleting drugs from the LCD, we interviewed department staff members to identify those factors that
the department considers in its cost analyses of drugs being reviewed and assessed the department's level of documentation used in these analyses.

We summarized the number of drugs added to and suspended from the LCD between October 1994 and November 1995, the first 14 months affected by the 1994

legislation, to ascertain whether the program resulted in a greater or lesser selection of drugs available to Medi-Cal beneficiaries without prior authorization.

To determine the total amount of state supplemental rebates collected by the department, we reviewed the department's budget estimates and payment records for supplemental rebates for fiscal year 1994-95, the first year affected by the 1994 legislation. We also summarized the total amount of supplemental rebates that the department collected for fiscal years 1990-91 through 1993-94.

Because of the lack of complete supporting documentation, we were unable to determine the number of instances in which therapeutically equivalent or superior drugs as compared to those drugs already on the LCD were rejected in place of more or equally costly drugs already on the LCD. However, we asked the department staff about the process of evaluating drugs to be included on the LCD, and we reviewed any documentation supporting its decisions to add, not add, retain, or remove drugs from the LCD. In addition, we determined the extent to which the department added or retained drugs on
the LCD that represented the lowest net cost to the State.

Chapter 1

The Department Has Not Collected Approximately $40 Million in Supplemental Rebates From Drug Manufacturers

Chapter Summary

The Department of Health Services (department) has not collected approximately $40 million in supplemental rebates owed to the State by drug manufacturers because it has not adequately administered the Medi-Cal drug rebate program (program). The department does not calculate and bill specific supplemental rebate amounts owed by manufacturers. Further, the department has failed to monitor and track supplemental rebate payments and sanction manufacturers who do not remit the required amounts owed to the State and the federal government. As a result, the State and the federal government do not receive all the rebates due from manufacturers.

Supplemental Rebates Should Generate Approximately $70 Million

The department calculated that the drug manufacturers who have signed supplemental rebate contracts owe the State approximately $70 million in supplemental rebates for drugs reimbursed through Medi-Cal during fiscal year 1994-95. However, the department has only collected approximately $30 million, or 43 percent of this total, as seen in Table 1. Therefore, a total of approximately $40 million remains due to the State and the federal government. Section 14105.335 of the Welfare and Institutions Code defines the supplemental rebate as equal to 10 percent of the average manufacturer's price (AMP). However, the department has not acquired the AMP data and thus cannot bill manufacturers for exact amounts owed.

Table 1

Comparison of Budget Estimates and Actual Rebates for Supplemental and Federal Rebates Collected Through February 1996 (in Millions)

	Supplemental Rebate	Federal Rebate
	Fiscal Year 1994-95	**Fiscal Years 1990-91 Through 1994-95**
Budget estimate	$70	$757
Rebates collected through February 1996	30	661
Difference	**$40**	**$ 96**
Percent of estimate received	43%	87%

Note: Although the department has collected 87 percent of the $757 million federal rebate budget estimate, it has collected only 81 percent of the $818 million federal rebate amounts that were invoiced. The department's budget estimate is less than the invoiced amount because the department reduces its budget estimate for invoices with unresolved disputes.

Ingredient costs can be used to estimate Medi-Cal drugs' AMPs.

Because the department has not acquired the AMP data, it estimated the total amount of supplemental rebates that the State was entitled to receive by calculating the adjusted total ingredient cost of all outpatient drug claims paid during calendar year 1994 and then multiplying this amount by 10 percent. The ingredient cost is the lowest of four predetermined bases and represents the price paid by the State to providers. These bases, defined by the federal government and industry data, are average wholesale price less 5 percent, estimated acquisition cost, federal allowable cost, and maximum allowable ingredient cost. The department adjusted the ingredient cost to approximately 80 percent to exclude drugs that were statutorily exempt from rebates, to account for differences between the AMP and ingredient cost pricing bases, and to account for the net reduction in rebates resulting from those manufacturers refusing to sign the supplemental rebate contracts. According to the chief of the department's Medi-Cal

contracting section (contracting section), the total ingredient cost, as adjusted, is a reasonable substitute for estimating supplemental rebate amounts that were owed.

To determine the relationship between AMP and ingredient cost, we selected a sample of 127 drugs of manufacturers who paid the supplemental rebate and who provided supporting calculations for the amounts remitted. Based on this information, we determined the AMP for these drugs. After comparing the AMP to the ingredient cost of each drug, we determined that, on average, the AMP represents approximately 80 percent of the ingredient cost of each drug. Considering that our estimate of the AMP as a percentage of ingredient cost is consistent with the department's estimate of the AMP as a percentage of adjusted ingredient cost, its rebate estimate of approximately $70 million in supplemental rebates appears reasonable. Therefore, the department has not collected approximately $40 million in supplemental rebates owed to the State and the federal government.

The Department Does Not Calculate Individual Supplemental Rebates

Invoices to manufacturers do not specify the dollar amount owed for the supplemental rebate.

The department does not calculate specific amounts due from each manufacturer for supplemental rebates when it prepares rebate invoices. Thus, the invoice that a manufacturer receives does not specify how much money is owed under the supplemental rebate program. Section 14105.335 of the Welfare and Institutions Code stipulates that the department use the AMP as the pricing base for calculating the supplemental rebate. The Welfare and Institutions Code refers to AMP as it is defined in the manufacturer's rebate contract with the federal Health Care Financing Administration (HCFA) under Section 1927 of the Social Security Act (42 U.S.C. 1396r-8). Manufacturers will routinely submit AMP data for their products to the HCFA. The HCFA uses the AMP data to compute pricing data provided to the department for the federal rebate. However, according to a HCFA administrator we contacted, HCFA will not release AMP data to the department because HCFA believes that the information is confidential.

Because AMP data are unavailable from the federal government, we would expect the department to invoice manufacturers for specific amounts based on drug utilization and AMP data it is required to use by the Welfare and Institutions Code. For example, for the federal rebate, the department has an electronic data processing system that invoices a manufacturer for a specific amount based on the drug utilization data it maintains and the federal rebate pricing data it receives from the HCFA. In addition, we would expect the State to require the drug manufacturer to provide its AMP data to the department within 30 days after the end of the quarterly rebate period just as the federal government requires of manufacturers for the federal rebate. Further, similar to the federal rebate legislation, we would expect the State to implement sanctions if this requirement is not met.

For the supplemental rebate program, we found that the department did not prepare an invoice specifically for the supplemental rebate that stated the drug utilization data, the AMP, the contract identification number on which the claim was based, or any penalties for nonpayment. Instead, the department stated on the federal rebate invoice that supplemental rebate amounts were not included in the invoice total and instructed the manufacturer to calculate and submit required supplemental rebates along with the federal rebate payment. In addition, the document instructed the manufacturer to provide the department with the supporting data needed to reconcile the amount of any supplemental rebate being remitted. However, we found that most of the manufacturers did not provide this information to the department with their supplemental rebate payments. The document sent to the manufacturer did not state AMP data because the department did not require it from the manufacturer and, according to the chief of the contracting section, has been unable to acquire it from the HCFA.

According to the chief of the contracting section, the legislation was written using AMP as the pricing base because
the supplemental rebate was designed to be assessed on the
amount of revenue that the manufacturer generated. However, according to the chief, the department was fully aware

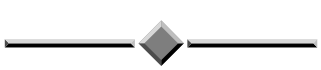
that it would not receive the AMP data before invoicing the manufacturers. Instead, the department believed that the manufacturers would provide the data when they paid the supplemental rebates.

Providing manufacturers with specific amounts owed generates a greater likelihood of payment.

Providing manufacturers with a specific amount due is important for several reasons. A specific amount on an invoice generates a greater likelihood of payment. For example, the department specifies the amount due for the federal rebate
and collects approximately 81 percent of amounts that are owed. In addition, identifying specific amounts on the invoice supports the department's collection efforts and allows for reconciliations of amounts received and due.

The Department Has Failed To Monitor and Track Supplemental Rebate Payments and Sanction Manufacturers

The department has failed to monitor and track supplemental rebate payments owed by manufacturers and has failed to sanction manufacturers who have not paid all rebates owed. Because it has not identified specific amounts owed by individual manufacturers and has not set up a system for monitoring payments, the department cannot determine whether amounts that are remitted are accurate. Also, the department does not promptly post payments to its records and does not track manufacturers who failed to submit rebates. Finally, if the department were to sanction manufacturers, it would assist them in receiving prompt and accurate information and receiving payments when they are due.



Some manufacturers pay incorrect rebate amounts and others do not pay at all.

For the manufacturers who are remitting supplemental rebates, the department has failed to verify the accuracy of these payments. Further, it does not ensure that all rebates are accompanied by AMP data and supporting calculations as required under provisions of the program. For example, we identified a quarterly rebate payment in which a manufacturer paid 10 percent of the total federal rebate instead of 10 percent of the AMP. We were unable to identify the total amount that was owed to the State and the federal government because of the lack of information provided by the manufacturer. Another quarterly rebate payment contained a sufficient level of detail to indicate

that the supplemental rebate calculated by the manufacturer was approximately 5.5 percent of the AMP, instead of the required 10 percent. Because of this difference, the department collected approximately $105,000 less than is owed.

Additionally, the department does not always post rebates received from manufacturers to its records promptly. As of February 1996, the department had not posted its quarterly rebate register to reflect the receipt of 24 rebate payments totaling approximately $6.1 million. Some of these remittances had been received and processed as far back as August 1995.

Although the department has the statutory authority to sanction manufacturers who do not agree to sign a state supplemental rebate contract by suspending their drugs from the Medi-Cal List of Contract Drugs (LCD), according to the chief of the contracting section, it does not have similar explicit statutory authority for manufacturers who signed these contracts and either paid an incorrect amount or did not pay any supplemental rebate. In addition, he stated that the department does not have explicit statutory authority to charge interest for late payments. For example, we identified one manufacturer who signed the supplemental rebate contract in August 1994 and owed the State and the federal government $35,485.18 in supplemental rebates for the period from July 1994 through June 1995. However, as of February 1996, the department has not received any supplemental rebates for three of the four quarterly billing periods and received a rebate of only
$841.40 for the other quarter, which represents less than 1 percent of the AMP. The department therefore has not collected $34,643.78 from this manufacturer and has not sanctioned the manufacturer.

According to the chief of the contracting section, the department does not have an aging process to identify those manufacturers who have not remitted supplemental rebates. He stated that manufacturers have a contractual obligation to provide accurate information as to the amount owed, and
the department has no independent means to determine if the amount being paid is correct.

At least 178 manufacturers contracting to pay supplemental rebates are delinquent.

Many manufacturers have failed to remit some or all of the supplemental rebates owed. As of January 1996, 319 manufacturers had signed supplemental rebate contracts. Of this total, 205 manufacturers owed supplemental rebates related to paid drug claims during one or more of the quarterly billing periods between July 1994 and June 1995. However, we determined that 178 of these 205 manufacturers, or approximately 87 percent, have not paid a supplemental rebate for one or more of the quarterly billing periods as of February 1996. Moreover, we determined that 92 of these 178 manufacturers, or approximately 52 percent, had not submitted any of their quarterly supplemental rebates as of February 1996. For many of those manufacturers remitting supplemental rebates, we were unable to determine if they had paid the correct amount because the payments lacked supporting AMP data.

The federal government believes accurate and prompt pricing information is important and has established sanctions for the federal rebate, of which the department collects approximately 81 percent of the amount it invoices. Section 1927 of the Social Security Act (42 U.S.C. 1396r-8[b]) provides for specific penalties related to the price information provided by manufacturers. These sanctions include a penalty of $10,000 per day if a drug manufacturer does not provide pricing information promptly, termination of the agreement if the information is not provided within 90 days of the due date, and a $100,000 penalty for each item of false information that the manufacturer knowingly provides. In addition, according to the department's billing invoice, interest will be charged on federal rebate payments that are late.

Between October 1994 and November 1995, the only drugs that the department suspended from the LCD were those that were produced by manufacturers who did not sign the supplemental rebate contracts. According to the chief of the contracting section, before October 1995, resolving manufacturers' disputes over federal rebate billing invoices was a priority because he believed the federal billing invoices represented significant outstanding receivables

and he allocated staff resources to this area instead of monitoring supplemental rebate payments.

In November 1995, the department implemented a procedure whereby it sends out a series of collection letters to manufacturers who have not remitted federal and supplemental rebates from previous quarters. These collection letters specify the quarter for which federal rebates are due and remind manufacturers to remit their state supplemental payments. According to the chief of the contracting section, the department is considering including the resolution of outstanding rebate obligations as part of its negotiation process with drug manufacturers to add drugs to the LCD.

Conclusion

The department's inadequate administration of the program as specified in the law has resulted in approximately $40 million of uncollected rebates owed to the State and federal government. Specifically, it has not identified specific amounts owed by individual manufacturers, has not tracked those failing to submit rebates, has not assessed whether the actual amounts received are appropriate, and has not determined whether it should be expecting rebates from certain manufacturers. In addition, it has failed to monitor and sanction manufacturers not complying with supplemental rebate contracts, which has contributed to the significant balance of uncollected rebates.

Recommendations

The department needs to strengthen its efforts to collect the supplemental rebates that are legally owed to the State and
the federal government. Specifically, the department should calculate a dollar amount for the supplemental rebate on each invoice it sends to manufacturers. If the department deems it impractical to collect and use AMP data before billing a manufacturer, it should seek statutory authority to use ingredient cost or another pricing base it already possesses as the statutorily approved pricing base.

The department also should focus on monitoring and sanctioning manufacturers. Each supplemental rebate payment should be verified for accuracy to ensure that the amount remitted is the amount owed. In addition, all receipts should be posted to the records promptly to assist in tracking manufacturers who owe rebates. The department also should establish sanctions for late information and inaccurate information. Moreover, it should sanction manufacturers who do not pay the rebate, do not pay the correct rebate, or pay the rebate late. If the department believes it does not have adequate statutory authority, it should seek legislative changes to allow the suspension of manufacturer's drugs from the LCD if it does not pay the rebate and to charge interest on late payments.

Chapter 2

The Department Does Not Clearly Document That Its Drug Reviews Address Legal Requirements

Chapter Summary

The Department of Health Services (department) uses two methods to modify the Medi-Cal List of Contract Drugs (LCD). One method is to conduct a therapeutic category review (TCR) that assesses a specific category of drugs designed to treat a particular symptom. The other is to conduct an individual drug review of a specific drug for addition to the LCD. When adding to, removing from, or retaining drugs on the LCD, the Welfare and Institutions Code requires the department to use the criteria of safety, effectiveness, essential need, misuse potential, and cost. Although the department prepares various types of documents related to its reviews and asserts that it conducts its drug reviews in accordance with criteria stipulated in the Welfare and Institutions Code, it does not uniformly prepare and maintain its documents in a manner that clearly demonstrates that these criteria were the basis for its decision.

The Department Uses Two Methods To Add Drugs to the LCD

The 1990 legislation describing the original drug discount program established the LCD. Those drugs that were part of the existing Medi-Cal Drug Formulary as of July 1, 1990, were automatically included on the LCD until the manufacturer and the department concluded contract negotiations. If the manufacturer did not agree to execute a contract offering its drugs at its best price, the manufacturer's drugs could be suspended from the LCD.

The department conducts therapeutic category reviews and individual drug reviews to modify the LCD.

The department uses two methods to add drugs to the LCD. One method is to conduct a TCR, which is a review

of a specific category of drugs designed to address a particular symptom or ailment. According to the supervising pharmaceutical consultant of the department's Medi-Cal contracting section (contracting section), the department selects the categories it plans to review based on areas of concern, such as cost, usage, and therapeutic value.

Another method is to conduct an individual drug review. According to the supervising pharmaceutical consultant, individual drug reviews result from a petition by a source outside the department, such as a manufacturer or a physician, or are initiated by the department staff.

The Department Cannot Demonstrate That It Conducts Drug Reviews in Accordance With Law

After the department announces a TCR or receives a petition, its pharmacy staff reviews the drug or drugs being considered. When the department adds drugs to, deletes them from, or retains them on the LCD, Section 14105.39(d) of the Welfare and Institutions Code requires the department to use the criteria of safety, effectiveness, essential need, misuse potential, and cost. Appendix C provides additional information on this review process. The department's written procedures consist of a one-page document that addresses the procedures for requesting recommendations from the Medi-Cal Contract Drug Advisory Committee (committee) members, sending correspondence of committee actions to the Pharmaceutical Research and Manufacturing Association, and notifying manufacturers that the committee will be reviewing their drugs. According to the supervising pharmaceutical consultant of the contracting section, pharmacy staff members adhere to the provisions in the Welfare and Institutions Code that outline the criteria to be followed, which he believes are sufficient to make decisions regarding changes to the LCD. Although the department may consider each of the five criteria stated in the law, we found that the documentation that the department prepares during its review process does not clearly demonstrate that it considered these provisions.

It is not clear whether the department followed all five criteria established in law when evaluating drugs for the LCD.

The department prepares various types of documents related
to its reviews but does not uniformly prepare and maintain its documents in a manner that clearly demonstrates that the criteria stated in the Welfare and Institutions Code were the bases for its decisions. As mentioned previously, the department solicits therapeutic recommendations from the committee for drugs being reviewed. Section 14105.4 of the Welfare and Institutions Code stipulates that these recommendations shall be in accordance with the criteria mentioned in the code. Ideally, the department should send evaluation forms to all committee members specifically requesting them to rate the safety, effectiveness, essential need, and misuse potential of the drugs being reviewed, along with explanations supporting their ratings and conclusions. Instead, the department requests that committee members provide "an evaluation as to which drugs being considered are essential for inclusion on the LCD to meet the health care needs of Medi-Cal beneficiaries." However, the department does not define or provide guidance for this evaluation. The department also asks the committee members to comment on those drugs that they believe are neither superior nor inferior, from a clinical and therapeutic point of view, relative to other drugs within the same therapeutic category. The department does not require or suggest a format for these comments.

Some drug advisory committee members recommended adding drugs to the LCD without providing supporting explanations.

As a result, the committee's responses do not specifically address the criteria specified in law and vary in their content. For example, some members stated in their responses that they were not recommending certain types of drugs because an adequate number of similar drugs were already on the LCD. Other members indicated that certain drugs should be added to the LCD but did not provide any explanations to support their recommendations. These responses did not specify whether the members considered the drugs being reviewed to be safe or effective, even though the Welfare and Institutions Code specifies that they use these criteria.

The department's pharmacy staff is responsible for reviewing the committee recommendations, performing analyses, and making recommendations on the drugs to be added, not added, removed, and retained. Pharmacy staff members also should be using a standard evaluation form

to document whether those drugs under review specifically meet the criteria in the Welfare and Institutions Code. Such a form would assist the department in establishing uniform evaluation parameters among its reviews. The files we reviewed did not uniformly or consistently document that the Welfare and Institutions Code criteria were the bases for actions taken. For example, one individual drug review file that we reviewed contained an analysis of the drug based on the criteria as well as an analysis of the costs. Another individual drug review file contained only a few notes discussing drug costs and no written therapeutic analysis that addressed safety, effectiveness, essential need, or misuse potential. For TCRs, the files contained cost analyses, correspondence to the drug manufacturers and to committee members requesting their input, and correspondence announcing committee recommendations and the department's decision. However, not all individual drug review files and TCR files included the same level of detail or support documenting the basis for decisions and verifying that all criteria were considered.

According to the supervising pharmaceutical consultant of the contracting section, individual pharmacists assigned to conduct the drug reviews are responsible for coordinating and supplying information to conduct these reviews. The supervising pharmaceutical consultant also stated that the pharmacy staff usually keeps this documentation at least until a decision is finalized and appeals are resolved, but the department does not have a formal policy for record retention in this area.

Further, according to the chief of the contracting section, the pharmacy staff does not prepare documents for individual drug reviews that specifically addressed that they considered the criteria stipulated in the Welfare and Institutions Code. He stated that the letter sent to the manufacturer indicating that its drug was not added identifies which of the criteria was the basis for the decision. If the letter indicates that the drug will not be added because of a concern with a therapeutic criterion, such as misuse potential, it can be implied that the other therapeutic criteria of safety, effectiveness, and essential need are acceptable. Cost may be a concern that needs to be addressed once the therapeutic concerns are

The department believes that it is not necessary to prepare written documentation addressing the five criteria.

resolved. Therefore, he believes that it is unnecessary to prepare internal written documentation addressing all five criteria.

Although the department asserts that it always considers the five criteria when it conducts drug reviews, without standardized and sufficient written documentation to support its conclusions, the department cannot document that all drugs are reviewed uniformly.

According to the chief of the contracting section, manufacturers are informed why their drugs are not added to the LCD. He indicated that manufacturers are aware of the therapeutic value of their own products in comparison with the products of their competitors. Further, he stated that manufacturers compete for formulary status with other manufacturers in the private sector as a regular part of their business operations and that the department's contracting activities are no different. He believes that manufacturers can assess how their drugs compare with other drugs in the market. The chief also stated that the department contacts manufacturers directly and negotiates rebates, so manufacturers should be aware of the cost evaluations performed by the department. Accordingly, manufacturers should know whether their drugs were rejected based on cost.

Conclusion

Although the department prepares various types of documents related to its reviews, it does not uniformly prepare and maintain its documents in a manner that clearly demonstrates that all evaluations are uniformly performed and that the criteria stated in the Welfare and Institutions Code were the basis for its decisions. As a result, the department cannot document that it considered all the criteria in the Welfare and Institutions Code when it made its decisions to include some drugs and exclude other drugs from the LCD.

Recommendations

The department should develop specific guidelines and documentation standards for conducting TCRs and individual drug reviews. Specifically, it should develop and retain standard evaluation documents and instruct the committee members and the pharmacy staff to use these during the review process. These documents should indicate whether the drug being reviewed meets each of the criteria stipulated in Section 14105.39(d) of the Welfare and Institutions Code.

In addition, pharmacy staff members should prepare schedules, analyses, and other relevant documentation to support their decisions.

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Chapter 3

The Supplemental Rebate Program Has Not Significantly Limited Accessibility to Drugs, and Potential Revenue From the Program Far Exceeds Program Costs

Chapter Summary

The supplemental rebate program has not significantly reduced the availability of drugs to Medi-Cal beneficiaries. Of the approximately 600 drugs on the Medi-Cal List of Contract Drugs (LCD) before July 1994, only 16 were suspended by the Department of Health Services (department) because the manufacturers of these drugs would not participate in the supplemental rebate program. In addition, the program is cost beneficial to the State. If the department properly administers the program, it can expect revenue of approximately $70 million, which is significantly higher than the total costs of $5 million required to administer the program.

The 1994 Legislation Has Had a Minimal Effect on Drug Availability

The original Medi-Cal drug discount program was established in 1990. One of the major objectives of this program was to ensure that Medi-Cal beneficiaries have access to appropriate drug therapies and a comprehensive range of drug products. Before this initial program was established, drugs for which Medi-Cal would reimburse could be added only by regulation.

New state legislation in 1994 implemented a supplemental rebate that manufacturers were required to submit for all drugs subject to the federal rebate, except for specific drugs exempted by state statute. This legislation stipulated that the drug products of any manufacturer who failed to sign a supplemental rebate contract by September 30, 1994, would be available to Medi-Cal

beneficiaries only through prior authorization. The department enforced this legislation by suspending 16 of the approximately 600 drugs on the LCD before July 1994 because six manufacturers would not participate in the supplemental rebate program.

The department initially identified 49 drugs subject to potential suspensions after the supplemental rebate law was implemented. As illustrated in Table 2, 17 of the 49 potential suspensions did not take effect because the manufacturers of these drugs signed the supplemental rebate agreement shortly after the department announced it would suspend these drugs from the LCD. Another 16 of the 49 drugs were not affected by the suspensions because they were still available on the LCD for various reasons. For example, Section 14105.35(a)(2) of the Welfare and Institutions Code stipulates that, in the absence of a contract with the manufacturer, the department's director may retain a drug on the LCD if she determines that an essential need exists for the drug and other drugs that meet the need are not on the LCD.

Table 2

Effect of the 1994 Legislation on the LCD

Total number of drugs initially designated by the department to be suspended		49
Number of drugs for which suspension was avoided because the manufacturers ultimately signed rebate contracts	17	
Number of drugs not affected by the suspensions	16	
Less: Total number of drugs that are still available on the LCD		33
Total Number of Drugs Suspended From the LCD as of November 1995		**16**

Only 16 drugs were suspended from the LCD because the manufacturers refused to participate in the program.

Another reason that the department did not suspend a drug from the LCD is that the drug is available from a different manufacturer who signed a supplemental rebate contract with the department. The remaining 16 drugs, produced by a total of six drug manufacturers refusing to sign the supplemental rebate contract, are not available in any form on the LCD as of November 1995. As seen in Appendix D, we found that these 16 drugs covered seven therapeutic categories. A drug that the department suspends from the LCD is still available without prior authorization to those beneficiaries who had access to the drug before its suspension. As a result, the only beneficiaries who would require prior authorization from the department were those who initially requested the drug after its suspension.

Between October 1994 and November 1995, the department added 17 new drugs to the LCD as a result of therapeutic category reviews and individual drug reviews. These drugs are not intended to replace the 16 drugs that the department suspended from the LCD as a result of the 1994 legislation. As shown in Appendix E, these 17 drugs covered seven therapeutic categories.

Potential Revenue From the Supplemental Rebate Program Far Exceeds the Program Costs

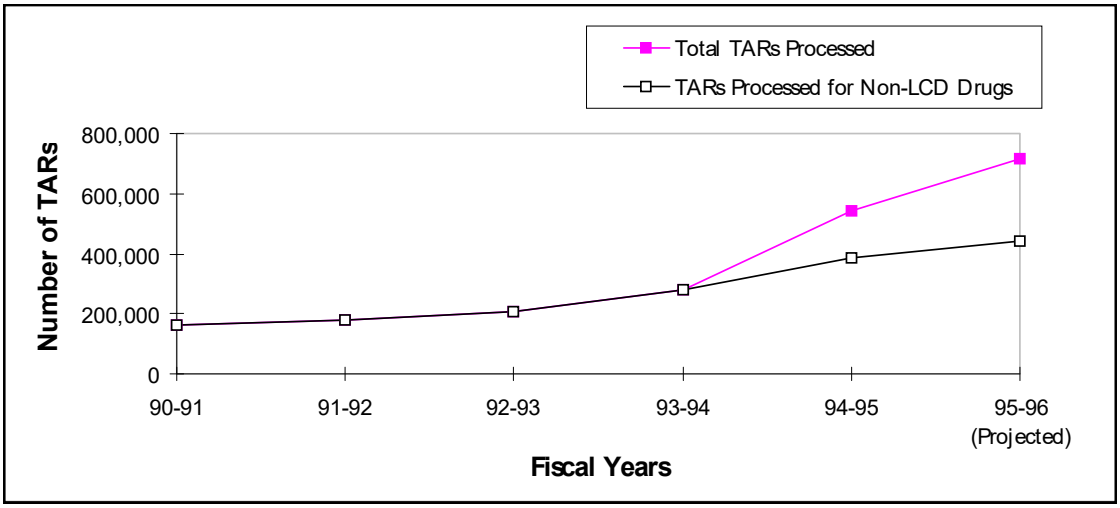
The suspension of the 16 drugs from the LCD resulted in only two TARs approved for these drugs during fiscal year 1994-95.

To determine whether the 1994 legislation establishing the supplemental rebate program resulted in administrative costs that outweigh the potential revenue that the supplemental rebate program could generate, we first analyzed the treatment authorization requests (TAR) for the 16 drugs that had been suspended from the LCD. A provider submits a TAR to request prior approval from the department for reimbursement for drugs not on the LCD prescribed for Medi-Cal beneficiaries. To determine if the suspension of the 16 drugs caused an increase in TAR activity, we identified the number of TARs approved for these drugs after the effective date of the 1994 legislation. We found that suspension of the 16 drugs resulted in a total of only two TARs approved for these drugs during fiscal year 1994-95. Therefore, the department did not incur any significant additional costs for approving TARs for these 16 drugs.

Next, we reviewed the change in the number of TARs processed by the department from fiscal year 1990-91 through fiscal year 1995-96. We projected fiscal year 1995-96 TARs processed based on actual data for the first six months of this year. As illustrated in Figure 1, the department processed 281,572 TARs in fiscal year 1993-94 and 544,824 TARs in fiscal year 1994-95. Of the fiscal year 1994-95 total, 387,872 TARs pertain to requests for drugs that were not on the LCD. The remaining 156,952 additional TARs processed pertain to a policy change that the department implemented during fiscal year 1994-95 that required providers to submit a TAR if a beneficiary exceeded a specific number of prescriptions.

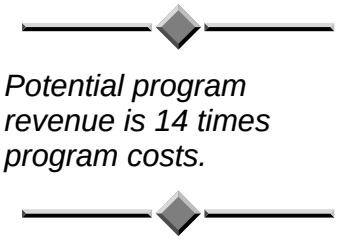
Figure 1

TARs Processed From Fiscal Year 1990-91 Through Fiscal Year 1995-96



Although we found that the number of TARs approved following suspension of the 16 drugs from the LCD was minimal, we identified the fiscal year 1994-95 administrative costs associated with operating the program. We have included the administrative cost of TARs that the department processed for drugs not on the LCD as well as the staffing costs of the department's Medi-Cal contracting section (contracting section), the section responsible for administering the program. First, we calculated the fiscal year 1994-95 administrative

costs associated with the department's processing of the 387,872 TARs described above. Based on the costs of processing TARs, including staffing costs for pharmacists, medical transcribers, and pharmaceutical consultants, as well as overhead costs, we calculated an average cost per TAR of $9.40 for fiscal year 1994-95. This amount includes additional costs of contract staff members whom the department brought in to assist with the processing of TARs during this period. Therefore, the department incurred costs of approximately $3.7 million to process TARs for drugs not on the LCD in fiscal year 1994-95.



Potential program revenue is 14 times program costs.

We also identified the fiscal year 1994-95 staffing costs of the department's contracting section. According to data provided by the department's budget division, fiscal year 1994-95 personnel costs for the department's contracting section were approximately $1.3 million. Therefore, we determined that the department incurred costs of approximately $5 million during fiscal year 1994-95 to administer the program. The potential revenue from the fiscal year 1994-95 supplemental rebates of approximately $70 million far exceeds the department's costs of administering the program.

In contrast, the department realized only $10.5 million in collections of fiscal year 1993-94 supplemental rebates from the program under the 1992 legislation, when the department aggressively negotiated with drug manufacturers for rebates. Clearly, the potential revenues from properly administering the present program far exceed the revenues actually received from the prior program.

Conclusion

The supplemental rebate program has not significantly reduced the availability of drugs to Medi-Cal beneficiaries. Only 16 drugs were suspended from the LCD by the department because the manufacturers of these drugs would not participate in the supplemental rebate program. In addition, the program is cost beneficial to the State. If the department properly administers the program, it can expect revenue of approximately $70 million, which is significantly higher than the total cost of approximately $5 million required to administer the program.

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

Respectfully submitted,

KURT R. SJOBERG
State Auditor

Date: March 27, 1996

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Appendix A

A History and Analysis of the Estimates of Savings Related to the Medi-Cal Drug Rebate Program

In the following pages, we have provided details of the specific estimates addressed in the fiscal year 1990-91 Governor's Budget Summary and a therapeutic category review (TCR) report submitted to the Legislature. Additionally, we have provided details of the estimated net savings that the Department of Health Services (department) included in its revised budget estimate policy changes prepared in May of each year. These estimates are made for both the current and budgeted years each November and are revised the following May. Each estimate accounts for both the federal and state portion of expected revenues or required funding. For estimation purposes, the department assumes an equal distribution between the federal government and the State. These policy change estimates have also been summarized in Appendix B.

State Original Drug Discount Program Rebates

In the fiscal year 1990-91 Governor's Budget Summary, the department estimated that a $50 million savings ($23.9 million to go to the State's General Fund) would be generated by implementing the proposed Medi-Cal Drug Discount Program, scheduled to become effective in January 1991. The estimate was developed in a May 1990 Medi-Cal policy change. The savings were associated with price reductions offered by drug manufacturers who were expected to contract with the State under the proposed program. Although no contracts had been negotiated at that time, the department estimated a 30 percent savings on the ingredient cost of all prescription drugs purchased under Medi-Cal. However, this program, which included a feature whereby the State would assume ownership of the drugs, was never approved. Alternatively, the department implemented a

drug discount program in July 1990. In the revised budget policy change for fiscal year 1990-91, the department estimated cash basis savings of $8.86 million ($4.43 million to go to the State's General Fund) from rebates related to the first 11 contracts negotiated under the program. According to the chief of the Medi-Cal contracting section (contracting section), the department did not make any further estimates to the original drug discount program because the focus of the contract negotiations changed as a result of the required rebates under the new federally mandated program. The chief also stated that the savings were difficult to estimate because conditions varied between contracts.

Federal Rebates

The nationwide mandated drug rebate program was implemented in January 1991. In the revised budget for fiscal year 1990-91, the department added a policy change that estimated cash basis savings of $3.5 million ($1.75 million for the State's General Fund) related to this new program. The estimate was based on 12 percent of annual paid prescriptions and allowed for the midyear program implementation date. At the time, federal regulation required a minimum 12.5 percent rebate on single-source and innovator multiple-source drugs, and a 10 percent rebate on all other drugs. The department has continued to estimate annual savings related to this program.

In the revised budget policy change for fiscal year 1991-92, the department estimated cash basis savings of $73.5 million ($36.75 million for the State's General Fund) based on the prior quarterly billing invoices and applying a 90 percent collection rate to account for billing disputes. Four quarters of data were available at that time. For fiscal year 1992-93, the department estimated cash and accrual basis savings of $234.7 million ($117.35 million for the State's General Fund) based on the prior six quarters of billing invoices and a 90 percent collection rate. For fiscal year 1993-94, the department estimated accrual basis savings of $217.26 million ($108.63 million for the State's General Fund) based on a five-quarter average and a 95 percent collection rate. Finally, for fiscal year 1994-95, the department estimated accrual basis savings

of $219.4 million ($109.7 million for the State's General Fund) based on a seven-quarter average and a 95 percent collection rate. The department reduced this estimate by an additional 5 percent to account for the implementation of prescription limitations placed on drug treatment authorization requests (TAR) during the fiscal year.

State Negotiated Supplemental Rebates

The 1992 legislation stipulated the State's expanded role in negotiating with drug manufacturers. Therefore, the department began to include a separate budget policy change estimating the negotiated supplemental rebates that resulted from the department's aggressive contract negotiations. These supplemental rebates and related contract negotiations evolved from the contracts first negotiated when the original drug discount program was implemented in July 1990. In the revised budget policy change for fiscal year 1992-93, the department estimated accrual basis savings from these negotiated contract rebates at $39.5 million ($19.75 million for the State's General Fund). According to the chief of the contracting section, these rebates were difficult to estimate because the terms of each contract varied by manufacturer. The department expected an additional 5 percent in rebates over and above the federal rebate amounts and used this assumption as the basis for the supplemental rebate estimate.

In the revised budget policy change for fiscal year 1993-94, the department estimated negotiated supplemental rebates on an accrual basis of $9.9 million ($4.95 million for the State's General Fund). The estimate represented one quarter of the fiscal year 1992-93 supplemental rebate estimate. According to the chief of the department's fiscal analysis unit, this program transitioned to the new state 10 percent supplemental rebate program, which was to be implemented in fiscal year 1994-95.

State 10 Percent Supplemental Rebates

The 1994 legislation implemented a 10 percent supplemental rebate, effective July 1, 1994. According to

the department's budget estimate documentation, the initial purpose of this rebate was to fill a $20 million ($10 million for the State's General Fund) budget deficit. This deficit was created by a budget year estimate, developed in May 1994, related to a proposed pharmacy management program that was never approved. The department determined that a rebate percentage of approximately 5 percent would generate $20 million over a six-month period.

According to the chief of the contracting section, the initial purpose of the rebate was to implement one component of a three-part negotiated budget agreement for fiscal year 1994-95. The 10 percent supplemental rebate was negotiated as a compromise to replace a previously proposed pharmacy management program that was reflected in the original fiscal year 1994-95 budget estimate. He further stated that the department's initial calculations assumed implementation of a 5 percent supplemental rebate but was ultimately doubled to 10 percent to balance the budget.

In the revised budget policy change for fiscal year 1994-95, the department estimated accrual basis savings of $69.8 million ($34.9 million for the State's General Fund) related to the 10 percent supplemental rebates. In developing this estimate, the department used the ingredient cost of total Medi-Cal drug claims paid during the calendar year 1994, excluding medical supplies and cancer and acquired immune deficiency syndrome (AIDS) drugs. This base amount was then reduced by approximately 21 percent to account for the difference between the ingredient cost and average manufacturer price and to account for manufacturers who would refuse to sign agreements. Adjustments were also made for the effect of the prescription limits placed on TARs during the fiscal year.

Other Savings and Costs Associated With the Program

The department submitted a report to the Legislature in February 1994 that addressed estimated savings related to its first three TCRs. For each drug category reviewed, the department projected annual savings related to lower ingredient cost expenditures and additional drug rebates.

These reviews covered the anti-ulcer agent category, the non-steroidal anti-inflammatory drug (NSAIDS) category, and the angiotension converting enzyme (ACE) inhibitor category. In the anti-ulcer agent category, the department estimated annual savings of $4.75 million as a result of deleting two drugs and renegotiating existing contracts for the retained drugs in this category. In the NSAIDS category, the department estimated annual savings of $8.57 million as a result of deleting one drug and renegotiating existing contracts. In the ACE inhibitor category, estimated annual savings were $6.85 million as a result of deleting seven drugs and renegotiating existing contracts. Total savings estimated as a result of the department's first three TCRs were $20.2 million. We did not attempt to validate any of these estimates.

As stated previously, the TCR report addressed savings to be generated from lowered ingredient costs as well as additional rebates. For budgeting purposes, the department included a separate policy change related to the savings that would be generated by limiting drugs as a result of TCRs. In the revised budget policy change for fiscal year 1993-94, the department budgeted for savings of $15.9 million ($7.95 million for the State's General Fund) expected as a result of restricting brand name and single-source drugs on the Medi-Cal List of Contract Drugs (LCD) through the TCR process. The additional rebate savings resulting from TCRs were included within the drug rebate policy change estimates.
Additionally, throughout the program, the department budgeted for various net costs related to maintaining the LCD. These amounts include costs of adding new drugs to the LCD as required by state law The amount of each of these budget estimates can be seen in Appendix B.

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Appendix B

Medi-Cal Drug Rebate Program Budget Estimates of Net Savings (in Thousands)

	Fiscal Year					Total Estimates	Rebates Collected	Percent Collected
	1990-91 1994-95	1991-92	1992-93	1993-94				
State original drug discount program rebates	$ 8,863					$ 8,863		
Federal rebates [a] [b]	3,540	$73,532	$234,735	$217,253	$219,408	748,468	$660,685	87%[c]
State negotiated supplemental rebates			39,500	9,875		49,375	13,118	27
State 10 percent supplemental rebates					69,741	69,741	29,891	43
Subtotal: Drug Rebates[d] (Revenue)	12,403	73,532	274,235[d]	227,128	289,149			
Other Savings and Costs Associated With the Program								
Perform therapeutic category reviews (Reduced cost)				15,918				
Add new drugs to the Medi-Cal List of Contract Drugs (Additional cost)	(5,559)	(1,597)	(9,582)	(1,997)	(5,997)			
Net savings related to the drug rebate program	**$ 6,844**	**$71,935**	**$264,653**	**$241,049**	**$283,152**			

[a] For fiscal year 1990-91, the department's accounting records commingled State original drug discount program rebate payments with the federal rebate payments. Accordingly, the total rebates collected and percent collected account for the original drug discount program rebate estimate of $8.863 million and the related payments.

[b] Federal rebates collected include rebates received for programs other than Medi-Cal. Based on the department's billing invoices, we determined that rebates related to these other programs are immaterial.

[c] Although the department has collected 87 percent of the $757 million federal rebate budget estimate, it has collected only 81 percent of the $818 million federal rebate amounts invoiced. The department budget estimate is less than the invoice amount because it reduces its budget estimate for invoices with unresolved disputes.

[d] During fiscal year 1992-93, estimates were converted from a cash basis to an accrual basis of accounting.

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Appendix C

The Medi-Cal List of Contract Drugs

Therapeutic Categories on the List of Contract Drugs

The List of Contract Drugs (LCD) contains various therapeutic categories associated with ailments relating to a particular function or area of the body. For example, the otic preparations category is for drugs related to the treatment of ear infections. Other categories include gastrointestinal drugs used in treating heartburn, anti-infectives used in treating conditions such as athlete's foot, and biological drugs, which include the flu vaccine. We have summarized the LCD into 14 major therapeutic categories, as seen in Table 3. As of November 1995, 594 specific drugs were listed on the LCD.

Table 3

Contract Drugs by Therapeutic Category as of November 1995

	Therapeutic Category	Number of Drugs on the LCD
1.	Anti-infectives	83
2.	Antineoplastics	57
3.	Autonomic drugs	47
4.	Biologicals	4
5.	Blood modifiers	10
6.	Central nervous system drugs	70
7.	Diuretics and cardiovasculars	71
8.	Gastrointestinal drugs	18
9.	Hormones	35

10.	Metabolic supplements	19
11.	Ophthalmic preparations	41
12.	Otic preparations	5
13.	Topical and local preparations	25
14.	Other	60
	Drugs with multiple categories	49
	Total	**594**

Source: Department of Health Services Medi-Cal contracting section.

The Department's Procedures for Adding Drugs to the LCD

As of February 1996, the Department of Health Services (department) has completed 11 therapeutic category reviews (TCR). The department completed its first TCR in January 1993 and finished its most recent TCR in February 1996. Refer to Table 4 for a summary of these TCRs. The department has also completed several individual drug reviews during the program's existence; however, it does not have a complete record of these reviews. According to the supervising pharmaceutical consultant of the department's Medi-Cal contracting section (contracting section), the department's list of individual drug reviews contains reviews performed only as far back as 1994. Table 5 summarizes the information we obtained from this list by major therapeutic category.

Table 4

Summary of TCRs Performed

	Date TCR Completed	Total Drugs Reviewed	Added to LCD	Retained on LCD	Removed From LCD	Not Added to LCD
1. Anti-ulcer agents	1/93	7	0	5	2	0
2. Angiotensin converting enzyme inhibitors	4/93	10	0	3	6	1
3. Non-steroidal anti-inflammatory drugs	4/93	25	0	14	1	10
Beta blockers	12/93	20	1	9	4	6

4.	Lipids	12/93	10	0	7	1	2
5.	Calcium blockers	12/93	13	2	9	0	2
6.	Asthma drugs	5/95	17	0	9	3*	5
7.	Antiparkinson drugs	2/95	14	1	9	0	4
8.	Dermatologic drugs	7/95	34	4	3	2*	25
9.	Antibiotics	9/95	136	6	50	5*	75
10.	Antidepressants	2/96	20	4	8	0	8
11.	**Total**		**306**	**18**	**126**	**24**	**138**

Source: Department of Health Services Medi-Cal contracting section.

* Section 14105.38 of the Welfare and Institutions Code requires the department to conduct a public hearing if it determines that a drug should be deleted from the LCD. As of November 1995, these drugs were still on the LCD because a public hearing had not been conducted.

Table 5

Summary of Individual Drug Reviews Initiated in 1994 and 1995

	Therapeutic Category	Total Reviews	Drugs Added	Drugs Not Added	Open, Deferred, or Canceled Reviews
1.	Anti-infectives	10	1	4	5
2.	Antineoplastics	0	0	0	0
3.	Autonomic drugs	22	2	17	3
4.	Biologicals	0	0	0	0
5.	Blood modifiers	1	0	1	0
6.	Central nervous system drugs	21	1	14	6
7.	Diuretics and cardiovasculars	12	4	7	1
8.	Gastrointestinal drugs	7	4	2	1
9.	Hormones	14	8	3	3
10.	Metabolic supplements	6	1	5	0
11.	Ophthalmic preparations	9	2	5	2
12.	Otic preparations	0	0	0	0
13.	Topical and local preparations	21	4	15	2
14.	Other	15	6	5	4
	Total	**138**	**33**	**78**	**27**

Source: Department of Health Services Medi-Cal contracting section.

The pharmacy staff at the contracting section contributes to both the TCR and individual drug reviews, with one pharmacist responsible for coordinating and supplying information necessary to conduct the review. After the department has decided to review a drug or category of drugs, both TCRs and individual drug reviews follow the same basic process. The department informs the manufacturers and the Medi-Cal Contract Drug Advisory Committee (committee) that it is conducting a TCR or an individual drug review. The committee consists of a separate advisory group comprised of at least one physician, a pharmacist, a Medi-Cal beneficiary, and a representative from schools of pharmacy or pharmacology. Committee members provide the department with recommendations on the therapeutic value of these drugs. The pharmacy staff considers these recommendations along with its own discussions of the specific drugs being reviewed.

The department considers the net cost of the drug to the State, which represents the amount reimbursed to providers less the rebate received from manufacturers. As explained in the following paragraph, in certain cases, the pharmacy staff performs a detailed cost analysis of the drugs under consideration. According to the chief of the contracting section, for TCRs, the pharmacy staff prepares its recommendations and the department's director makes the final decision. For individual drug reviews, the pharmacy staff prepares its recommendations and the chief of the contracting section makes the final decision. The department notifies committee members and manufacturers of the decisions. If necessary, the department's director decides on the outcome of appeals.

The Effect of TCRs on Drug Treatment Authorization Request Activity

To assess the effect of TCRs on drug treatment authorization request (TAR) activity, we reviewed the composition of TARs approved in fiscal year 1994-95 for

drugs not included on the LCD. During this year, three of the antidepressant category drugs, Paxil, Wellbutrin, and Prozac, comprised approximately 12.6 percent of these approved TARs. In February 1996, the department conducted a TCR for this category and added these three drugs to the LCD. As a result, we would expect the increase in the number of TARs for antidepressants in future fiscal years to be lower than it would have been without the TCR.

Consideration of Cost During the Review Process

As noted above, one of the components of the review process is a cost analysis. TCR cost analyses consist of computer spreadsheets that have several columns detailing various aspects of drug costs, including net cost to the State. The analyses are set up to depict a baseline mix, which represents the current status of drugs on the LCD along with a best rebate offer mix and several other mixes representing different combinations of drugs on the LCD. The pharmacy staff does not necessarily include all drugs in this analysis. According to the supervising pharmaceutical consultant, for TCRs, the staff discusses the various mixes and identifies the mix of drugs that results in the highest acceptable therapeutic value with an acceptable net cost to the State. He stated that for TCRs, the evaluation process includes a discussion of potential offsetting costs, such as adding a particular drug to save hospitalization costs in the future. However, according to the supervising pharmaceutical consultant, therapeutic superiority may outweigh lowest cost. Through October 1995, for six of the eight complete TCR cost analyses available, the department selected a mix that did not project the lowest net cost. For two of the eight, the department selected the lowest cost drug combination.

In November 1995, the department continued to compute net cost to the State when performing its cost analysis for the TCR of the antidepressant category. However, for this TCR, the pharmacy staff included quantifiable offsetting costs,

such
as hospitalization costs, as part of its overall analysis. According to the supervising pharmaceutical consultant, although quantifiable offsetting costs were not included as part of the overall analysis until the TCR for the antidepressant category was conducted, unquantifiable offsetting costs have been considered and used as part of the overall evaluation process for the previous TCRs.

According to the supervising pharmaceutical consultant, the pharmacy staff always evaluates the cost of a drug during an individual drug review. However, the department has not retained cost analysis documentation for all drugs.

Important Therapeutic Gain Drugs

Section 14105.39(c) of the Welfare and Institutions Code specifies that any new drug designated as having an important therapeutic gain and approved for marketing by the federal Food and Drug Administration (FDA) shall be immediately included on the LCD for a period of three years provided that certain conditions are met. Before 1992, the FDA developed a drug classification and priority review policy to use in identifying new drugs that it scheduled to review. The drugs that the FDA rated "A" were considered drugs that had an important therapeutic gain. Those drugs that were rated "B" or "C" were considered drugs that had a modest therapeutic gain or little or no therapeutic gain.

In January 1992, the FDA revised its drug classification and priority review policy and classified new drugs with a "P" or "S" rating. The new policy focused on identifying the drugs that had a priority status for FDA review, which were coded "P," and those that could be reviewed through the standard process, which were coded "S." The code "P" drugs included, among others, those that represented a therapeutic advance with respect to available drug therapy. The code "S" drugs were those that appeared to have therapeutic qualities similar to
those of one or more already marketed drugs. According to the chief of the contracting section, the current FDA "P" and
"S" drug classification and priority review policy does not

designate drugs as having important therapeutic gain. Therefore, he believes that Section 14105.39(c) of the Welfare and Institutions Code is obsolete and cannot be enforced because there is no unbiased source of information to designate which drugs represent important therapeutic gain.

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Appendix D

Therapeutic Classifications of the 16 Drugs Suspended From the List of Contract Drugs as a Result of the 1994 Legislation

Anti-infectives	Cefonicid Sodium Cefuroxime Axetil Oxiconazole Nitrate*
Autonomic drugs	Diphenidol Ondansetron
Central nervous system drugs	Ethosuximide Fentanyl Methsuximide Phensuximide
Diuretics and cardiovasculars	Quinapril Hydrochloride Triamterene
Otic preparations	Hydrocortisone with Neomycin and Colistin
Topical and local preparations	Alclometasone Dipropionate Anthralin Oxiconazole Nitrate*
Other	Ambenonium Chloride Auranofin

*This drug has two therapeutic classifications.

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Appendix E

Therapeutic Classifications of the 17 Drugs Added to the List of Contract Drugs Between October 1994 and November 1995

Anti-infectives	Amikacin Sulfate Ceftazidime Ceftriaxone Sodium Erythromycin Base Flucytosine Piperacillin Sodium
Antineoplastics	Medroxyprogesterone Acetate* Vinorelbine Tartrate
Autonomic drugs	Pergolide Mesylate
Biologicals	Immune Globulin, RH_o (D), Intravenous
Central nervous system drugs	Doxepin Hydrochloride Temazepam
Hormones	Estrogens, Conjugated with Medroxyprogesterone Acetate Estrogens, Esterfied with Methyltestosterone Medroxyprogesterone Acetate* Metformin Hydrochloride
Topical and local preparations	Fluocinonide Prednicarbate

*This drug has two therapeutic classifications.

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California State Auditor's Comments:

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

We agree with the department that there is some uncertainty as to the exact amount of supplemental rebates collected. As stated on page 4 of our report, the amount we calculated represents the rebates that the department collected through February 29, 1996, based on data we obtained from the accounting records. We did not determine the accuracy of all of this data; however, we corrected for errors that came to our attention. The nature of these errors could cause the supplemental rebate collections to be understated and the federal rebate collections to be overstated.

The department misinterpreted our recommendation. If using average manufacturer price for billing is impractical, we recommended that the department seek statutory authority to use ingredient cost or another pricing base it already possessed as the statutorily approved pricing base. Our intention was a replacement for the price component of the calculation rather than a surrogate that would require a labor intensive reconciliation. We added the phrase "as the statutorily approved pricing base" to clarify our recommendation.