California State Auditor

BUREAU OF STATE AUDITS

Department of Health Services:

Its Drug Management Techniques Are Similar to Those of Health Maintenance Organizations

December 1997
96038

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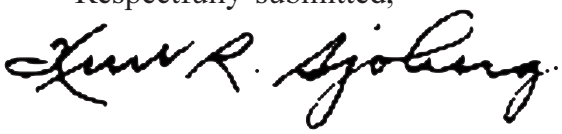
The Governor of California
President pro Tempore of the Senate
Speaker of the Assembly
State Capitol
Sacramento, California 95814

Dear Governor and Legislative Leaders:

As required by Chapter 197, Statutes of 1996, the Bureau of State Audits presents its audit report concerning the drug management techniques of the Department of Health Services Medi-Cal drug contracting program. This report concludes that generally the department's use of drug management techniques is on a par with the HMOs we surveyed. Although it could expand its use of some techniques, it generally employs all those that are suited to the Medi-Cal Program.

Respectfully submitted,



KURT R. SJOBERG
State Auditor

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Summary

Audit Highlights . . .

We compared the department's drug management techniques to those of HMOs and found that although they are generally on a par, the manner or extent to which the department uses some of them may differ. Specifically, the department:

- ☑ ***Uses 11 of the 14 drug management techniques that HMOs employ.***
- ☑ ***Has a formulary that is comparable in size and range to the HMOs' formularies but offers fewer of the most commonly prescribed drugs.***
- ☑ ***Does not employ drug use reviews as extensively as HMOs and does not use them to identify drugs for possible addition to the formulary.***
- ☑ ***Has more drugs on its formulary covered by rebate agreements but, unlike the HMOs, cannot calculate the rebate and bill the manufacturers for the amount owed.***

Results in Brief

The Department of Heath Services (department) is responsible for administering the California Medical Assistance Program (Medi-Cal). Medi-Cal provides a wide array of heath care services, including payment for prescription drugs to public assistance recipients and low-income families. The department employs a number of drug management techniques designed to optimize care while minimizing costs.

Generally, the department's drug management techniques are on a par with those of Health Maintenance Organizations (HMOs). We compared them to those used by 14 HMOs and found the department employs 11 of the 14 techniques. Of the 3 it does not employ, 1 is not widely used by the HMOs and 2 are not applicable to the state program. While the department uses most of the same techniques, it does not use some in the same manner or to the same extent as the HMOs. There are differences in the list of preferred drugs (formulary), drug use reviews, and rebates.

The Medi-Cal formulary is comparable to those of HMOs in the number and range of drugs it offers. However, it offers fewer of the most commonly prescribed medications because the drugs either cost more than other comparable drugs or are prone to misuse. Nonetheless, if medically necessary, a Medi-Cal recipient can obtain these drugs with the department's approval.

Also, although the department employs drug use reviews, it does not do so as extensively as the HMOs. Both use on-line computer messages or screens to alert pharmacists of a drug's potential adverse effects, but the department screens only a few of the drugs on the Medi-Cal formulary while the HMOs screen all drugs on their formularies. Additionally, unlike some HMOs, the department does not obtain or review nonformulary drug use statistics to identify drugs for possible inclusion on the formulary.

Further, the department and most HMOs negotiate rebate agreements with drug manufacturers. However, while the HMOs base their rebates on a price that is published and readily available, the department bases its on a price known only to the drug's manufacturer. Thus, unlike the department, HMOs can calculate rebates and bill manufacturers for the amount owed.

Recommendations

The department should continue to expand its use of drug management techniques. Additionally, it should stay abreast of new techniques HMOs and other third-party payers use to manage their prescription benefit plans and consider adopting those methods that are effective and suited to the Medi-Cal program. Finally, the department should calculate state rebates using an available price base.

Agency Comments

The department concurs with our recommendations and is interested in generating a report to identify high-demand drugs and developing additional step care guidelines. In addition, it expects to add more drug alert screens in the near future and is committed to seek out and implement new drug management techniques when possible. Finally, the department states that it is now able to negotiate rebate agreements using a basis that will allow it to calculate rebates.

Introduction

Background

The Department of Health Services (department) is responsible for administering the California Medical Assistance Program (Medi-Cal). Medi-Cal provides a wide array of health care services, including payment for prescription drugs to public assistance recipients and low-income families. Over five million Californians receive Medi-Cal benefits, and most of these participate in the traditional fee-for-service plan. Although Medi-Cal also offers managed care plans, the focus of this report is on the drug management techniques used in the fee-for-service plan.

Under the fee-for-service plan, Medi-Cal patients may obtain services or supplies from any physician or pharmacist who has agreed to serve them. The department establishes reimbursement rates and the physician or pharmacist bills it for services or supplies provided to the Medi-Cal patient.

Health Maintenance Organizations (HMOs) are the oldest form of managed care plans. They offer members a range of health benefits, including preventive care, for a set monthly fee. The HMO provides patients a list of doctors from which to choose a primary care physician. The primary care physician coordinates the patient's care, which means the patient must contact his or her doctor to be referred to a specialist. If the patient goes outside the HMO for care without a referral from the plan, he or she may be responsible for the total cost of services. Managed care's emphasis on primary care is intended, in part, to increase the use of preventive services and thus reduce costs.

Two major differences exist between the Medi-Cal fee-for-service and managed care programs. One difference is the amount of physician oversight or management of care. Specifically, though not encouraged, Medi-Cal allows the patient to see a number of physicians. In fact, one physician may not be aware that the patient has sought help elsewhere for a given complaint. In contrast, managed care programs coordinate which physicians patients consult. This integrated approach allows the physicians to be more aware of patient history and facilitates their ability to manage patient health care.

Another significant difference between Medi-Cal and managed care programs is the amount of responsibility physicians assume for controlling health care costs. Specifically, while Medi-Cal places reimbursement limits on specific procedures or medical services provided to its patients, physicians assume little responsibility for ensuring that patients receive the most cost-effective health care. In contrast, managed care plans are responsible for providing case management and health maintenance on a capitated per-month fee. If a patient's health care costs exceed that fee, the plan risks losing money. For example, some managed care plans give physicians a monthly drug budget, penalizing them if they go over it. This "risk sharing" provides physicians an incentive to consider the cost-effectiveness of the drugs they prescribe.

The Medi-Cal List of Contract Drugs and Drug Rebates

Two of the techniques the department uses to ensure that Medi-Cal fee-for-service patients receive prescription drug benefits that are both therapeutic and cost effective are the Medi-Cal List of Contract Drugs (Medi-Cal formulary) and rebate negotiation with drug manufacturers. A drug formulary is a list of preferred drugs from which a physician can prescribe and for which a pharmacy can seek reimbursement.

The department adds drugs to the Medi-Cal formulary in two ways. One method requires a therapeutic category review (TCR) to assess a group of drugs designed to treat a particular symptom. The other calls for an individual drug review. According to the supervising pharmaceutical consultant, the department selects the categories for a TCR based on areas of concern such as cost, usage, and therapeutic value. Although the department may initiate an individual drug review, generally an outside source such as a drug manufacturer initiates it by petitioning the department.

Both of these reviews follow the same basic process. First, the department informs drug manufacturers and the Medi-Cal Drug Advisory Committee (committee) that it is conducting a TCR or individual drug review. It requests the committee, which consists mainly of physicians and pharmacists, to evaluate the drugs under consideration. The committee evaluates the drugs using specific criteria, including safety, effectiveness, essential need, misuse potential, and cost. Based on this evaluation, the committee recommends for inclusion on the formulary those drugs it finds are essential to meet the health care needs of Medi-Cal patients.

Meanwhile, the department's staff meet with manufacturers to discuss a drug's therapeutic aspects and to negotiate rebates. In addition, the department's pharmacy staff reviews each drug using the same criteria as the committee. In their evaluation, the staff consider the committee's findings, the manufacturer's input, and other sources of information, such as clinical studies. They then submit their recommendation for TCRs to the department director, who makes the final decision, or their recommendation for individual drugs to the chief of the department's Medi-Cal contracting section, who decides. The process is designed to ensure that Medi-Cal patients have access to a range of drug products the department considers both therapeutic and cost effective.

The State also receives federal rebates from drug manufacturers in addition to the rebates the department negotiates when adding drugs to the formulary. In January 1991, the federal government implemented a nationwide mandatory drug rebate program. Under this federal program, drug manufacturers are required to submit quarterly rebates directly to states for each drug reimbursed through the medical assistance program, as described in the contract between the manufacturer and the federal government. As a result, all drugs on the Medi-Cal formulary are covered under a federal rebate agreement and some are also covered under a state rebate agreement.

Scope and Methodology

Chapter 197, Statutes of 1996, requires the Bureau of State Audits (bureau) to compare the drug management techniques of the department's drug contracting program with those of private sector third-party payers, such as HMOs.

To determine how the department manages drug benefits for Medi-Cal recipients in the fee-for-service plan, we interviewed department staff and reviewed laws, regulations, and prior bureau audits.

To query the HMOs on general drug management techniques, formularies, and rebate negotiation and collection processes, we designed a drug management technique survey based on interviews with department and HMO pharmacists and a representative from a drug manufacturer interest group. We sent the survey, consisting of 44 questions, to the department and 14 HMOs, including the 9 largest in California. We also asked each HMO in our survey to send us a formulary for analysis. All 14 HMOs completed and returned the survey; 8 provided us with copies of their formularies. From these

formularies we selected 3 HMOs, one large (more than 500,000 members), one medium (250,000 to 500,000 members), and one small (fewer than 250,000 members) for comparison to the Medi-Cal formulary.

To compare the Medi-Cal formulary to the others, we designed a database and entered the generic name and major therapeutic category for every drug on the formularies. To render the formularies comparable, we did not include over-the-counter medications or drugs requiring prior authorization. We also excluded Medi-Cal formulary drugs that are administered intravenously or which require a health care professional to inject, since the HMOs did not list such drugs. Finally, because the generic drug names varied considerably among the formularies, we standardized drug names to conform with the department's.

Once we eliminated certain drugs and matched others to the correct drug or therapeutic category on the Medi-Cal formulary, we sorted each drug by Medi-Cal therapeutic category. We then counted the drugs under each category and calculated the percentage of Medi-Cal drug matches for the three HMO formularies. Additionally, we compared the percentages and, where the department count differed from the HMO average by more than four drugs, analyzed the assortment of drugs listed to determine why they differed. Finally, we obtained a list of the top 200 brand name drugs prescribed in the United States in 1996. (This list represented only 131 different generic drugs because some generic drugs go by more than one brand name.) Using the generic name, we calculated the percentage included on the department's and the three HMO formularies.

Analysis

The Department of Health Services Uses Many Drug Management Techniques HMOs Employ

Summary

The Department of Health Services (department) generally uses the same drug management techniques for the Medical Assistance Program (Medi-Cal) that health maintenance organizations (HMOs) employ to manage their prescription drug benefits. Our survey of 14 HMOs revealed the department uses 11 of the 14 drug management techniques that HMOs do, although the manner or extent to which the department uses a particular technique may vary. Further, although the department does not currently use three of the techniques the HMOs reported using, one is not widely used. The remaining two are not suited to Medi-Cal's fee-for-service program.

The Department Uses 11 of 14 HMO Drug Management Techniques

The department employs a variety of methods to ensure that Medi-Cal recipients in the fee-for-service plan receive drugs that are both therapeutic and cost effective. To determine whether these methods are similar to those HMOs use, we surveyed 14 HMOs in California. We asked each HMO a general question regarding its drug management techniques and more in-depth questions about how it established them. A summary of the survey results is provided in Appendix A, and the HMO survey participants are listed in Appendix B.

The HMOs surveyed employ 14 drug management techniques; the department uses 11 of these. Table 1 lists these 14 techniques and shows those the department uses.

Table 1

Drug Management Techniques

Used by HMOs	Used by the Department
1. Drug formulary	✔
2. Prior authorization process for drugs not listed on the formulary	✔
3. Step care guidelines or treatment algorithms	✔
4. Minimum dispensing quantities	✔
5. Limitations on the frequency of billing	✔
6. Price ceilings on certain drug ingredients	✔
7. Maximum allowable cost lists	✔
8. Generic substitutions	✔
9. Rebate negotiation with drug manufacturers	✔
10. Maximum dispensing quantities	✔
11. Drug use reviews	✔
12. Limitations on the number of refills a doctor can indicate on a prescription	
13. Physician report cards	
14. Physician capitations or incentives	

Of the techniques the department uses, it implements three through the prescribing physician or the pharmacist who fills the prescription and the remaining eight through the pharmacist, through the department itself, or both.

Two of the management techniques implemented through the physician or pharmacist are the drug formulary and the prior authorization process for nonformulary drugs. Drug formularies are designed to assist physicians in prescribing medically appropriate, cost-effective drug therapy. For drugs not listed on the formulary, the physician or pharmacist must justify the need for a particular drug over those listed on the formulary and

The prior authorization process allows the physician to deviate from the formulary when medically necessary.

obtain prior authorization. Thus, the prior authorization process allows the physician to deviate from the formulary when medically necessary.

Step care guidelines or treatment algorithms, which stipulate a certain sequence or order of prescription drug therapy, is the third technique implemented through the physician. For example, the recommended treatment for gastroesophageal reflux disease and its associated symptom of heartburn begins with either over-the-counter antacid medications or changes in the patient's lifestyle. If these steps are not successful, more expensive prescription drug therapy is used. This drug management technique both educates prescribing physicians and controls cost. The guideline typically informs physicians about cost-effective therapy by stipulating the least expensive treatment first; then more expensive therapy is applied as necessary. The department implemented its first step care guideline in October 1997.

The department uses an additional five drug management techniques, implemented through the pharmacist who fills the prescription, primarily to contain costs. These techniques include minimum dispensing quantities, limitations on the frequency of billing, price ceilings on certain drug ingredients, maximum allowable cost lists, and generic substitutions. Minimum dispensing quantities and restrictions on frequency of billings limit the amount pharmacists charge to fill the prescriptions. Similarly, price ceilings on certain drug ingredients and maximum allowable costs control expenses by capping the amount pharmacists are reimbursed for the drugs they provide to patients. Finally, generic substitutions further reduce costs by requiring pharmacists to dispense the least expensive generic equivalent that meets the patient's medical needs.

An additional cost-cutting technique shared by the department and the HMOs surveyed is rebate negotiation with drug manufacturers. Like most HMOs, the department does not buy drugs directly from manufacturers. Rather, the patient takes a prescription to a pharmacy, and the department or HMO reimburses the pharmacy for each prescription it fills. Each quarter the department or HMO calculates the type and number of drugs reimbursed through pharmacies and, for each drug covered under a rebate agreement, bills the drug's manufacturer. This technique is designed to decrease the amount paid for drugs based upon agreements with the various drug manufacturers.

Two drug management techniques, maximum dispensing quantities and drug use reviews, contain costs by protecting the patient against overprescribing by the physician and misuse of drugs by the patient.

The two remaining techniques, maximum dispensing quantities and drug use reviews, are designed to contain costs by protecting the patient against overprescribing by the physician or misuse of prescription drugs by the patient. Maximum dispensing quantities limit the number of drugs patients can receive for a given period. If the patient needs to exceed the maximum, the pharmacist must obtain prior authorization to fill the prescription. For such cases, prior authorization requires the physician or pharmacist to evaluate the patient's total drug therapy and determine whether the prescription that exceeds the maximum is therapeutic.

Drug use reviews are performed before and after the patient receives a drug. Prospective reviews are performed on-line as the pharmacist fills the prescription. As pharmacists fill prescriptions for drugs, they enter them into their computers, which are connected to the department's or HMO's computer system. The computer system compares the prescription to a patient's history, which might include the patient's age, gender, and other current prescriptions. If, for example, a prescription reacts adversely to drugs the patient is already taking, the computer system will send back an "alert," informing the pharmacist. The pharmacist can then contact the prescribing physician and alert him or her to prescribe an alternative medication. This particular drug use review screen is called drug vs. drug interaction. The department and many HMOs have multiple drug alert screens, such as drug vs. pregnancy conflict and drug vs. age conflict, to inform pharmacists of various adverse drug effects.

Retrospective reviews, performed by the department or HMO after the patient receives drugs, analyze the number and type of prescriptions. These reviews include analysis of the prescribing, dispensing, and drug use trends to detect potential fraud or abuse by patients and providers and to ensure that prescriptions are appropriate. Prescribing trends can also be used to support decisions regarding a drug's addition or deletion from the formulary.

The Department Does Not Use Three Drug Management Techniques That Some HMOs Employ

The department does not use three of the drug management techniques employed by one or more of the HMOs surveyed. All of these techniques are implemented through the prescribing physician.

The department, like most HMOs, does not limit refills a doctor may order on a prescription and believes this control technique is not cost-beneficial.

Like most HMOs, the department does not place a limitation on the number of refills the doctor may indicate on a prescription. Limiting refills is designed to ensure that the doctor reevaluates the patient before continuing drug therapy. The department states that this control is not cost-beneficial to the program. Currently it allows the physician to decide on the number of refills and frequency of follow-up visits on a case-by-case basis, rather than specifying a number of refills. The department believes that it is less expensive to pay for the prescription refills than to encourage potentially unnecessary office visits. Only three of the fourteen HMOs surveyed use this technique.

The remaining two drug management techniques, physician report cards (or feedback) and physician capitation (budgets or limits) and incentives (monetary rewards), are not applicable to the Medi-Cal fee-for-service program. Physician report cards are provided to prescribing physicians by the HMO. The report summarizes and assesses the doctor's prescribing patterns. Typically, it compares the doctor's per-patient drug cost to the HMO average, indicating whether the doctor tends to prescribe more expensive drugs than the average doctor. The report may also provide suggestions on how the doctor can improve drug therapy or reduce costs. Physician capitation and incentives are based on an allowance that HMOs give each doctor for each patient. The HMO may monetarily reward doctors who prescribe below this allowance or average. In contrast, the HMO may penalize the doctors who go over this per-patient, per-month allowance. Both of these techniques attempt to minimize prescription drug costs through the physician based on an agreement reached and signed between the doctor and the HMO. Since the department does not contract with physicians for provider status, the Medi-Cal program cannot use report cards, feedback, capitation, and incentives.

The Department Could Increase Its Use of Some Drug Management Techniques

While the department uses 11 of the 14 techniques described above, it does not use some in the same manner or to the same extent as the HMOs. There are differences in the drug formulary, drug use reviews, and rebates.

The Department's Method of Establishing Its Formulary and Formulary Coverage Is Similar to That of HMOs

The department's process of establishing its formulary is similar to that of HMOs. All of the HMOs in our survey assess individual drugs or categories of drugs for addition to their formulary. In addition, all of them use a drug advisory committee consisting of physicians and pharmacists to aid in deciding whether to add, delete, or retain a drug on the formulary. Finally, both the HMOs and the department use the same criteria to recommend adding drugs to the formulary.

The department's formulary coverage is much like that of HMOs; however, the Medi-Cal formulary does not provide as many frequently prescribed drugs that either cost more or are prone to misuse.

The department's process of adding drugs renders a formulary that provides coverage much like that of HMOs; however, we found that the Medi-Cal formulary does not provide as many frequently prescribed drugs that either cost more or are prone to misuse. In addition, it contains more cancer medications and some medications that are not widely used. Table 2 compares the number of drugs under each major therapeutic category on the Medi-Cal formulary to that of three HMOs.

Although its total drug count is below the HMO average, the department does not always provide fewer drugs under each of the various therapeutic categories. Specifically, while the department provides for fewer drugs under four categories, including the central nervous system, gastrointestinal, topical and local preparation, and miscellaneous categories, it provides for more drugs under the anti-infectives, antineoplastics, and ophthalmic preparations categories. In the remaining five therapeutic categories, the department's offering is not significantly different from the HMO average, within four drugs, of the average HMO count.

Generally, the Medi-Cal Formulary Provides as Broad a Range of Drug Therapies as HMOs 'Do

When comparing the various drug counts, it is important to note that the number of drugs in a formulary is not as important as the range of drug therapy it provides. A formulary consists of many drugs under the various therapeutic categories and provides a range of drugs from which to choose. For example, in the gastrointestinal category a variety of drugs are used to treat a condition known as gastroesophageal reflux disease (GERD). GERD causes the stomach contents to back up into

Table 2

Formulary Drug Counts by Therapeutic Category

Drug Therapeutic Category[1]	Medi-Cal[2]	HMO 1	HMO 2	HMO 3	HMO Average
Anti-infectives[3]	95	67	83	94	81
Antineoplastic[3]	34	5	9	27	14
Autonomic[4]	47	43	48	59	50
Blood modifiers[5]	3	2	2	3	2
Central nervous system drugs[6]	78	76	100	114	97
Diuretics and cardiovasculars	59	46	54	83	61
Gastrointestinal drugs	11	17	17	22	19
Hormones	47	44	46	56	49
Metabolic supplements[7]	10	13	12	16	14
Ophthalmic preparations[3]	70	48	48	63	53
Topical and local preparations	30	40	56	68	55
Miscellaneous	44	42	57	77	59
Totals	528	443	532	682	
Drugs classified under more than one therapeutic category	48	34	37	41	
Total Drug Count	**480**	**409**	**495**	**641**	**515**

[1]This table does not include one Medi-Cal therapeutic category because it is composed of medications that must be administered by a health care professional either intravenously or by injection. For this analysis, we eliminated such drugs.

[2]These drug counts do not include all drugs listed on the Medi-Cal formulary. Specifically, they do not reflect over-the-counter medications or drugs that must be administered by a health care professional either intravenously or by injection. For this analysis, we eliminated approximately 110 such drugs.

[3]This therapeutic category is described in the text on page 13.

[4]Autonomic drugs include drugs to treat asthma, vomiting, allergies, and migraines.

[5]Blood modifiers include drugs that either increase or inhibit coagulation.

[6]Central nervous system drugs include pain killers, anti-anxiety medications, antidepressants, appetite stimulants, and sedatives.

[7]Metabolic supplements include calcium, fluoride, potassium, and vitamins.

the esophagus, resulting in heartburn. The drugs available to treat GERD can either inhibit the acid production of the stomach or speed up the emptying of the stomach or upper gastrointestinal tract. Both would alleviate the symptom of heartburn using a different mode of treatment. Depending on the individual patient and his or her history, the physician would decide which mode of treatment is appropriate. Thus, a formulary should include both types of treatment to provide a range of drug therapy.

In some categories, the department compensates for lower prescription drug counts with over-the-counter alternatives.

For most categories where the department provides fewer drugs, we found that the range of drug therapy provided on the Medi-Cal formulary is generally comparable to that of the HMOs. The department compensates in part for the lower prescription drug counts with over-the-counter alternatives. None of the HMOs cover over-the-counter medications; thus, if a physician determines that over-the-counter drugs would be sufficient to treat a condition, the HMO would not compensate the patient for the drug's cost. In contrast, Medi-Cal covers over-the-counter medications. For example, unlike the HMOs, the department offers and covers many over-the-counter antacid medications in the gastrointestinal category. When the over-the-counter alternatives are added, the Medi-Cal drug count exceeds the HMO average for gastrointestinal drugs, equals the HMO average for miscellaneous drugs, but is still less than the HMO average for topical and local preparations.

One reason the Medi-Cal formulary includes fewer central nervous system drugs is that, in selecting drugs for inclusion, the department places greater emphasis on their misuse potential than do the HMOs. For example, the Medi-Cal formulary lists just four of the eight anti-anxiety drugs the HMOs carry. According to the department, when drugs have a high potential for misuse, it may not list them on the formulary. If so, it makes them available through prior authorization.

As illustrated by their responses to our survey, the HMOs do not place the same level of importance on a drug's misuse potential. We asked all participants to indicate the criteria they consider when choosing drugs and to rank the importance of each criterion. The criteria included the drug's safety, effectiveness, misuse potential, and cost. The department's ranking of each criterion was similar to the HMOs', with two exceptions. While the department ranked misuse potential and

cost of the drug as very important, the HMOs ranked these as moderately important. The reason the department considers the misuse potential and cost of a drug to be of greater importance than do the HMOs is likely due to the differences between fee-for-service and managed care described in the introduction.

In selecting drugs for the formulary, the department considers the misuse potential and cost of drugs to be of greater importance than HMOs do.

The department's concern with the misuse and cost of a drug also affects the number of most frequently prescribed drugs in the formulary. The Medi-Cal formulary includes 74.8 percent of the 131 medications most frequently prescribed in the United States, compared to an HMO average of 86.8 percent. Fifteen of these top drugs were covered by all three HMO formularies but not by Medi-Cal. Specific examples of these drugs included Claritin (an allergy medication), Vicodin (a pain medication), and Resperidone (an antipsychotic medication). When we asked why, the department stated it has added or will add 3 of these 15 drugs, and a fourth is under review. Of the remaining 11, the department said that alternative drugs with lower misuse potential and cost were available on the formulary. In addition, if medically necessary, any of these drugs can be obtained by Medi-Cal patients through prior authorization.

Sometimes the Department Offers More Choice Than the HMOs Do

In the instances where the department includes more drugs than the HMOs, we found the difference is mostly attributable to laws and regulations governing the Medi-Cal formulary. For example, the Medi-Cal formulary includes more antineoplastic drugs in its category than do the HMOs. The antineoplastics category includes drugs used to treat cancer. State law requires that the Medi-Cal formulary include all drugs approved by the FDA for the treatment of cancer.

The anti-infective and ophthalmic categories provide another example. Anti-infectives include antibiotics, antifungals, and drugs used to treat tuberculosis and malaria. The ophthalmic category includes medications used to treat eye conditions. Medi-Cal's formulary contains drugs not listed by the HMOs and not widely prescribed by physicians. The department states that it has not yet removed these drugs because state law requires it to hold a public hearing to do so. Because a public hearing is time-consuming and other more pressing issues, such as adding new drugs to the formulary, have taken precedence, the department has not yet deleted these drugs from its formulary. Further, although physicians do not frequently prescribe these medications, their inclusion on the formulary poses no threat to Medi-Cal patients or additional cost to the State. When these less frequently prescribed drugs are deleted,

Medi-Cal anti-infective and ophthalmic drug counts become more comparable to the HMO average but still exceed the average counts by 10 percent and 15 percent, respectively.

The Department Does Not Employ Drug Use Reviews as Extensively as the HMOs Surveyed

There are both similarities and differences in the manner in which the department and HMOs employ drug use reviews. Generally, the department does not use prospective and retrospective drug use reviews as extensively as the HMOs.

Both the department and the majority of HMOs perform prospective drug reviews using on-line computer messages or screens to alert pharmacists of potential adverse drug effects. While the department has more drug use review screens, it applies these screens to fewer drugs than do the HMOs surveyed. Drug use review screens can alert the pharmacist to many different situations such as a drug vs. drug interaction, drug vs. pregnancy conflict, drug vs. age conflict, or drug vs. gender conflict. The department employs a total of 13 different drug use review screens and applies these screens to approximately 13 percent of the drugs on its formulary. In contrast, the 11 HMOs that use them have an average of 6 different screens and 10 apply them to all formulary drugs. While the department plans to expand its use of screens in the future, it believes that applying the screens to a select group of drugs provides more significant information to the pharmacist. Therefore, the department has decided to limit the application of screens to those drugs that are frequently prescribed or have the most significant adverse treatment potential. The department believes that Medi-Cal patients are best served by this approach.

The department applies drug use review screens, intended to alert pharmacists to potential adverse drug effects, to only 13 percent of its formulary.

The department, like most HMOs surveyed, performs retrospective reviews that analyze prescribing, dispensing, and drug use trends to detect fraud and abuse by the patient or provider. However, it limits these reviews to the drugs on the formulary. Unlike most of the HMOs surveyed, the department does not use retrospective reviews to identify drugs for possible addition to its formulary. Although the department stated it is aware of the drugs frequently requested through prior authorization, it does not generate reports or analyze prior authorization requests to identify high-demand drugs. Performing such an analysis would be useful, as adding

high-demand drugs to the formulary eliminates the cost of processing multiple prior authorizations. Costs can be reduced further if the department negotiates a rebate with the drug's manufacturer.

The Department Does Not Calculate Rebates the Same Way as HMOs

Like the department, the majority of HMOs surveyed negotiate with drug manufacturers to receive rebates on the drugs they purchase through pharmacies. However, the department uses a different basis to calculate its rebate amounts.

Of the 14 HMOs surveyed, 11 negotiate for rebates with drug manufacturers. The number of drugs covered under rebate agreements ranges from 1.5 percent to 50 percent of all drugs on the formulary. In contrast, each drug on the Medi-Cal formulary is covered under a federal rebate agreement, and approximately 17 percent of these have additional state rebate agreements.

Rebates are calculated using an agreed-upon formula. The rebate is usually a percentage of the average cost of a drug somewhere between the manufacturer's price and the wholesaler's charge to pharmacies. We asked the department and the various HMOs what price they use to calculate the rebate amount. Only the department reported using the average manufacturer's price as the primary basis of calculating the rebate amounts. In a previous report entitled, *"Department of Health Services Has Not Collected $40 Million in Supplemental Rebates from Drug Manufacturers,"* issued by the Bureau of State Audits in March 1996, we found that the average manufacturer's price is an amount known only to the drug's manufacturer. Thus, when the department bills the drug manufacturer for the state rebate, it does not stipulate a total amount but provides the manufacturer with the number of drugs reimbursed through pharmacies so the manufacturer can calculate and remit the rebate. Our previous report recommended that another basis be used so the department can calculate and bill for the rebate amounts itself, thus increasing the likelihood of payment and facilitating collection efforts.

Unlike the department, HMOs are able to calculate rebates and bill the manufacturers for the amount owed.

Our survey revealed that while the HMOs use a variety of prices to calculate rebate amounts, most of these can be obtained and verified by an independent source. For example, 10 of the 11 HMOs who negotiate rebates reported using the

average wholesale price, a price published and updated by sources independent of the drug's manufacturer. Thus, unlike the department, HMOs are able to calculate rebates and bill the manufacturers for the amount owed.

Recommendations

The department should continue to expand its use of drug management techniques. Specifically, it should consider broadening its use of retrospective reviews to include identifying drugs for inclusion on the formulary. It should also consider increasing its use of alert screens and step care guidelines. Additionally, it should stay abreast of new techniques HMOs and other third-party payers use to manage their prescription benefit plans and consider adopting those methods that are effective and suited to the Medi-Cal program. Finally, the department should base state rebates on a price that is available so it can calculate rebates and bill manufacturers for specific amounts.

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

Respectfully submitted,

KURT R. SJOBERG
State Auditor

Date: December 9, 1997

Staff: Sylvia L. Hensley, CPA
Kathleen M. Sergeant, CPA

Appendix A

Summary of Survey Responses on Drug Management Techniques

	Department of Health Services (Department) Yes/No	Number of HMOs	
		Yes	No
Utilization tools: 1. Which of the following drug utilization tools does your HMO use?			
Open drug formulary[1]	No	1[2]	13
Restricted drug formulary[3]	Yes	14	0
Maximum number of refills per prescription	No	3	11
Minimum dispensing quantities	Yes	2	12
Maximum dispensing quantities	Yes	13	1
Limitations on the frequency of billing	Yes	7	7
Price ceilings on certain drug ingredients	Yes	8	6
Maximum allowable costs lists	Yes	13	1
Generic substitutions	Yes	14	0
Step care guidelines or treatment algorithms	No[4]	12	2
Prior authorization process for drugs not on the formulary	Yes	12	2
Drug use reviews	Yes	13	1
Physician report cards or feedback	No	13	1
Physician capitation or incentives	No	6	8
Other	No	0	14

[1]An open drug formulary allows physicians to deviate from the list of drugs without obtaining prior authorization.

[2]One HMO indicated that it had both an open formulary and a restricted formulary depending on the health plan the member selected.

[3]A restricted drug formulary generally requires the physician to obtain prior authorization from the HMO or department before prescribing drugs not listed on the formulary. All 14 of the HMOs in our survey had some form of restricted formulary: 12 required the physician to obtain prior authorization before prescribing a drug not listed on the formulary; 1 allowed the physician to override the formulary using a special prescription form; and 1 allowed the patient to receive nonformulary drugs at a higher co-payment.

[4]The department issued its first step care guideline in October 1997.

	Department Yes/No	Number of HMOs	
		Yes	No
Formulary process:			
2. Do you use a pharmacy benefit management (PBM) division or company?	No	10	4
3. Who ultimately decides which drugs are added to or deleted from the formulary?			
Department or HMO	Yes	3	11
Committee	No	9	5
Joint decision between committee and HMO or PBM	No	2	12
4. Do you use an advisory committee in making decisions about a drug's inclusion in the formulary? (If yes, please answer questions 5, 6, and 7; if no, skip to question 8.)	Yes	14	0

	Department Number	HMO Numbers
5. What is the composition of your drug advisory committee? Please indicate the number of each of the following:		
Physicians	3	7 HMOs had 4-10; 5 HMOs had 12-18; 1 HMO had 20-30; 1 HMO stated "varies"
Pharmacists	2	10 HMOs had 2-4; 3 HMOs had 5-7; 1 HMO stated "varies"
Registered nurses	0	3 HMOs had 1-2
Other	1-School of Pharmacy representative; 1-Medi-Cal beneficiary	1 HMO indicated ad hoc– general council
6. Which committee members, if any, are employed by your organization?	None	Responses ranged from none to all
7. How often does your drug advisory committee meet?	Approximately 6 times a year	11 HMOs indicated quarterly; 2, bi-monthly; 1, monthly

	Department Percentages	HMO Percentages
8. When drugs are considered for addition to the formulary, what percentage are initiated by:		
Drug manufacturers	20%	5 HMOs indicated drug manufacturers: 4 HMOs at 10%; 1 at 50%
Provider physicians	3%	13 HMOs indicated provider physicians: 8 HMOs at 2-10%; 1 at 30%; 1 at 50%; 3 at 70-90%
PBM personnel	0%	7 HMOs indicated PBM personnel: 1 HMO at 15%; 1 at 50%; 5 at 80-100%
Provider pharmacists	2%	7 HMOs indicated provider pharmacists: 4 at 1-5%; 2 at 10%; 1 at 20%
Other	75% department staff	5 HMOs indicated other: 1 indicated 90% utilization 1 indicated 15% plan staff 1 indicated 90% product evaluation pharmacists 1 indicated 80% therapeutic category reviews 1 indicated 80% HMO pharmacists

	Department Yes/No	HMOs	
		Yes	No
9. When considering drugs for addition to the formulary, does your organization typically assess			
Individual drugs?	Yes	12	2
Combination of drugs under a therapeutic category?	Yes	6	8

	Rank by Department	Number of HMOs	Ranking
10. When drugs are considered for addition to the formulary, what criteria is examined? (Please rank each of the following criteria from 1, very important; to 5, least important; or 0, not considered.)			
Safety	1	13 1	1 2
Effectiveness	1	14	1
Essential need	1	5 9	1 2
Misuse potential	1	1 3 7 2 1	1 2 3 4 5
Patient quality of life	2	2 7 4 1	1 2 3 4
Cost of the drug	1	5 4 5	2 3 4
Drug's effect on doctor's office visits	2	3 7 1 2 1	2 3 4 5 0
Drug's effect on hospitalization costs	2	1 6 4 1 1 1	1 2 3 4 5 0
Required lab tests	2	1 10 1 1 1	2 3 4 5 0
Side effects	1	10 3 1	1 2 3
Other	0	2[5]	

[5] One considers utilization and state regulations and the other considers comparisons to equivalent products on the formulary.

	Department Yes/No	HMOs	
		Yes	No
11. When analyzing the above criteria, do you use drug monographs[6] produced by the:			
Drug's manufacturer	Yes	5	9
Independent source	Yes	13	1

	Department	HMOs
12. How often is your formulary updated?	Monthly	9 HMOs update quarterly; 1, biennially; 2, as needed; 2, continuously
13. How is the formulary information communicated to physicians, pharmacists, and members?	Physicians and pharmacists by Medi-Cal provider bulletins. Beneficiaries are notified only when drugs are removed from the formulary.	All HMOs indicated that their formularies are mailed or faxed to provider physicians. Some, 6 of 14, notify members of changes to the formulary.
Formulary composition: 14. How many drugs are on your formulary?	Approximately 600	Varied– low 550; high 1,400[7]

	Department Yes/No	HMOs	
		Yes	No
15. What types of drugs are included on your formulary? (Check all that apply.)			
Over-the-counter	Yes	5	9
Prescription	Yes	14	0
Inpatient	No	1	13
Outpatient	Yes	14	0
Injectables	Yes	6	8
Diabetic supplies	Yes	11	3
16. Does your formulary include any investigational or experimental drugs?	No	0	14

[6]Drug monographs are detailed descriptions of a particular drug and include its chemical composition, treatment indications, side effects, and may include the results of clinical studies.

[7]Variations in drug counts are partly attributable to differences in how HMOs and the department count drugs. Many HMOs count the various dosage forms and strengths as separate drugs, while the department counts each generic drug name just once.

	Department	HMOs
17. What is the process for adding drugs recently approved by the federal Food and Drug Administration (FDA) to the formulary?	(1) Petition by the manufacturer to the department for addition to the formulary. (2) Review by outside advisory committee, the California Medical Association, and California Pharmacists Association. (3) Department pharmacist and negotiator meet with the manufacturer. (4) Evaluation and decision by the department. (5) If decision is made to add the drug, a price rebate contract between the department and the manufacturer is negotiated and secured. (6) After the department obtains signed contracts, the drug is added to the formulary.	Responses varied. Most indicated that their drug advisory committees review drugs recently approved by the FDA before they add the drugs to their formularies. 1 indicated that most new FDA drugs are automatically added the first 6 months, then utilization information is reviewed for a formulary status decision. In contrast, another indicated that a drug is not considered until 6 months following FDA approval, then utilization data is reviewed to see if it should be added to the formulary.

	Department	HMOs
18. When drugs recently approved by the FDA are considered for inclusion on the formulary, what percentage is initiated by:		
Drug manufacturers	90%	5 HMOs indicated drug manufacturers: 1 indicted 5%; 3 indicated 10%; 1 indicated 30%
Provider physicians	0%	12 HMOs indicated provider physicians: 7 indicated 2-15%; 2 indicated 50%; 3 indicated 70-80%
PBM personnel	0%	7 HMOs indicated PBM personnel: 1 indicated 15%; 1 indicated 50%; 5 indicated 80-100%
Provider pharmacists	0%	7 HMOs indicated provider pharmacist: 1 indicated 1%; 5 indicated 5-10%; 1 indicated 20%
Other	10% Self-initiated by department staff.	5 HMOs indicated other: 1 indicated 90% utilization 1 indicated 15% plan staff 1 indicated 98% product evaluation pharmacists 1 indicated 100% internal review 1 indicated 80% medical directors and pharmacists

	Department Yes/No	HMOs	
		Yes	No
19. Does your HMO have established procedures for considering drugs previously approved by the FDA and previously considered for addition to your formulary but which have new treatment indications, dosage strengths, or forms?	Yes	11	3
	Generally, the manufacturer must petition the department to consider new indications, dosage strengths, or forms. If the department previously denied the drug's addition, generally it will accept a new petition from the manufacturer when there is significant new clinical information.	6 of the 14 HMOs stated that new dosage forms are treated as line extensions and are automatically covered if the drug is on the formulary. 11 indicated that if it is a new treatment indication, the drug would be reviewed and treated like a new drug.	

	Department	HMOs
20. Are any types of drugs, for example, AIDS or cancer drugs, automatically added to your formulary?	AIDS and cancer drugs.	10 of the 14 HMOs automatically add AIDS and/or cancer drugs.
21. How many therapeutic categories does your formulary have?	13 - Major 125 - Subtherapeutic categories	Varied– low 8, high 145
22. How are these therapeutic categories established or defined?	By a combination of therapeutic uses and pharmacological classifications.	Varied– 6 of the 14 indicated they used the American Hospital Formulary Services as a basis.
Beneficiary formulary restrictions: 23. If a doctor prescribes a drug not on the formulary, what options does the beneficiary have in obtaining the drug as a covered benefit?	The prescriber or the dispensing pharmacist must obtain prior authorization from the department. If the prior authorization request is denied, the provider can appeal the decision. The beneficiary has the right to a fair hearing for final determination of the prior authorization request.	12 of the 14 HMOs indicated that the prescribing physician could seek prior authorization; 5 of 14 stated that the beneficiary could pay for the drug or pay a higher co-payment; 3 of 14 stated the beneficiary had the option to appeal the decision.

	Department Yes/No	Number of HMOs	
		Yes	No
24. Are on-line National Drug Code lockouts[8] used at the pharmacy to enforce the formulary?	Yes	13	1
25. Does your organization have a prior authorization process for drugs not included on the formulary but prescribed by a physician? (If yes, please answer questions 26 and 27; if no, skip to question 28.) **Note: 12 of the 14 HMOs answered questions 26 and 27.**	Yes	12	2[9]

	Department	Number of HMOs
26. On average, how long does the prior authorization take?	24 hours or less	9 indicated 24 hours or less 2 indicated 24-48 hours 1 indicated 1-3 days
27. On average, what percentage of the prior authorization requests are approved?	85%	3 indicated 50-65% 5 indicated 70-80% 4 indicated 80-98%

[8]These alert pharmacists that the drug is not on the formulary.

[9]One of the two HMOs allows physicians to override the formulary at their discretion; the other allows the patient to receive the drug only at a higher co-payment.

	Department Yes/No	Number of HMOs	
		Yes	No
28. Does your organization have an on-line process to review drug utilization at the point of sale? (For example, drug/drug interactions.) (If yes, please answer questions 29 and 30; if no, skip to question 31.) **Note: 11 of the 14 HMOs answered questions 29 and 30.**	Yes	11	3

	Department	HMOs
29. How many or what percent of the drugs in your formulary are covered under this prospective utilization process?	13%	10 indicated 100%; 1 indicated 0.1%
30. What type of drug utilization screens are included in this process (drug/drug interaction, drug/disease conflict)? Please provide a list of the various screens used by your organization.	Drug/drug interaction Drug/disease conflict Therapeutic, or pharmacologic duplication Ingredient duplication Incorrect drug dosage Incorrect duration of treatment Drug/allergy conflict Underutilization Overutilization Clinical misuse/addictive toxicity Drug/age conflict Drug/gender conflict Drug/pregnancy conflict	All had drug/drug interaction screens. The number of screens each had ranged from 1 to 10, with an average of 5.6.

	Department Yes/No	Number of HMOs	
		Yes	No
31. Does your organization review the use of formulary drugs retrospectively, or after the fact?	Yes	13	1
32. Are the retrospective reviews used in considering a drug's addition to or deletion from the formulary?	No	11	3
33. Are the retrospective reviews used to determine potential fraud or abuse? **Note: 11 of the 14 HMOs answered question 34; 12 answered question 35.**	Yes	13	1

	Department	HMOs
34. What was your per-member, per-month (PMPM) cost in 1996?	$28.59[10]	$ 8.54 low $16.07 high $11.81 average
35. What was your number of prescriptions per member, per year (RxPMPY) in 1996?	9[11]	5.0 low 7.6 high 6.0 average

	Department Yes/No	Number of HMOs	
		Yes	No
Rebate negotiations with drug manufacturers: 36. From which of the following does your organization purchase drugs?			
Drug manufacturers	No	2	12
Pharmacies	Yes	13	1
Wholesalers	No	1	13
37. Does your organization negotiate rebates with drug manufacturers? (If yes, please answer questions 38 through 44; if no, skip to 45.) **Note: 11 of the 14 HMOs answered questions 38 - 44.**	Yes	11	3

	Department	Number of HMOs	Percentage
38. What percentage of drugs on your formulary are covered under a rebate agreement?	100%[12]	1 indicated 1 indicated 4 indicated 5 indicated	1.5% 5% 20-30% 40-50%

[10] The department's PMPM is more than the HMOs', due in part to 2 factors. First, the department charges a small ($1) or no co-payment for each prescription while HMOs generally charge $5 or more per prescription. Second, the department's number of prescriptions per member per year is 50 percent higher than the HMO average.

[11] The department's RxPMPY is driven up, in part, by over-the-counter medications covered by the department but not by the HMOs.

[12] All Medi-Cal formulary drugs are covered under a rebate agreement negotiated by the federal government. Further, 17 percent of all formulary drugs are also covered by agreements negotiated by the department.

	Department Yes/No	HMOs	
		Yes	No
39. What basis is used for calculating the rebate amount? (Check all that apply.)			
Average Manufacturer's Price (AMP)[13]	Yes	1	10
Average Wholesale Price (AWP)[14]	No	10	1
"Best Price"[15]	Yes	8	3
Wholesaler's Acquisition Cost (WAC)[16]	No	7	4
Other	No	3[17]	8

	Department	HMOs
40. How often are the rebates calculated and drug manufacturers billed?	Quarterly	11 indicated quarterly
41. How are billing disputes handled?	Through cooperative and negotiated review between manufacturers and the department of paid Medi-Cal claims data and audits of provider records.	Varied– 3 indicated arbitration; others indicated "it's never happened," "handled by our PBM," or "formal process per contract terms."

	Department Yes/No	Number of HMOs	
		Yes	No
42. Do you offer drug manufacturers incentives for prompt payment?	No	0	11

	Department	HMOs
43. If a drug manufacturer fails to pay a rebate, what action does your organization take?	The department notifies manufacturers and applies the federal interest penalty.	Varied– 4 indicated that it has never happened; others indicated they would either take legal action, arbitrate, or terminate the contract.

[13] AMP is the average price drug manufacturers charge wholesalers for drugs distributed to pharmacies. This amount is determined by the drug's manufacturer and reported to the federal government.

[14] AWP is the average price pharmacies pay to wholesalers for a particular drug. These prices are published by sources independent of the drug's manufacturer.

[15] "Best price" is the negotiated price or the manufacturer's lowest price available to any class of trade organization or entity.

[16] WAC is the amount wholesalers pay manufactures for a drug at a particular point in time.

[17] One HMO indicated distributor list price; one, volume discounts and market share incentives; and one, the director catalog price.

	Department Yes/No	Number of HMOs	
		Yes	No
44. Are drugs ever suspended from the formulary based on a manufacturer's failure to pay rebates?	Yes	1	10

Appendix B

Survey Participants

Aetna Health Plans of California, Inc.*
Blue Shield of California*
Blue Cross of California*
CIGNA Health Care of California
Foundation Health*
Health Net
Health Plan of the Redwoods
Kaiser Permanente*
Lifeguard, Inc.
Maxicare*
National Health Plans*
Omni Healthcare
PacifiCare of California
Prudential HealthCare*

* These HMOs provided a copy of their formularies.

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Memorandum

Date: November 25, 1997

To: Kurt R. Sjoberg
State Auditor
600 J Street, Suite 300

From: Director's Office
714 P Street, Room 1253
657-1425

Subject: Report :Department of Health Services: Its Drug Management Techniques are Similar to Those of Health Maintenance Organizations

This memorandum is in response to your draft report entitled, "Department of Health Services: Its Drug Management Techniques Are Similar to Those of Health Maintenance Organizations." Thank you for the opportunity to review and comment on the draft. *

After reviewing the draft audit report, the Department of Health Services (DHS) found no significant concerns with regard to its contents. However, we have the following comments on the recommendations (recommendations are shown in italics) made in the report:

- *DHS should consider broadening its use of retrospective reviews to include identifying drugs for inclusion on the formulary.*

  We concur: DHS has always relied on both direct communication with the Medi-Cal field offices and findings from annual on-site field office reviews to determine the need for new drug additions to the formulary from the provider community's point of view. While this method provides DHS with ongoing information in terms of requests for nonformulary drugs, it is our belief that a report generated specifically for the purpose of identifying high-demand drugs would be helpful. Therefore, we intend on following up on this course of action.

- *DHS should consider increasing its use of alert screens associated with prospective Drug Use Review (DUR).*

  We concur: We would like to emphasize the fact that DHS provides a relatively detailed use of DUR alert screens by utilizing 13 different DUR screens to a designated group of high volume and clinically important drug compared to the health maintenance organization's (HMO's) use of an average of 6 screens and applies them to all drugs on their formulary. We believe applying the screens to a select group of drugs provides more significant information to the dispensing pharmacist. Applying the screens to all

*The California State Auditor's comments on this reponse start on page 35.

drugs would duplicate existing software programs that pharmacies currently utilize. However, the DUR Board is currently evaluating the possibility of expanding the list of target drugs which can trigger the use of the alert screens. As a result of the Board's evaluation, we anticipate expanding this list in the near future.

- *DHS should consider increasing the use of step care guidelines*.

We concur: Recent publication of our step care guidelines on gastroesophageal reflux disease has resulted in many inquiries regarding the possibility of developing additional step care guidelines for other disease states. DHS remains interested in pursuing this possibility for selected disease states .

- *DHS should stay abreast of new techniques HMO's and other third party payers use to manage their prescription benefit plans and consider adopting those methods that are effective and suited to the Medi-Cal program.*

We concur: DHS, as a drug investment manager, is committed to seek out drug management techniques employed in the private sector to optimize drug utilization while controlling costs in Medi-Cal. To the extent possible, new techniques will be implemented to accomplish these goals.

- *DHS should base state rebates on a price that is available so it can calculate rebates and bill manufacturers for specific amounts*.

We concur in principle: The audit correctly identifies the fact that DHS does not calculate rebates the same way as the majority of HMOs. The reason for this is because rebates paid to states through the federal rebate program have always been based on the "average manufacturer price" (AMP) which is defined in federal statute and supplied by manufacturers to the federal Health Care Financing Administration. Despite requests by the DHS, HCFA will not release the AMP to DHS. Also, up until December 1996, state law required the mandatory state supplemental rebates to be calculated based on AMP. However, since the mandatory rebates have expired and recently DHS has begun negotiating drug rebate agreements with manufacturers that would allow the rebate to be calculated without the AMP, DHS believes this recommendation probably could be implemented without significant additional workload impact.

In addition, as previously indicated to your staff by DHS, we question the relevance of the information regarding the percentage of drugs on the formulary that have state supplemental rebate agreements. We believe that it would be more relevant to compare the HMO's total drug (1)

expenditures less rebates as compared to that same calculation for DHS. However, it is our understanding that HMOs may not have been willing to share such information. Also, we believe that the percentage expressed as the percentage of all drugs on the formulary is misleading. For example, if the analysis were limited to the percentage of single-source drugs added in the last year that have additional state rebate agreements, the percentage would be significantly higher (nearly 96 percent) than when expressed as a percentage of all drugs on the Medi-Cal formulary. Unlike most HMOs, the Medi-Cal formulary includes over-the-counter drugs which typically are already relatively inexpensive compared to single-source drugs and for which DHS does not typically get supplemental rebates. Also, we wish to emphasize the fact that due to federal law, manufacturers are required to give states the best price available to any other purchaser. So, although some HMOs may appear to secure a higher percentage of rebates than DHS secures in state supplemental rebates, they cannot get a better price than DHS already gets through the federal rebate program.

Again, thank you for your unbiased review of drug management techniques. We look forward to the final report. If you have any questions, please contact Mr. Joseph A. Kelly, Chief, Medi-Cal Policy Division, at (916) 657-1542.

Barbara Hooker
FOR S. Kimberly Belshé
Director

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Comment

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

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

(1) To determine how extensively they use rebates, we asked the department and each of the HMOs in our survey the percentage of drugs on their formularies covered by rebate agreements. We find it interesting that the department questions the relevance of the state supplemental rebate percentage since we did not specifically request such information. However, because the department included both the percentage of drugs covered under federal rebates and the percentage covered by state rebates in its response to our questionnaire, we published them. We believe our question and use of the data are appropriate and relevant.

cc: Members of the Legislature
Office of the Lieutenant Governor
Attorney General
State Controller
Legislative Analyst
Assembly Office of Research
Senate Office of Research
Assembly Majority/Minority Consultants
Senate Majority/Minority Consultants
Capitol Press Corps