Elaine M. Howle
State Auditor
Doug Cordiner
Chief Deputy

CALIFORNIA STATE AUDITOR
Bureau of State Audits

555 Capitol Mall, Suite 300 Sacramento, CA 95814 916.445.0255 916.327.0019 fax www.bsa.ca.gov

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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:

This letter report presents additional information from the Bureau of State Audits (bureau) concerning three of the 14 recommendations that the bureau made to the governor on March 9, 2011, for ways to reduce government waste, increase revenue, and improve efficiency. Specifically, the bureau focused on three key recommendations related to the Department of Health Care Services (Health Services): resolve disputed drug rebates, revise the pharmaceutical reimbursement method, and eliminate optional drug classifications.

Health Services administers the State's Medicaid program, referred to as Medi-Cal, and in doing so purchases drugs for Medi-Cal beneficiaries, generally low-income individuals and families who receive public assistance or lack health care coverage. The state and federal governments jointly finance health care services provided under the Medi-Cal program, including optional services such as prescription drugs.

Resolve Disputed Drug Rebates

The federal Medicaid Drug Rebate Program began in 1991. Federal law requires that for a manufacturer's covered outpatient drugs to be eligible for funding, the manufacturer must enter into a rebate agreement with the federal Centers for Medicare and Medicaid Services (CMS) and pay quarterly rebates to the states. Federal regulations require manufacturers to report product and pricing information for covered outpatient drugs to CMS not later than 30 days after the end of the rebate period. Manufacturers must also report revisions to their pricing information to the CMS for a period not to exceed 12 quarters from the quarter in which the data were due.

In addition to receiving federal rebates, state law authorizes Health Services to contract with all drug manufacturers to obtain high-volume discount prices. State law also requires Health Services to submit quarterly invoices to each drug manufacturer for the federal and applicable state supplemental rebates within 30 days of receipt of CMS' file containing manufacturer rebate information. The supporting utilization data from Health Services' prescription drug paid claims tapes are to accompany the quarterly invoices. A manufacturer may contest Health Services' utilization data or the CMS' rebate information shown on an invoice by mailing a notice to Health Services within 38 days of the date Health Services mailed the quarterly invoice and accompanying utilization data. For purposes of state accounting practices only, the contested balance shall not be considered an accounts receivable amount until final resolution of the dispute results in a finding of an underpayment by the manufacturer.

State law expresses the Legislature's intent that Health Services and manufacturers shall cooperate and make every effort to resolve rebate disputes within 90 days of the manufacturers notifying Health Services of a dispute in the calculation of rebate payments.[1] However, if the dispute is resolved in the manufacturer's favor, the State is charged interest 38 days from the date it mailed the invoice until it resolves the dispute. Similarly, if the dispute is resolved in the State's favor, the manufacturer is charged interest 38 days from the mailing of the invoice until the resolution of the dispute.

In its audit report issued in April 2003 titled *Department of Health Services: Its Efforts to Further Reduce Prescription Drug Costs Have Been Hindered by Its Inability to Hire More Pharmacists and Its Lack of Aggressiveness in Pursuing Available Cost-Saving Measures* (Report 2002-118), the bureau found that Health Services had just begun to work with manufacturers to reconcile the $216 million in disputed rebates accumulating from January 1991 to September 2001. In the bureau's follow-up report issued in June 2007 titled *Pharmaceuticals Follow-Up: State Departments That Purchase Prescription Drugs Have Not Yet Fully Implemented Recommendations to Further Refine Their Cost Savings Strategies* (Report 2007-501), Health Services indicated that it had reduced the amount of disputed rebates we previously reported by $63 million, down to $153 million. However, Health Services also stated that the total amount of the disputed rebates from January 2002 to December 2006 stood at roughly $270 million, which resulted in a combined total of $423 million in disputed rebates.

Table 1 on the following page presents the rebate year, invoiced principal amount, outstanding principal amount, and percent of invoiced principal amount outstanding. The rebate year represents the year associated with the original invoice. Table 1 does not include any potential interest that may be owed by the manufacturers.

Health Services' data indicate it was able to reduce the disputed rebate amount for rebate years 1991 through 2006 from $423 million to the roughly $285 million shown in Table 1, which is a reduction of $138 million. However, Health Services was unable to provide the bureau with a breakdown of how much of the $138 million reduction was attributable to payments received from the manufacturers as opposed to amounts it wrote off in the Rebate Accounting and Information System (RAIS). Instead, Health Services stated that on July 1, 2011, it will implement an internal tracking process to capture the following information on a prospective basis: accounting adjustment/write offs of disputed paid or unpaid balances due to accounting, billing, or input errors; write off of disputed amounts owed but deemed uncollectible; and amounts paid by the manufacturer. On June 17, 2011, Health Services provided us with a copy of its written procedures and the spreadsheet it will use to capture the information, both of which appear reasonable.

In its document titled "Joint Legislative Audit Committee Hearing Response to the State Auditor's "Top 10 List," Health Services stated that, in order to prevent the number of aged disputed rebates from growing, it gives priority to resolving new disputes as they arise. However, when we asked Health Services to provide its plan for resolving the older disputed rebates, Health Services stated that it regularly works on disputes from all time periods. In addition, Health Services stated that it recently completed work on the older disputed rebates from rebate years 1991 through 1996, which has an outstanding balance of $26.7 million. Specifically, Health Services stated that it completed its review

[1] In its document titled "Joint Legislative Audit Committee Hearing Response to the State Auditor's "Top 10 List," Health Services stated that "at the time of the bureau's 2003 audit the State had only 90 days from the date of notice to resolve a dispute. Per changes to federal regulations in the past few years, this time requirement has been reduced to only 38 days." Health Services subsequently stated to the bureau that it was mistaken when referring to changes in federal regulations. Instead, Health Services stated it was referring to CMS issuing a revised "Medicaid Drug Rebate Data Guide for States" (revised February 23, 2009), which does not specifically state that the dispute must be resolved in 38 days, but does say the State must pay interest after 38 days.

of the appropriate dispute resolution documents and information and sent this information to the appropriate manufacturers for their review and consideration. According to Health Services, the final resolution and close out of the outstanding balance will depend on how the manufacturers respond. Health Services also stated it has shifted its focus to resolving the disputed amounts from rebate years 1997 to present, which are roughly $355 million.

We recommended to the governor that Health Services eliminate or substantially reduce its backlog of disputed rebates with drug manufacturers. To implement this recommendation, Health Services will need to work more aggressively toward resolving the remaining roughly $355 million in disputed rebates and making a determination as to whether or not the amounts are collectible or uncollectible.

Table 1

The Department of Health Care Services Has Yet to Resolve Disputed Rebates Totaling Roughly $382 Million

REBATE YEAR	INVOICED PRINCIPAL AMOUNT	OUTSTANDING PRINCIPAL AMOUNT	PERCENT OF INVOICED PRINCIPAL AMOUNT OUTSTANDING
1991	$93,149,575	$3,034,356	3%
1992	163,630,038	2,472,973	2
1993	193,205,376	3,986,562	2
1994	233,746,865	4,797,849	2
1995	267,053,200	6,330,750	2
1996	307,934,206	6,067,456	2
1997	347,186,364	12,155,484	4
1998	465,401,298	14,574,209	3
1999	610,109,919	14,304,500	2
2000	755,708,623	21,509,016	3
2001	966,691,920	20,546,757	2
2002	1,286,699,685	27,322,085	2
2003	1,613,533,738	38,779,052	2
2004	1,953,372,951	41,834,035	2
2005	2,220,474,806	43,673,385	2
2006	1,105,968,558	23,511,921	2
Subtotals	**$12,583,867,122**	**$284,900,390**	**2%**
2007	1,230,937,009	33,934,806	3
2008	1,416,226,002	32,415,480	2
2009	1,484,632,596	30,451,088	2
Totals	**$16,715,662,729**	**$381,701,764**	**2%**

Sources: The amounts shown for rebate years 1991 through 2006 were obtained from the Department of Health Care Services' (Health Services) Paid and Outstanding Principal Report—All Programs as of February 28, 2011, which was generated from its Drug Rebate Tracking System that was converted to its Rebate Accounting and Information System (RAIS). The amounts shown for rebate years 2007 through 2009 were obtained from an Excel spreadsheet prepared by Health Services, which was generated using data from RAIS as of April 18, 2011. The Bureau of State Audits did not test the reliability of the data.

Note: Health Services stated it did not provide information for 2010 because it has not received the manufacturers' unit rebate amounts from the federal Centers for Medicare and Medicaid Services (CMS). In a letter dated September 28, 2010, CMS estimated that it would provide states with the updated unit rebate amounts in early May 2011.

Revise Pharmaceutical Reimbursement Method

We recommended to the governor that Health Services use the Average Acquisition Cost (AAC) instead of the Average Wholesale Price (AWP) to reimburse Medi-Cal pharmacy providers. Legislation effective March 24, 2011, states that it is the intent of the Legislature to enact legislation by August 1, 2011, that provides for the development of a new reimbursement methodology that will enable Health Services to achieve savings while continuing to reimburse pharmacy providers in compliance with federal law. In addition, the legislation authorizes Health Services to require providers, manufacturers, and wholesalers to submit any data the director determines necessary or useful in preparing for the transition from a methodology based on AWP to a methodology based on actual acquisition cost.

The bureau asked Health Services to provide the specific steps it plans to undertake prior to August 1, 2011, to implement the newly enacted legislation. Health Services stated that the legislation did not give it enough authority to begin the collection of data from the pharmacy providers. For example, Health Services stated it believes that making it voluntary for pharmacies to respond to the data request, as opposed to imposing a penalty if the pharmacies do not respond to the request, could skew the outcome of the data because only those pharmacies that would benefit from reporting their prices would respond. In addition, Health Services stated that, in order to collect the data, it would need to enter into a contract with a data collection firm. Further, Health Services stated that the newly enacted legislation did not give it an exemption from the Public Contract Code so that it could avoid the extremely lengthy contracting process. Based on Health Services' response, it appears as though it will not be taking any significant actions to prepare for the transition from a methodology based on AWP to a methodology based on actual acquisition cost before the Legislature enacts additional legislation. Finally, Health Services did not provide us with an estimate of the costs associated with implementing a new reimbursement methodology. Instead, Health Services stated that the cost model would be dependent on the nature and scope of the new legislation.

The bureau asked Health Services if it intends to use CMS' database to develop a new reimbursement methodology. Health Services stated that it does not plan to use CMS' database because it does not know if and when CMS expects to release it. Health Services also expressed concerns about whether or not the outcome of CMS' survey or the database would meet the specific needs for California pricing because it is unknown how many California pharmacies, if any, would voluntarily participate in the survey. Finally, Health Services asserted that CMS has announced publicly its expectation that all Medicaid state plan amendments requesting a change to the pharmacy reimbursement methodology include an evaluation of the pharmacies' dispensing fees. Health Services stated there was no indication that CMS' database will include a dispensing fee component.

The bureau contacted CMS to determine when it expects to complete the survey and make the database available to the states. On May 2, 2011, a CMS representative stated only that CMS is in the process of procuring a vendor to assist with the survey and database and that he was unable to provide any additional information. First DataBank, Inc., the State's primary price reference source for the AWP, has announced that it will cease publishing the Blue Book AWP data field for all drugs no later than September 26, 2011. Without the enactment of new legislation by the State or the development of CMS' database, it appears as though Health Services may not be prepared to implement this recommendation by the end of September 2011.

Proposed legislation (Assembly Bill 399 of the 2011–12 Regular Session (AB 399) and Assembly Bill 102 of the 2011–12 Regular Session (AB 102)), if either is enacted, would authorize Health Services to direct the fiscal intermediary to establish a process with the primary price reference source vendor to temporarily report the AWP until Health Services fully implements the AAC methodology. In addition, this proposed legislation would authorize Health Services to establish the AAC in one of a few ways, including using a national pricing benchmark obtained from CMS. Finally, this proposed legislation would address other concerns raised by Health Services such as exempting it from certain provisions of the Public Contract Code. However, of the two bills, AB 102 is the only one that would require Medi-Cal pharmacy providers to submit drug price information to Health Services or a vendor designated by Health Services for the purposes of establishing the AAC.

Eliminate Optional Drug Classifications

We recommended to the governor to discontinue all or a portion of the remaining optional drug therapeutic classifications for the Medi-Cal program. In the bureau's April 2003 report, Health Services' data showed that had it excluded the optional classes of drugs as part of its pharmacy benefit, it might have saved the State nearly $80 million during 2001. The bulk of this cost, $70 million, represented Health Services' reimbursement for cough and cold drugs.

In its March 2011 document titled Joint Legislative Audit Committee Hearing Response to State Auditor's "Top 10 List," Health Services stated it was having difficulty reconciling to the amounts cited in the bureau's 2003 report. However, Health Services was subsequently able to provide data for 2010 that includes the same drug classifications it used to create the 2001 data. Table 2 on the following page presents a comparison of the 2001 and 2010 data for optional drugs and classes of drugs.

Federal regulations require Health Services to implement a utilization program to, among other things, control the provision of Medi-Cal services to safeguard against any unnecessary or inappropriate use of those services or excess payments and to assess the quality of services rendered. State law specifies that Health Services may require providers to receive its authorization before rendering such services, known as "prior authorization" when the director determines that the provider has been providing unnecessary services. State regulations define prior authorization as an authorization granted by a designated Medi-Cal consultant or by a primary care case management (PCCM) plan that is obtained through the submission and approval of a treatment authorization request (TAR). The *Manual of Criteria for Medi-Cal Authorization* published by Health Services is the basis for the professional judgments of the consultants or the PCCM plan in decisions on authorizations for services or conditions listed in the manual. Health Services stated that most of the optional drug categories were under prior authorization and approved only when medical necessity has been demonstrated. However, our analysis of Health Services' pharmacy claims data indicate that only $23.5 million, or 17 percent, of the $139.2 million reimbursement amount for 2010 had a TAR control number.

Table 2
Comparison of Optional Drug Medi-Cal Reimbursement Amounts for 2001 and 2010

OPTIONAL DRUGS AND CLASSES OF DRUGS	2001	2010	PERCENT CHANGE
Agents when used for anorexia, weight loss, or weight gain	$584,397	$3,939,378	574.09%
Agents when used for the symptomatic relief of cough and cold			
Antihistamines	46,162,643	21,386,019	(53.67)
Antihistamine combinations	*	881,578	*
Cough and cold preparations	10,543,421	11,317,444	7.34
Eye, ear, nose, and throat preparations	13,800,973	19,375,286	40.39
Agents when used to promote smoking cessation	1,042,658	1,133,525	8.71
Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations	*	7,173,966	*
Barbiturates	826,546	764,363	(7.52)
Benzodiazepines	6,829,095	16,049,617	135.02
Nonprescription drugs	*	57,140,501	*
Agents when used for cosmetic purposes or hair growth	*	5,280	*
Totals	**$79,789,733**	**$139,166,957**	

Sources: Federal law establishes limitations on the coverage of drugs for the Medicaid program and states that the drugs or classes of drugs, or their medical uses, shown in Table 2 may be excluded from coverage or otherwise restricted. Federal law also lists as excluded those agents when used to promote fertility and when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition other than sexual or erectile dysfunction for which the agents have been approved by the Food and Drug Administration. However, these agents are not presented in Table 2 because the Department of Health Care Services' (Health Services) data show no reimbursements for them.

Health Services provided the data from its Medi-Cal Management Information System Decision Support System. The Bureau of State Audits did not test the reliability of the data. The reimbursement amounts do not include manufacturers' rebates.

* These optional drugs or classes of drugs were not included in the 2001 data.

Federal law establishes the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) program. Beneficiaries can receive screening, vision, dental, and hearing services. In addition, beneficiaries can receive such other health care, diagnostic services, treatment, and other measures, including prescribed drugs, to correct or ameliorate defects and physical and mental illnesses and conditions discovered by the screening, whether or not such services are covered under the Medi-Cal state plan. Thus, EPSDT beneficiaries are entitled to receive optional drugs if they need them. Health Services' data indicate that only $617, or less than 1 percent, of the $139.2 million reimbursement amount for 2010 was for pharmacy claims related to EPSDT beneficiaries. Excluding pharmacy claims that had a TAR control number and those for EPSDT beneficiaries reduces the 2010 reimbursement amount from $139.2 million to $115.7 million as shown in Table 3 on the following page.

As part of its data request, the bureau asked Health Services to include the beneficiary diagnosis code. However, Health Services stated that the claims data available within the department do not provide a reliable link of drug to diagnosis because physicians do not routinely provide the diagnosis code next to each drug listed on a valid prescription. In addition, Health Services stated that it would be an obstacle to the access of medications if the pharmacy providers had to contact the prescribing physician to obtain the diagnosis code for every prescription before filling and billing them, which is why it does not require the pharmacy providers to enter the diagnosis code when submitting a claim. Finally, Health Services stated that, even if the pharmacy provider enters a diagnosis code voluntarily, it cannot verify the accuracy of that diagnosis code to the drug being billed. Consequently, the bureau asked Health Services to provide its perspective on why the majority of the drugs were not subject

Table 3
2010 Medi-Cal Reimbursement Amounts for Pharmacy Claims That Did Not Have a Treatment Authorization Request Control Number or Were Not Reimbursed for Early and Periodic Screening, Diagnostic and Treatment Beneficiaries

OPTIONAL DRUGS AND CLASSES OF DRUGS	TOTAL MEDI-CAL REIMBURSEMENT AMOUNT	REIMBURSEMENT AMOUNT FOR CLAIMS WITH A TREATMENT AUTHORIZATION REQUEST (TAR) CONTROL NUMBER	REIMBURSEMENT AMOUNT FOR CLAIMS PAID FOR EARLY AND PERIODIC SCREENING, DIAGNOSTIC, AND TREATMENT (EPSDT) BENEFICIARIES	REMAINING MEDI-CAL REIMBURSEMENT AMOUNT
Agents when used for anorexia, weight loss, or weight gain	$3,939,378	$351,621	-	$3,587,757
Agents when used for the symptomatic relief of cough and cold				
Antihistamines	21,386,019	3,389,254	$4	17,996,761
Antihistamine combinations	881,578	120,758	-	760,820
Cough and cold preparations	11,317,444	508,783	-	10,808,661
Eye, ear, nose, and throat preparations	19,375,286	2,433,136	-	16,942,150
Agents when used to promote smoking cessation	1,133,525	492,523	-	641,002
Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations	7,173,966	1,506,135	56	5,667,775
Barbiturates	764,363	77,121	-	687,242
Benzodiazepines	16,049,617	8,676,356	16	7,373,245
Nonprescription drugs	57,140,501	5,951,482	541	51,188,478
Agents when used for cosmetic purposes or hair growth	5,280	1,632	-	3,648
Totals	**$139,166,957**	**$23,508,801**	**$617**	**$115,657,539**

Sources: The Department of Health Care Services (Health Services) provided the data from its Medi-Cal Management Information System Decision Support System. The Bureau of State Audits (bureau) did not test the reliability of the data. The reimbursement amounts do not include manufacturers' rebates.

Using Health Services' data, the bureau identified the reimbursement amounts shown for claims with a TAR control number and claims reimbursed for EPSDT beneficiaries.

to prior authorization, as evidenced by a TAR control number, as it had originally stated. Below the bureau presents Health Services' response and an analysis of each of the drugs and classes of drugs shown in tables 2 and 3.

- Health Services stated the drugs used for anorexia, weight loss, or weight gain were only available to Medi-Cal beneficiaries through prior authorization. However, Health Services' data indicate that claims totaling $3.6 million, or 92 percent, of the $3.9 million were reimbursed without a TAR control number. Health Services stated that the primary drug paid without a TAR control number was "megestrol acetate." The federal Food and Drug Administration (FDA) originally approved the use of megestrol acetate in August 1971 for the palliative treatment of advanced carcinoma of the breast or endometrium (i.e., recurrent, inoperable, or metastatic diseases) and the drug was later approved for treatment of anorexia, cachexia, or unexplained significant weight loss in AIDS patients in July 2005. Health Services stated it placed megestrol acetate on its Contract Drug List (CDL) because of this drug's primary use in treating various types of cancer. State law and regulations require the director to use the following five criteria when evaluating drugs to add and delete from the CDL: cost, efficacy, essential need, misuse potential, and safety. State regulations also allow the director to restrict usage of any drug or therapeutic category of drugs on the CDL. Finally, according to state regulations, Code 1 drugs on the CDL marked "*" require prior

authorization unless used under the conditions specified on the CDL. Megestrol acetate appears on the CDL but not as a Code 1 drug. Our review of Health Services' data found that all of the claims reimbursed without a TAR control number were for megestrol acetate.

- Health Services stated that drugs used solely for cosmetic purposes are not a benefit of the Medi-Cal program. Health Services also stated that cosmetics can be subject to prior authorization if they are used to treat a diagnosis for which medical necessity can be established. However, Health Services' data indicate that $3,648, or 69 percent, of the $5,280 was reimbursed without a TAR control number. Health Services stated that the majority of the claims paid without a TAR control number were for the drug "tazarotene." The FDA originally approved the use of tazarotene in June 1997 for patients with stable plaque psoriasis of up to 20 percent body surface area involvement and patients with facial acne vulgaris of mild to moderate severity. Health Services stated it added tazarotene to the CDL based on its review of the five criteria stated in the law and regulations. The CDL lists this drug as Code 1 and restricts its use to the treatment of psoriasis. Our review of Health Services' data found that 14 claims totaling $3,435 were reimbursed for tazarotene. The data also indicate that there were three claims totaling $213 reimbursed without a TAR control number for finasteride, which is not listed on the CDL. Finasteride was originally approved by the FDA in December 1997 for the treatment of male pattern hair loss (androgenetic alopecia) in male patients only. Health Services stated that the claims for this drug were not straight Medi-Cal Fee-for-Service claims, but were claims authorized through the Genetically Handicapped Persons Program for the conditions associated with a cystic fibrosis patient.

- Health Services stated that changes related to cough and cold drugs have occurred since the bureau's May 2003 report. Health Services stated it made an internal decision in 2003, based on the clinical information available at the time, to include antihistamines in the cough and cold category. According to Health Services, the implementation of the federal Medicare Part D prescription drug benefit program in January 2006 provided additional clinical information for it to consider. For example, the federal Medicare Part D prescription drug benefit program excludes drugs or classes of drugs that are similar to those the Medi-Cal program excludes. Subject to the drugs the federal Medicare Part D prescription drug benefit program excludes, the program covers drugs that may be dispensed only upon a prescription, which CMS interprets to mean a drug that is recognized by the FDA as a prescribed drug requiring "Rx only" on its label per section 503(b) (4) of the federal Food, Drug, and Cosmetic Act. The federal Medicare Part D prescription drug benefit program covers "Rx only" antihistamines and decongestant combinations that are not used for symptomatic relief of cough and cold. Based on guidelines for the federal Medicare Part D program, Health Services has chosen to no longer consider "Rx only" antihistamines and decongestant combinations that are not used for symptomatic relief of cough and cold as optional drugs. State law refers to the "Rx only" drugs as legend drugs.

  Health Services' data indicates that $35.7 million was reimbursed for antihistamines, antihistamine combinations, and eye, ear, nose, and throat (EENT) preparations. The data also indicate $8.7 million, or 24 percent, of the $35.7 million was reimbursed for nonprescription or over-the-counter (OTC) antihistamines, antihistamine combinations, and EENT preparations. State law refers to these OTC drugs, which are drugs that were not a prescribed drug requiring "Rx only" on its label, as nonlegend drugs. Health Services stated that it made these nonlegend drugs available without requiring a TAR based on its evaluation of the five criteria stated in the law and regulations. Our review of Health Services' data found that 743,009 claims totaling $8.7 million were reimbursed

for 11 drugs, which are listed on the CDL but not as Code 1 drugs. We also found that Health Services reimbursed 31 claims totaling $1,100 without a TAR control number for Cetirizine HCL, which it suspended from the CDL effective June 1, 2005.

Health Services' data indicate $10.8 million was reimbursed for cough and cold preparation drugs, of which $8.4 million was for legend drugs and $2.4 million was for nonlegend drugs. State regulations do not specifically list legend cough and cold drugs as one of the items that are not covered under the Medi-Cal program. Our review of Health Services' data found that 559,188 claims totaling $8.4 million were reimbursed for five drugs, which are listed on the CDL but not as Code 1 drugs. We also found that Health Services reimbursed three claims totaling $40 without a TAR control number for two drugs that are not on the CDL.

The regulations do, however, state that only nonlegend cough and cold products that meet the requirements of Part 3 of the CDL are covered. Our review of Health Services' data found that 246,051 claims totaling $2.4 million were reimbursed for 14 drugs, which are listed on the CDL but not as Code 1 drugs. We also found that Health Services reimbursed 10 claims totaling $73 without a TAR control number for one drug that is not on the CDL. Health Services' data also indicate it reimbursed 180 claims totaling $1,600 for individuals under 2 years of age without a TAR control number. The CDL states that all nonlegend cough and cold drug products are restricted to individuals 2 years of age and older and that authorization is required for individuals under 2 years of age.

Legislation effective on March 24, 2011, provides that, as of 90 days after April 1, 2011, nonlegend cough and cold products selected by Health Services are not covered benefits, except for EPSDT beneficiaries. Health Services stated that it eliminated the 14 nonlegend cough and cold drugs that we discuss in the previous paragraph in the fiscal year 2011–12 budget.

- Health Services' data indicate that $641,002 was reimbursed for smoking cessation drugs, specifically nicotine and bupropion HCL. Both drugs appear on the CDL as Code 1 drugs. Effective October 1, 2010, as a result of changes made by the Patient Protection and Affordable Care Act (PPACA), pregnant women in the Medicaid program can receive prescription and nonprescription smoking cessation drugs approved by the FDA. However, the smoking cessation drugs must be recommended in accordance with the "Treating Tobacco Use and Dependence: 2008 Update: A Clinical Practice Guideline", published by the federal Public Health Service. In addition, effective January 1, 2014, as a result of changes made by the PPACA, smoking cessation drugs will no longer be optional drugs.

  Health Services recently took action to reduce reimbursements associated with smoking cessation drugs. Specifically, Health Services placed Code 1 utilization controls on nicotine, effective March 1, 2011. The utilization controls require beneficiaries to be part of a comprehensive smoking cessation treatment program that includes behavioral modification support. The utilization controls also include dispensing guidelines. In addition, effective March 1, 2011, Health Services placed similar Code 1 utilization controls on bupropion HCL manufactured by GlaxoSmithKline under the brand name of Zyban.

- Health Services' data indicate that $5.7 million was reimbursed for vitamin and mineral preparations. State regulations list vitamin combinations for persons over five years of age, except for prenatal vitamin-mineral combination products included in Part 2 of the CDL or legend prenatal vitamin-mineral combination products, subject to prior authorization, for use during pregnancy as items that are not covered under the Medi-Cal program. Health Services stated that

vitamins not shown on its CDL require a TAR for reimbursement. Health Services has placed the following vitamin combinations on the CDL but not as Code 1 drugs: Vitamins A, D and C; Vitamins A, D and C with iron; and Vitamins A, D and C with sodium fluoride. The CDL indicates that these vitamin combinations are reimbursable for children up to their fifth birthday only. In addition, Health Services has placed the following single entity vitamins on the CDL: calcitroil, cyanocobalamin (Vitamin B-12), folic acid, leucovorin calcium, levocarnatine, niacin, phytonadione (Vitamin K), pyridoxine (Vitamin B-6), and thiamine (Vitamin B-1). Folic acid, levocarnatine, and niacin are on the CDL as Code 1 drugs but the other drugs are not. Health Services' data indicate that 811 claims for vitamin combinations totaling $12,804 were reimbursed without a TAR control number for beneficiaries between the ages of 6 and 72. The data also indicate Health Services reimbursed 482 claims totaling $16,384 without a TAR control number for multivitamins that are not on the CDL. Finally, the data indicate Health Services reimbursed 124 claims totaling $1,744 without a TAR control number for single entity vitamins that are not on the CDL.

- Health Services stated that many of the nonprescription, OTC, or nonlegend drugs require a TAR for approval. Health Services also stated that, because both legend and nonlegend drugs require a physician's prescription in order to bill the drug to the department, the pharmacy providers are more willing to provide a covered prescription drug rather than a restricted nonlegend drug that requires them to go through the process of obtaining an approved TAR. Health Services' data indicate that $51.2 million, or 90 percent, of the $57.1 million was reimbursed for drugs without a TAR control number. The 10 drugs and classes of drugs discussed below comprise $46 million, or 90 percent, of the $51.2 million that was reimbursed without a TAR control number.

  1. Health Services reimbursed $7.1 million for acetaminophen, of which $2 million was for beneficiaries under the age of 21 and the remaining amount was for beneficiaries older than 21. Acetaminophen is listed on the CDL as a Code 1 drug. Legislation effective March 24, 2011, provides that, as of 90 days after April 1, 2011, nonlegend acetaminophen-containing products (with the exception of children's acetaminophen-containing products) selected by Health Services are not covered benefits, except for EPSDT beneficiaries. Health Services placed utilization controls on acetaminophen effective April 1, 2011. The utilization controls state that the tablets and capsules are restricted to claims with dates of service from March 1, 1984, through March 31, 2011. The utilization controls also state that the liquid and drops are restricted to individuals who are younger than 21 years of age. These controls should reduce future reimbursements associated with acetaminophen.

  2. Health Services reimbursed $7.5 million for aspirin, of which $11,083 was for beneficiaries under the age of 21 and the remaining amount was for beneficiaries older than 21. Aspirin is listed on the CDL but not as a Code 1 drug. Health Services stated that it has historically made this drug available without a TAR because it is the drug of choice for preventing initial and subsequent heart attacks and strokes.

  3. Health Services reimbursed $1 million for aluminum hydroxide, magnesium hydroxide, and simethicone, of which $46,463 was for beneficiaries under the age of 21 and the remaining amount was for beneficiaries older than 21. Aluminum hydroxide, magnesium hydroxide, and simethicone, which is under the specific therapeutic classification of antacids, is listed on the CDL but not as a Code 1 drug. Health Services stated that antacids are the first line drugs recommended to relieve heartburn and mild dyspepsia or gastric indigestion. Health Services

also stated it added antacids to the CDL based on its review of the five criteria stated in the law and regulations. Health Services does not have any utilization controls on any of the antacids on the CDL.

4. Health Services reimbursed $3.6 million for calcium carbonate, of which $62,738 was for beneficiaries under the age of 21 and the remaining amount was for beneficiaries older than 21. Calcium carbonate, which falls under the specific therapeutic classification of calcium replacements, is listed on the CDL but not as a Code 1 drug. Health Services stated calcium is far less costly than alternative therapies used to treat osteoporosis and that it added this drug to the CDL based on its review of the five criteria stated in the law and regulations.

5. Health Services reimbursed $4.8 million for calcium phosphate/Vitamin D3, of which $3,150 was for beneficiaries under the age of 21 and the remaining amount was for beneficiaries older than 21. Calcium phosphate/Vitamin D3, which falls under the specific therapeutic classification of calcium replacements, is listed on the CDL but not as a Code 1 drug. Health Services stated this combination drug is used to treat conditions such as osteoporosis, weak bones (osteomalacia/rickets), decreased activity of the parathyroid gland (hypoparathyroidism), and a certain muscle disease (latent tetany). Health Services stated it added this drug to the CDL based on its review of the five criteria stated in the law and regulations.

6. Health Services reimbursed $5.3 million for docusate sodium, of which $160,131 was for beneficiaries under the age of 21 and the remaining amount was for beneficiaries older than 21. Docusate sodium, which falls under the specific therapeutic classification of laxatives and cathartics, is listed on the CDL but not as a Code 1 drug. Section 10 of Health Services' Manual of Criteria excludes coverage for laxatives and agents affecting fecal consistency, except by prior authorization for beneficiaries diagnosed with end-stage renal disease, paraplegia or quadriplegia, multiple sclerosis, and poliomyelitis. Health Services stated that, as opposed to laxatives and drugs used to affect stool consistency for purposes of stimulating or decreasing frequency or intensity of bowel movements, docusate sodium simply works to keep stools soft enough to pass naturally. Health Services also stated that it placed docusate sodium on the CDL without a requirement for a TAR or any utilization controls because the cost of providing the drug compared to the cost of treating the consequences of impactions, rectal strains and tears, adverse cardiac consequences of straining, or post-surgical straining is minimal.

7. Health Services reimbursed $4.7 million for ferrous sulfate, of which $688,413 was for beneficiaries under the age of 21 and the remaining amount was for beneficiaries older than 21. Ferrous sulfate, which falls under the specific therapeutic classification of iron replacements, is listed on the CDL. It is a Code 1 drug for the suspension drops but not for tablets, other drops, and liquids. Health Services stated it added this drug to the CDL based on its review of the five criteria stated in the law and regulations. Health Services also stated that it placed ferrous sulfate on the CDL without a requirement for a TAR or utilization controls, with the exception of the suspension drops, because alternative treatments for iron deficiency anemia are far more costly.

8. Health Services reimbursed $8.1 million on human insulin, of which $164,860 was for beneficiaries under the age of 21 and the remaining amount was for beneficiaries older than 21. Insulin is listed on the CDL but not as a Code 1 drug. Health Services stated it added this drug to the CDL based on its review of the five criteria stated in the law and regulations. Health Services also stated that it placed insulin on the CDL without a requirement for a TAR or

utilization controls due to the relative low cost of providing this drug to the diabetic beneficiary population, as opposed to the well-known catastrophic consequence of inadequately treated or untreated diabetes.

9. Health Services reimbursed $2.3 million for omeprazole magnesium, of which $145,154 was for beneficiaries under the age of 21 and the remaining amount was for beneficiaries older than 21. Omeprazole magnesium, which falls under the specific therapeutic classification of proton pump inhibitor, is listed on the CDL as a Code 1 drug. Health Services stated that it placed this drug on the CDL based on its review of the five criteria stated in the law and regulations and due to the cost involved in resolving the negative consequences of limiting access to this drug such as gastrointestinal bleeding and esophageal cancer. Health Services placed a Code 1 utilization control on this drug that restricts its distribution to package quantities of 28 and 42 from one manufacturer. However, Health Services did not place a utilization control on this drug to restrict its use to the treatment of certain conditions.

10. Health Services reimbursed roughly $1.6 million on prenatal vitamins, which are listed on the CDL as a Code 1 drug. State regulations list vitamin combinations for persons over five years of age, except for prenatal vitamin-mineral combination products included in Part 2 of the CDL or legend prenatal vitamin-mineral combination products, subject to prior authorization, for use during pregnancy as items that are not covered under the Medi-Cal program. Health Services placed a Code 1 utilization control on prenatal vitamins restricting their use to expectant females with confirmed positive pregnancy tests conducted by their physician.

- Health Services' data indicate that $687,242 was spent on barbiturates, specifically phenobarbital and phenobarbital sodium. Phenobarbital is listed on the CDL but not as a Code 1 drug. Health Services stated it added this drug to the CDL based on its review of the five criteria stated in the law and regulations. Health Services also stated that phenobarbital is used primarily to treat epilepsy and seizures but the drug is also used for a short time to help calm and/or assist sleep during periods of anxiety. Effective January 1, 2014, as a result of changes made by the PPACA, barbiturates will no longer be an optional drug. Health Services stated it currently has no plans to require a TAR or place utilization controls on phenobarbital between now and December 31, 2013.

- Health Services' data indicate that $7.4 million was reimbursed for benzodiazepines, which include alprazolam, clonazepam, diazepam, and lorazepam. Three of these drugs (clonazepam, diazepam, and lorazepam) are listed on the CDL as Code 1 drugs. Health Services stated it added these drugs to the CDL based on its review of the five criteria stated in the law and regulations. Health Services also stated that the benzodiazepines are used therapeutically to produce sedation, induce sleep, relieve anxiety and panic disorders, diminish or relieve muscle spasms, and prevent seizures. Effective November 1, 2010, Health Services placed a Code 1 utilization control on diazepam, restricting its use to beneficiaries diagnosed with cerebral palsy, athetoid states, and spinal cord degeneration. This restriction should reduce reimbursements associated with diazepam. However, Health Services did not place similar utilization controls on clonazepam and lorazepam, which comprise $6.7 million of the $7.4 million, to restrict their use to the treatment of certain conditions. Specifically, Health Services placed utilization controls on clonazepam to restrict the maximum dispensing quantity to 90 tablets and to establish a maximum of three dispensings of any strength in a 75-day period only. Similarly, Health Services placed utilization controls on lorazepam to restrict the maximum dispensing quantity to 30 tablets and to establish a maximum of three dispensing of lorazepam tablets per patient within any 75-day period. Effective January 1, 2014, as a result of changes made by the PPACA, benzodiazepines will no longer be an optional drug. Health Services

stated it currently has no plans to require a TAR or place additional utilization controls on these three drugs between now and December 31, 2013. Table 2 indicates that reimbursements for benzodiazepines have grown by 135 percent between 2001 and 2010. Finally, alprazolam is not listed on the CDL. Health Services stated this drug always requires a TAR. However Health Services' data indicate it reimbursed 29 claims totaling $345 without a TAR control number.

In the bureau's 2003 report, we recommended that Health Services conduct a study to identify the effect of discontinuing all or a portion of the optional drug therapeutic classifications from its benefits on Medi-Cal beneficiaries and Medi-Cal's drug costs. We advised Health Services that if it determined it was cost-effective to do so, it should discontinue some or all of the optional drug classifications. In the bureau's report issued in February 2005 titled *Implementation of State Auditor's Recommendations Audits Released January 2003 Through December 2004* (Report 2005-406), Health Services stated that it analyzed the effect of discontinuing all or a portion of the optional drug categories on Medi-Cal beneficiaries and on drug expenditures. Health Services concluded that the savings would be minimal and the potential for detrimental impact on beneficiaries could be significant. However, the analysis Health Services provided to the bureau did not calculate the amount of net savings or loss. Health Services indicated that to perform this type of analysis would require a long-term or a very large retrospective study. As of June 30, 2011, the bureau has not received the results of such a study from Health Services.

The bureau's analysis indicates that opportunities continue to exist to reduce reimbursements for optional drugs. Federal law establishes limitations on the coverage of drugs for the Medicaid program and states that the drugs or classes of drugs shown in tables 2 and 3 may be excluded from coverage or restricted. Health Services stated that its determination to list the drugs on the CDL and whether or not to implement specific utilization controls, including prior authorizations and Code 1 restrictions, is based on its analysis of the primary and secondary uses of the drugs in the Medi-Cal beneficiary population using the process outlined in state law and regulations for evaluating the five criteria. Our analysis indicates that Health Services reimbursed numerous claims without a TAR control number, some of which were for drugs that are not on the CDL. However, Health Services is unable to provide a reliable link of drug to diagnosis. Consequently, neither it nor the bureau can verify that the drugs were reimbursed for the purposes stated by Health Services without examining each claim. The bureau has identified several opportunities for Health Services to potentially reduce reimbursements for those drugs not identified as a Code 1 drug and generate savings for the State. Specifically, Health Services could place Code 1 utilization controls on those drugs and classes of optional drugs on the CDL, restricting their use to the primary and secondary uses it identified when evaluating the drugs for placement on the CDL. In accordance with state regulations, these Code 1 utilization controls would require prior authorization unless used under the conditions specified on the CDL.

At this time it is unknown what impact placing Code 1 utilization controls on the optional drugs would have on Health Services' TAR pharmacy field offices. In its audit report issued in May 2010 titled *Department of Health Care Services: It Needs to Streamline Medi-Cal Treatment Authorizations and Respond to Authorization Requests Within Legal Time Limits* (Report 2009-112), the bureau discussed staffing shortages at the northern pharmacy field office that resulted in a 10- to 15-day backlog of drug TARs that carried over into 2007. According to the chief, Utilization Management had a one-day backlog of drug TARs by June 30, 2009, and eliminated that backlog by March 24, 2010. In its May 2011 one-year response to this audit, Health Services stated that it hired a contractor to perform a cost-benefit analysis of the TAR process for medical services and drugs. Health Services also stated that the contractor's draft report, although not yet finalized, is broadly supportive of the TAR process citing savings well in excess of operating costs, a strong deterrent factor in stemming fraud

and abuse, and a favorable assessment of program efficiencies among its findings. Thus, it appears as though the benefits could potentially outweigh any costs associated with placing Code 1 utilization controls on the optional drugs.

Conclusion

This letter report addresses information presented to the Legislature by Health Services and relevant actions related to three recommendations that we made to the governor in March 2011. We continue to believe that these recommendations merit consideration as state leaders work toward the goal of helping California become more fiscally sound.

This additional information was gathered under the authority vested in the California State Auditor by Section 8543 et seq. of the California Government Code. The bureau limited its procedures to those areas specified in this letter report.

Respectfully submitted,

Elaine M. Howle

ELAINE M. HOWLE, CPA
State Auditor

Staff: Joanne Quarles, CPA, Audit Principal
Mike Henson

Legal Counsel: Donna Neville, Associate Chief Counsel

For questions regarding the content of this letter, please contact Margarita Fernández, Chief of Public Affairs, at 916.445.0255.