



April 29, 2011

TO: Donald M. Berwick, M.D.
Administrator
Centers for Medicare & Medicaid Services

FROM: /George M. Reeb/
Acting Deputy Inspector General for Audit Services

SUBJECT: Review of California's Invoicing of Rebates for Medicaid Compound Drug Expenditures—Electronic Claims (A-09-10-02006)

Attached, for your information, is an advance copy of our final report on California's invoicing of rebates for Medicaid compound drug expenditures. We will issue this report to the California Department of Health Care Services within 5 business days.

If you have any questions or comments about this report, please do not hesitate to contact me at (410) 786-7104 or through email at George.Reeb@oig.hhs.gov or Lori A. Ahlstrand, Regional Inspector General for Audit Services, Region IX, at (415) 437-8360 or through email at Lori.Ahlstrand@oig.hhs.gov. Please refer to report number A-09-10-02006.

Attachment



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Office of Audit Services, Region IX
90 – 7th Street, Suite 3-650
San Francisco, CA 94103

May 5, 2011

Report Number: A-09-10-02006

Mr. Toby Douglas
Director
Department of Health Care Services
1501 Capitol Avenue, MS 0000
Sacramento, CA 95899

Dear Mr. Douglas:

Enclosed is the U.S. Department of Health & Human Services (HHS), Office of Inspector General (OIG), final report entitled *Review of California's Invoicing of Rebates for Medicaid Compound Drug Expenditures—Electronic Claims*. We will forward a copy of this report to the HHS action official noted on the following page for review and any action deemed necessary.

The HHS action official will make final determination as to actions taken on all matters reported. We request that you respond to this official within 30 days from the date of this letter. Your response should present any comments or additional information that you believe may have a bearing on the final determination.

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site. Accordingly, this report will be posted at <http://oig.hhs.gov>.

If you have any questions or comments about this report, please do not hesitate to call me, or contact Jessica Kim, Audit Manager, at (323) 261-7218, extension 702, or through email at Yun.Kim@oig.hhs.gov. Please refer to report number A-09-10-02006 in all correspondence.

Sincerely,

/Lori A. Ahlstrand/
Regional Inspector General
for Audit Services

Enclosure

Direct Reply to HHS Action Official:

Ms. Jackie Garner
Consortium Administrator
Consortium for Medicaid and Children's Health Operations
Centers for Medicare & Medicaid Services
233 North Michigan Avenue, Suite 600
Chicago, IL 60601

Department of Health & Human Services

**OFFICE OF
INSPECTOR GENERAL**

**REVIEW OF CALIFORNIA'S
INVOICING OF REBATES FOR
MEDICAID COMPOUND
DRUG EXPENDITURES—
ELECTRONIC CLAIMS**



Daniel R. Levinson
Inspector General

May 2011
A-09-10-02006

Office of Inspector General

<http://oig.hhs.gov>

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Section 8L of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site.

OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

EXECUTIVE SUMMARY

BACKGROUND

Pursuant to Title XIX of the Social Security Act (the Act), the Medicaid program provides medical assistance to low-income individuals and individuals with disabilities. The Federal and State Governments jointly fund and administer the Medicaid program. At the Federal level, the Centers for Medicare & Medicaid Services (CMS) administers the program. Each State administers its Medicaid program in accordance with a CMS-approved State plan. Although the State has considerable flexibility in designing and operating its Medicaid program, it must comply with applicable Federal requirements. In California, the Department of Health Care Services (the State agency) administers the Medicaid program.

In addition to providing mandatory Medicaid services, States may offer certain optional services, such as outpatient prescription drugs, to eligible Medicaid beneficiaries. Most States, including California, administer their Medicaid prescription drug programs in accordance with the Medicaid drug rebate program (the program). The program generally pays for covered outpatient drugs if the drug manufacturers have rebate agreements with CMS and pay rebates to the States. Under the program, CMS provides the States with a quarterly Medicaid drug tape, which lists all covered outpatient drugs.

Section 1927(b)(2)(A) of the Act requires States to (1) maintain drug utilization data that identify, by drug code, the number of units of each covered outpatient drug for which the State reimbursed providers and (2) provide the drug utilization data to manufacturers and CMS. The number of units is multiplied by the unit rebate amount to determine the total rebate amount due from each manufacturer. States report drug utilization data to manufacturers on a quarterly invoice.

Pharmacists create compound drugs by combining two or more prescription or nonprescription drug products and then repackaging them into a new form. For each compound drug claim, CMS guidance states that the drug code and corresponding quantity for each ingredient must be included on the claim for Medicaid reimbursement.

In June 2010, we issued a report on California's invoicing of manufacturers for rebates for manually claimed Medicaid compound drug expenditures for fiscal years (FY) 2004 and 2005 (A-09-09-00055). For \$15.5 million of manual claims, we estimated that the State agency failed to invoice manufacturers for and collect approximately \$2.1 million (\$1.1 million Federal share) in rebates for eligible compound drug ingredients. That review excluded claims for compound drug expenditures that were processed electronically (electronic claims), the subject of this report. For this report, we also included electronic claims for FY 2006 through the third quarter of FY 2009.

OBJECTIVE

Our objective was to determine whether the State agency's electronic claims for Medicaid compound drug expenditures complied with Federal requirements related to invoicing manufacturers for rebates and reporting drug utilization data to CMS.

SUMMARY OF FINDINGS

For the period October 1, 2003, through June 30, 2009, the State agency's \$142 million of electronic claims for Medicaid compound drug expenditures did not comply with Federal requirements related to invoicing manufacturers for rebates and reporting drug utilization data to CMS. Specifically, the State agency did not invoice drug manufacturers for any rebates associated with the electronic claims or report to CMS the total number of units for compound drug ingredients. We estimated that the State agency failed to invoice manufacturers for and collect \$26.7 million (\$13.6 million Federal share) in rebates for eligible compound drug ingredients.

The State agency had inadequate internal controls to ensure that compound drug expenditures billed on electronic claims complied with Federal requirements. The State agency informed us that its Rebate Accounting Information System (RAIS) was not designed to invoice rebates for compound drug ingredients. According to State agency personnel, the quarterly drug utilization file sent to CMS included only drugs that had been invoiced; therefore, compound drugs were not reported in the drug utilization data. In August 2010, the State agency instructed its fiscal intermediary to implement a system change in the RAIS that will enable invoicing of eligible compound drug ingredients.

RECOMMENDATIONS

We recommend that the State agency:

- invoice manufacturers for the estimated \$26.7 million in rebates for eligible compound drugs and refund the Federal share of the rebates collected by reporting it on Form CMS-64 as a reduction to the Federal reimbursement for Medicaid expenditures and
- strengthen internal controls, including modifying the RAIS, to (1) invoice manufacturers for eligible compound drug ingredients and (2) report drug utilization data to CMS.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency provided information on actions that it planned to take to address the recommendations. The State agency's comments are included in their entirety as Appendix C.

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INTRODUCTION

BACKGROUND

Medicaid Program

Pursuant to Title XIX of the Social Security Act (the Act), the Medicaid program provides medical assistance to low-income individuals and individuals with disabilities. The Federal and State Governments jointly fund and administer the Medicaid program. At the Federal level, the Centers for Medicare & Medicaid Services (CMS) administers the program. Each State administers its Medicaid program in accordance with a CMS-approved State plan. Although the State has considerable flexibility in designing and operating its Medicaid program, it must comply with applicable Federal requirements. In California, the Department of Health Care Services (the State agency) administers the Medicaid program.

State Medicaid programs must provide certain medical services, including inpatient and outpatient hospital, physician, and family planning services. States also may offer certain optional services, such as outpatient prescription drugs, as long as the services are included in their approved State plans.

Medicaid Outpatient Prescription Drug Program

All States offer outpatient prescription drugs to eligible Medicaid beneficiaries. Most States, including California, administer their Medicaid prescription drug programs in accordance with the Medicaid drug rebate program (the program).¹ The program generally pays for covered outpatient drugs if the drug manufacturers have rebate agreements with CMS and pay rebates to the States. The rebate agreements and related regulations (42 CFR § 447.510) require manufacturers to provide a list of all covered outpatient drugs to CMS quarterly. CMS includes these drugs on a quarterly Medicaid drug tape, makes adjustments for any errors, and sends the tape to the States. The tape includes information that the States use to claim rebates from drug manufacturers, including a drug's unit rebate amount (URA). Drugs are identified on the tape by a unique 11-digit numerical code (drug code) that indicates the manufacturer, product, and package size. CMS guidance instructs the States to use the tape to verify coverage of the drugs for which they claim reimbursement and to calculate the rebates that the manufacturers owe.

Section 1927(b)(2)(A) of the Act requires States to maintain drug utilization data that identify, by drug code, the number of units of each covered outpatient drug for which the State reimbursed providers. Section 1927(b)(2)(A) of the Act also requires States to provide the manufacturers and CMS with the drug utilization data not later than 60 days after the end of each rebate quarter. The number of units is multiplied by the URA to determine the total rebate amount due from each manufacturer. States report drug utilization data to manufacturers on a quarterly invoice.

¹ The Omnibus Budget Reconciliation Act of 1990 established the program effective January 1, 1991. The program is set forth in section 1927 of the Act. Arizona is the only State that does not participate in the program.

States report drug rebate accounts receivable data on Form CMS-64.9R, Drug Rebate Schedule. This form is part of Form CMS-64, Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program, which summarizes actual Medicaid expenditures for each quarter and is used by CMS to reimburse States for the Federal share of Medicaid expenditures. The Federal share of drug rebates paid by manufacturers is reported on Form CMS-64 as a reduction to the Federal reimbursement to States for Medicaid expenditures.

Compound Drugs

Pharmacists create compound drugs by combining two or more prescription or nonprescription drug products and then repackaging them into a new form.² For each compound drug claim, CMS guidance states that the drug code and corresponding quantity for each ingredient must be included on the claim for Medicaid reimbursement.³

Prior Office of Inspector General Report

In June 2010, we issued a report on California's invoicing of manufacturers for rebates for manually claimed Medicaid compound drug expenditures for fiscal years (FY) 2004 and 2005.⁴ For \$15.5 million of manual claims, we estimated that the State agency failed to invoice manufacturers for and collect approximately \$2.1 million (\$1.1 million Federal share) in rebates for eligible compound drug ingredients. That review excluded claims for compound drug expenditures that were processed electronically (electronic claims), the subject of this report. For this report, we also included electronic claims for FY 2006 through the third quarter of FY 2009.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether the State agency's electronic claims for Medicaid compound drug expenditures complied with Federal requirements related to invoicing manufacturers for rebates and reporting drug utilization data to CMS.

² The U.S. Pharmacopeia provides that "compounding involves the preparation and mixing of one or more components according to a written prescription specifically for individual patients." U.S. Pharmacopeia, *Compounding Background*, September 2008.

³ The CMS guidance was published in 72 Fed. Reg. 39142, 39220 (July 17, 2007), in response to a commenter's question about billing of compound drugs.

⁴ *Review of California's Invoicing of Rebates for Medicaid Compound Drug Expenditures—Manual Claims* (A-09-09-00055), issued June 25, 2010.

Scope

The audit scope was 468,768 electronic claims for compound drug expenditures⁵ totaling approximately \$142 million (\$74.5 million Federal share) that the State agency claimed for Federal reimbursement for the period October 1, 2003, through June 30, 2009. The 468,768 claims consisted of:

- 169,553 claims totaling approximately \$58 million (\$29.4 million Federal share) for the period October 1, 2003, through September 30, 2005, and
- 299,215 claims totaling approximately \$84 million (\$45.1 million Federal share) for the period October 1, 2005, through June 30, 2009.

We limited our internal control review to the State agency's procedures for invoicing manufacturers for rebates and reporting drug utilization data to CMS. We did not review the accuracy or completeness of the quarterly Medicaid drug tapes.

We performed our audit from November 2009 to July 2010 and conducted fieldwork at the State agency's offices in Rancho Cordova, California.

Methodology

To accomplish our objective, we reviewed applicable Federal laws, regulations, and program guidance and the State plan. We interviewed State agency personnel responsible for identifying, monitoring, and reporting drug expenditures and for reporting rebates. We also verified that the State agency had not invoiced manufacturers for rebates for compound drug ingredients by reviewing 32 compound drug claims in the State agency's Rebate Accounting Information System (RAIS).

For the 169,553 compound drug claims totaling \$57,952,544 (\$29,373,406 Federal share) that the State agency submitted for Federal reimbursement for the period October 1, 2003, through September 30, 2005, we obtained and reviewed a detailed list of outpatient compound drug claims by quarter. For each claim, we:

- identified the ingredients and quantities dispensed,
- compared the ingredients with drug codes included on the CMS drug tape applicable for the quarter,

⁵ For compound drugs, the State agency reimbursed providers the lesser of (1) total ingredient costs and fees or (2) the total amount billed by the provider. The State agency determined an ingredient's cost as the lesser of (1) the maximum payment that the State would make for that ingredient based on its quantity or (2) the amount that the provider billed for that ingredient. According to State agency personnel, discrepancies related to quantities invoiced to manufacturers and rebate amounts would be resolved by the State agency's Drug Rebate Resolution team and manufacturers.

- calculated rebate amounts that the State agency had not invoiced to manufacturers by multiplying the ingredient quantities identified on the claim by the URAs contained on the applicable quarterly drug tape,
- limited the calculated rebate to the amount reimbursed to the provider when the calculated rebate amount exceeded the reimbursed amount for the claim, and
- calculated the Federal share of rebates that had not been invoiced using the lowest Federal financial participation (FFP) rate applicable for the quarter.

For the compound drug claims that the State agency submitted for Federal reimbursement for the period October 1, 2005, through June 30, 2009, we:

- identified a sampling frame of 299,215 claims totaling \$84,081,723 (\$45,130,702 Federal share);
- selected from the sampling frame a stratified random sample of 100 compound drug claims totaling \$23,832 (\$12,643 Federal share);
- obtained supporting documentation for each sampled claim and:
 - identified the ingredients and quantities dispensed,
 - compared the ingredients with the drug codes listed in the RAIS and obtained URAs for each eligible drug code,
 - verified that drug codes and URAs from the RAIS were listed on the CMS drug tape applicable for the quarter,
 - calculated rebate amounts that the State agency had not invoiced to manufacturers by multiplying the ingredient quantities identified on the claim by the URAs obtained from the RAIS,
 - limited the calculated rebate to the amount reimbursed to the provider when the calculated rebate amount exceeded the reimbursed amount for the claim, and
 - calculated the Federal share of rebates that had not been invoiced using the lowest FFP rate applicable for the quarter; and
- used the sample results to estimate the total amount and Federal share of the rebates that had not been invoiced to manufacturers.

See Appendix A for the sample design and methodology and Appendix B for the sample results and estimates.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

FINDINGS AND RECOMMENDATIONS

For the period October 1, 2003, through June 30, 2009, the State agency's \$142 million of electronic claims for Medicaid compound drug expenditures did not comply with Federal requirements related to invoicing manufacturers for rebates and reporting drug utilization data to CMS. Specifically, the State agency did not invoice drug manufacturers for any rebates associated with the electronic claims or report to CMS the total number of units for compound drug ingredients. We estimated that the State agency failed to invoice manufacturers for and collect \$26.7 million (\$13.6 million Federal share) in rebates for eligible compound drug ingredients.

The State agency had inadequate internal controls to ensure that compound drug expenditures billed on electronic claims complied with Federal requirements.

FEDERAL REQUIREMENTS

Section 1927(b)(1)(A) of the Act states: "A rebate agreement ... shall require the manufacturer to provide ... a rebate for ... covered outpatient drugs of the manufacturer ... for which payment was made under the State plan"

Section 1927(b)(2)(A) of the Act states that it is the responsibility of the State to "... report to each manufacturer not later than 60 days after the end of each rebate period ... information on the total number of units of each [drug code] of each covered outpatient drug dispensed ... for which payment was made under the [State] plan during the period, and shall promptly transmit a copy of such report to [CMS]."

Section 1927(b)(1)(B) of the Act states: "Amounts received by a State under [a rebate agreement] ... in any quarter shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance"

The CMS *Medicaid Drug Rebate Operational Training Guide*, page E3, states: "Within 15 days after receiving the URA data tape from CMS, states must submit invoices to each [manufacturer] for any [drug codes] the state reimbursed a pharmacy for during the past quarter." Furthermore, "... each state must generate a separate record for each [drug code] billed to the [manufacturers] and submit a tape to CMS containing all utilization for the quarter."

REBATES NOT INVOICED FOR COMPOUND DRUG INGREDIENTS

The State agency did not invoice drug manufacturers for rebates or report to CMS the total number of units for compound drug ingredients for the period October 1, 2003, through June 30, 2009.

For the period October 1, 2003, through September 30, 2005, we reviewed 169,553 electronic claims for which the State agency failed to invoice manufacturers for \$7,743,921 (\$3,921,068 Federal share) in rebates for eligible compound drug ingredients.

For the period October 1, 2005, through June 30, 2009, we reviewed a random sample of 100 electronic claims, of which 96 claims included compound drug ingredients that were eligible for rebates. For the 96 claims, rebates for the eligible ingredients totaled \$4,268 (\$2,184 Federal share). Based on our sample results, we estimated that the State agency failed to invoice manufacturers for \$18,973,663 (\$9,645,226 Federal share) in rebates for eligible compound drug ingredients.

EFFECT OF REBATES NOT INVOICED

The State agency did not collect any rebates for or credit the Medicaid program for eligible compound drug ingredients. We estimated that the State agency failed to invoice for and collect rebates totaling \$26.7 million (\$13.6 million Federal share) for October 1, 2003, through June 30, 2009. The total value of the rebates not invoiced and the Federal share are shown in the table.

Value of Rebates Not Invoiced

Period	Value of Rebates Not Invoiced	Value of Rebates Not Invoiced (Federal Share)
October 1, 2003, to September 30, 2005	\$7,743,921	\$3,921,068
October 1, 2005, to June 30, 2009	18,973,663	9,645,226
Total	\$26,717,584	\$13,566,294

INADEQUATE INTERNAL CONTROLS

The State agency had inadequate internal controls to ensure that compound drug expenditures billed on electronic claims complied with Federal Medicaid requirements related to invoicing manufacturers for rebates and reporting drug utilization data to CMS.

The State agency informed us that the RAIS was not designed to invoice rebates for compound drug ingredients. According to State agency personnel, the RAIS was not capable of extracting ingredient information from the compound drug claim to include on invoices for manufacturers.

Because the quarterly drug utilization file sent to CMS included only drugs that had been invoiced, compound drugs were not reported in the drug utilization data.

In August 2010, the State agency instructed its fiscal intermediary to implement a system change in the RAIS that will enable invoicing of eligible compound drug ingredients.

RECOMMENDATIONS

We recommend that the State agency:

- invoice manufacturers for the estimated \$26.7 million in rebates for eligible compound drugs and refund the Federal share of the rebates collected by reporting it on Form CMS-64 as a reduction to the Federal reimbursement for Medicaid expenditures and
- strengthen internal controls, including modifying the RAIS, to (1) invoice manufacturers for eligible compound drug ingredients and (2) report drug utilization data to CMS.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency provided information on actions that it planned to take to address the recommendations. Regarding the first recommendation, the State agency said that it planned to modify the RAIS to capture compound drug claims, which will enable retroactive collection of rebates. Regarding the second recommendation, the State agency said that the RAIS modification would enable invoicing of manufacturers for compound drugs on an ongoing basis and reporting of drug utilization data to CMS. The State agency's comments are included in their entirety as Appendix C.

APPENDIXES

APPENDIX A: SAMPLE DESIGN AND METHODOLOGY

POPULATION

The population consisted of electronically processed compound drug claims that the California Department of Health Care Services (the State agency) submitted for Federal reimbursement under the Medicaid outpatient prescription drug program for the period October 1, 2005, through June 30, 2009. The State agency claimed a total of \$84,081,723 on Form CMS-64, Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program, and received \$45,130,702 in Federal reimbursement.

SAMPLING FRAME

The sampling frame consisted of 299,215 compound drug claims totaling \$84,081,723 for which the State agency received \$45,130,702 in Federal reimbursement under the Medicaid outpatient prescription drug program for the period October 1, 2005, through June 30, 2009.

SAMPLE UNIT

The sample unit was an individual electronic claim for a compound drug expenditure.

SAMPLE DESIGN

We used a stratified random sample. We stratified the sampling frame into two strata: (1) claims with a date of service before implementation of Medicare Part D and (2) claims with a date of service on the date of or after implementation of Part D.¹

Stratum	Period	No. of Paid Claims	Total Expenditure	Federal Share
1	October 1 to December 31, 2005	51,191	\$15,080,204	\$7,766,761
2	January 1, 2006, to June 30, 2009	248,024	69,001,519	37,363,941
Total		299,215	\$84,081,723	\$45,130,702

SAMPLE SIZE

We selected a sample of 50 compound drug claims from each stratum, resulting in a total sample of 100 claims.

¹ The State agency informed us that approximately 1 million Medicaid beneficiaries also eligible for Medicare transitioned to the Part D drug program in 2006. According to the State agency, these beneficiaries may have had an impact on the total amount of Medicaid drug rebates invoiced to manufacturers.

SOURCE OF THE RANDOM NUMBERS

We used the Office of Inspector General, Office of Audit Services (OAS), statistical software to generate 50 random numbers for each stratum.

METHOD OF SELECTING SAMPLE ITEMS

We consecutively numbered the sample units in each stratum. After generating 50 random numbers for each stratum, we selected the corresponding frame items.

ESTIMATION METHODOLOGY

We used the OAS statistical software to estimate the total amount and Federal share of rebates that were not invoiced to manufacturers.

APPENDIX B: SAMPLE RESULTS AND ESTIMATES

Sample Results: Total Amounts

Stratum	Frame Size	Value of Frame	Sample Size	Value of Sample	No. of Claims With Eligible Compound Drug Ingredients	Value of Rebates Not Invoiced
1	51,191	\$15,080,204	50	\$10,352	47	\$938
2	248,024	\$69,001,519	50	13,480	49	3,330
Total	299,215	\$84,081,723	100	\$23,832	96	\$4,268

Sample Results: Federal Share Amounts

Stratum	Frame Size	Value of Frame (Federal Share)	Sample Size	Value of Sample (Federal Share)	No. of Claims With Eligible Compound Drug Ingredients	Value of Rebates Not Invoiced (Federal Share)
1	51,191	\$7,766,761	50	\$5,300	47	\$479
2	248,024	\$37,363,941	50	7,343	49	1,705
Total	299,215	\$45,130,702	100	\$12,643	96	\$2,184

Estimates of Rebates Not Invoiced
(Limits Calculated for a 90-Percent Confidence Interval)

	<u>Total Rebate Amount</u>	<u>Federal Share</u>
	<u>Not Invoiced</u>	
Point estimate	\$18,973,663	\$9,645,226
Lower limit	4,092,896	2,060,298
Upper limit	33,854,431	17,230,153

APPENDIX C: STATE AGENCY COMMENTS



State of California—Health and Human Services Agency
Department of Health Care Services



EDMUND G. BROWN JR.
Governor

March 1, 2011

Ms. Lori A. Ahlstrand
Regional Inspector General for Audit Services
Office of Audit Services, Region IX
Office of Inspector General
90 – 7th Street, Suite 3-650
San Francisco, CA 94103

Dear Ms. Ahlstrand:

The California Department of Health Care Services (DHCS) has prepared its response to the U.S. Department of Health and Human Services, Office of Inspector General (OIG), draft report entitled "Review of California's Invoicing of Rebates for Medicaid Compound Drug Expenditures – Electronic Claims" (A-09-10-02006). DHCS appreciates the work performed by the OIG and the opportunity to respond to the draft report.

Please contact Ms. Traci Walter, Audit Coordinator, at (916) 650-0298 if you have any questions.

Sincerely,

Original Signed By

Toby Douglas
Director

cc: See next page

Ms. Lori A. Ahlstrand
Page 2
March 1, 2011

cc: Ms. Vanessa Baird
Deputy Director
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**Department of Health Care Services
Response to the Office of Inspector General's Draft Report Entitled**

***Review of California's Invoicing of Rebates for
Medicaid Compound Drug Expenditures – Electronic Claims
(A-09-10-02006)***

Recommendation: Invoice manufacturers for the estimated \$26.7 million in rebates for eligible compound drugs and refund the Federal share of the rebates collected by reporting it on Form CMS-64 as a reduction to the Federal reimbursement for Medicaid expenditures.

Response: System Development Notice (SDN) 10020, dated August 4, 2010, has been written and submitted by the Department of Health Care Services (DHCS) Fiscal Intermediary (FI), HP Enterprise Services, to address the capturing of pharmacy compound drug claims beginning with the fourth quarter of 2003. DHCS's Rebate Accounting and Information System (RAIS) will be modified through this SDN to retroactively collect these rebates. Collection of the rebates will be tracked and reported on the Medicaid Drug Rebate Form CMS-64 upon receipt. At this time, DHCS does not have an implementation date due to takeover activities that are occurring as a result of DHCS contracting with a new FI contractor, Affiliated Computer Services, Inc. It is estimated that the RAIS modifications will take appropriately 12 to 16 months to complete.

Recommendation: Strengthen internal controls, including modifying the Rebate Accounting Information System (RAIS), to (1) invoice manufacturers for eligible compound drug ingredients and (2) report drug utilization data to the Centers for Medicare & Medicaid Services (CMS).

Response: As stated above, SDN 10020 has been written to address the retroactive collection of pharmacy compound drug claims beginning with the fourth quarter of 2003. This modification will allow the RAIS to invoice on an ongoing basis for compound drugs while reporting drug utilization data to CMS.