October 13, 2011

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

FROM: /Daniel R. Levinson/
Inspector General

SUBJECT: Multi-State Review of Centers for Medicare & Medicaid Services Medicaid Drug Expenditure Controls (A-07-10-06003)

The attached final report provides the results of our multi-State review of Centers for Medicare & Medicaid Services Medicaid drug expenditure controls.

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that the Office of Inspector General (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 your staff may contact Brian P. Ritchie, Assistant Inspector General for the Centers for Medicare & Medicaid Audits, at (410) 786-7104 or through email at Brian.Ritchie@oig.hhs.gov. We look forward to receiving your final management decision within 6 months. Please refer to report number A-07-10-06003 in all correspondence.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MULTI-STATE REVIEW OF CENTERS FOR MEDICARE & MEDICAID SERVICES MEDICAID DRUG EXPENDITURE CONTROLS

Daniel R. Levinson
Inspector General

October 2011
A-07-10-06003

Office of Inspector General

http://oig.hhs.gov

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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

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. Each State administers its Medicaid program in accordance with a Centers for Medicare & Medicaid Services-approved (CMS) State plan. Although the State has considerable flexibility in designing and operating its Medicaid program, it must comply with applicable Federal requirements.

State Medicaid programs may offer optional services, such as outpatient prescription drugs.

Medicaid Outpatient Prescription Drug Program and Use of Quarterly Medicaid Drug Tape

All States offer outpatient prescription drugs to eligible Medicaid beneficiaries. All States except Arizona administer their Medicaid prescription drug programs in accordance with the Medicaid drug rebate program. Federal Medicaid funding is generally available for covered outpatient drugs if the drug manufacturers have rebate agreements with CMS and pay rebates to the States. The agreements 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 indicates the drugs' termination dates, if applicable; specifies whether the drugs are less than effective; and includes information that the States use to claim rebates from manufacturers. 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) of the Act requires each State to report drug utilization data to CMS quarterly. CMS compares the utilization data with the information on the quarterly drug tape and identifies any drugs classified as less than effective or drugs not listed on the tape. CMS reports the discrepancies to each State on the quarterly Utilization Discrepancy Report, which is CMS's mechanism for notifying the States of potential problems with their utilization data.

Terminated Drugs, Less-Than-Effective Drugs, and Drug Expenditure Reimbursement

Pursuant to 21 CFR § 211.137, each drug must have an expiration date to ensure that the drug meets certain standards, including strength and quality, at the time of its use. The expiration date effectively establishes a shelf life for the drug. A drug's termination date is generally defined by CMS as (1) the expiration date of the last batch of a discontinued drug sold by the manufacturer or (2) the date that the Food and Drug Administration (FDA) or the manufacturer withdraws a drug from the market for health and safety reasons or orders such withdrawal. In this report, we refer to drugs whose termination dates have passed as "terminated drugs."

Less-than-effective drugs are drugs that FDA found to be safe for their approved indications before the Drug Amendments of 1962 (P.L. No. 87-781) but that FDA subsequently found to be less than effective for all of their FDA-approved indications. CMS requires manufacturers to provide it with a list of all their covered outpatient drugs identifying any less-than-effective drugs.

The State Medicaid agencies (State agency) claim Medicaid expenditures on a standard form. CMS reimburses each State agency based on the Federal medical assistance percentage for Medicaid outpatient drug expenditures (drug expenditures).

OBJECTIVE

Our objective was to determine whether 14 selected State agencies' claims for reimbursement of drug expenditures complied with Federal requirements.

SUMMARY OF FINDINGS

The 14 selected State agencies' claims for reimbursement of drug expenditures did not always comply with Federal requirements. Of the approximately $41.6 billion in drug expenditures claimed by the 14 State agencies, the unallowable and potentially unallowable drug expenditures totaled $258,791,245 ($166,579,985 Federal share): $68,668,509 (Federal share) for drugs not listed on the quarterly drug tapes, $58,140,937 (Federal share) for terminated drugs, $428,838 (Federal share) for less-than-effective drugs, and $39,341,701 (Federal share) for inadequately supported drug expenditures.

For the remaining approximately $41.3 billion (approximately $23.4 billion Federal share), we identified no other drugs that were not included on the quarterly drug tapes or were terminated, less than effective, or inadequately supported.

Neither CMS nor the 14 State agencies had adequate controls to ensure that all drug expenditures complied with Federal requirements. CMS did not always ensure that the quarterly drug tapes listed all covered outpatient Medicaid drugs, nor did it always provide the termination dates to the State agencies before the termination dates became effective. Additionally, CMS reported some unallowable and potentially unallowable drug expenditures to State agencies on quarterly Utilization Discrepancy Reports. However, during our audit period, CMS did not require the State agencies to amend their claimed drug expenditures, nor did it follow up with the State agencies to ensure that they had done so.

The 14 State agencies generally did not use the quarterly drug tapes to determine whether drugs were eligible for coverage and did not contact CMS to determine whether drugs were eligible for coverage if the drugs were not listed on the quarterly drug tapes.

These shortcomings in internal controls adversely affected the efficiency of the Medicaid outpatient prescription drug program. Our audits of the 14 State agencies identified potential cost savings to Medicaid that can be realized through the implementation of our

recommendations. Furthermore, use of terminated or less-than-effective drugs poses potential quality-of-care implications for the beneficiaries for whom they are prescribed.

RECOMMENDATIONS

We recommend that CMS:

- instruct State agencies to develop and implement controls to ensure that claimed drug expenditures comply with all Federal requirements and monitor State agencies to ensure that they institute policies and procedures so that they:

    - use the quarterly drug tapes to verify whether their drug expenditures are eligible for Medicaid coverage and notify CMS if drugs are missing from the tapes,

    - do not claim expenditures for drugs that have been designated as less than effective, and

    - maintain documentation supporting all drug expenditures claimed as required;

- report terminated drug expenditures to State agencies on the quarterly Utilization Discrepancy Reports, require State agencies to use these reports to ensure that their drug expenditures comply with Federal requirements, and follow up as necessary with State agencies to ensure that claimed drug expenditures comply with Federal requirements;

- work with the drug manufacturers and strengthen controls to ensure that the information on the quarterly drug tapes is complete and accurate and take appropriate action against manufacturers if they are not timely in providing information to CMS for all of their covered drugs; and

- develop policies and procedures to inform State agencies immediately when a drug has been terminated, instruct State agencies to claim expenditures only for drugs dispensed before the termination dates, and require State agencies to review and reject all current and prior claims for terminated drugs.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In written comments on our draft report, CMS concurred with our third recommendation, did not concur with our second recommendation, and partially concurred with our other recommendations. CMS also described corrective actions that it has taken or plans to take. CMS's comments appear in their entirety as Appendix B.

OFFICE OF INSPECTOR GENERAL RESPONSE

Nothing in CMS's comments has caused us to change our findings or recommendations. As the administrator of the Medicaid program at the Federal level, CMS has the primary responsibility to ensure that the State agencies are administering their Medicaid programs appropriately.

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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.

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 and Use of Quarterly Medicaid Drug Tape

All States offer outpatient prescription drugs to eligible Medicaid beneficiaries. All States except Arizona administer their Medicaid prescription drug programs in accordance with the Medicaid drug rebate program.[1] Federal Medicaid funding is generally available for covered outpatient drugs if the drug manufacturers have rebate agreements with CMS and pay rebates to the States. The agreements 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 indicates the drugs' termination dates, if applicable; specifies whether the drugs are less than effective; and includes information that the States use to claim rebates from manufacturers. 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) of the Act requires each State to report drug utilization data to CMS quarterly. CMS compares the utilization data with the information on the quarterly drug tape and identifies any drugs classified as less than effective or drugs not listed on the tape. CMS reports the discrepancies to each State on the quarterly Utilization Discrepancy Report (UDR), which is CMS's mechanism for notifying the States of potential problems with their utilization data.

[1] The Omnibus Budget Reconciliation Act of 1990, P.L. No. 101-508, established the Medicaid drug rebate 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.

Terminated Drugs

Pursuant to 21 CFR § 211.137, each drug must have an expiration date to ensure that the drug meets certain standards, including strength and quality, at the time of its use. The expiration date effectively establishes a shelf life for the drug. A drug's termination date is generally defined by CMS as (1) the expiration date of the last batch of a discontinued drug sold by the manufacturer or (2) the date that the Food and Drug Administration (FDA) or the manufacturer withdraws a drug from the market for health and safety reasons or orders such withdrawal. In this report, we refer to drugs whose termination dates have passed as "terminated drugs."

Less-Than-Effective Drugs

Less-than-effective drugs are drugs that FDA found to be safe for their approved indications before the Drug Amendments of 1962 (P.L. No. 87-781) but that FDA subsequently found to be less than effective for all of their FDA-approved indications. When FDA finds a lack of substantial evidence that a pre-1962 drug is effective for all intended uses, it publishes a notice in the *Federal Register* concerning its proposal to withdraw approval of the drug. The drug is considered less than effective until the manufacturer can prove its effectiveness.

For the Medicaid drug rebate program, CMS relies on drug manufacturers to identify their less-than-effective drugs. CMS requires manufacturers to provide it with a list of all their covered outpatient drugs, identifying any less-than-effective drugs.

Reimbursement of Medicaid Expenditures

In general, the State Medicaid agencies (State agency) claim Medicaid expenditures on standard Form CMS-64, Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program (CMS-64 report). CMS reimburses each State agency based on the Federal medical assistance percentage for the majority of claimed Medicaid expenditures, including Medicaid outpatient drug expenditures (drug expenditures).

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether 14 selected State agencies' claims for reimbursement of drug expenditures complied with Federal requirements.

Scope

This report summarizes the results of our audits of 14 State agencies: California, Colorado, Connecticut, Illinois, Iowa, Michigan, Missouri, Montana, Nebraska, New York, Pennsylvania, Tennessee, Texas, and West Virginia. The audit periods reviewed for each of these State agencies varied. (See Appendix A.)

The audit scope for this report comprised approximately $41.6 billion (approximately $23.5 billion Federal share) in drug expenditures that the 14 State agencies claimed for the respective periods reviewed. We limited our testing of these expenditures to determining compliance with specific Federal requirements and guidance related to whether the drugs were terminated, less than effective, supported with adequate documentation, or included on the quarterly drug tapes.

We limited our internal control review to the procedures in place at the 14 State agencies and at CMS for determining whether the outpatient drugs claimed were eligible for Medicaid coverage and were accurately claimed.

We conducted fieldwork at the State agencies' offices in each of the 14 States and at CMS headquarters in Baltimore, Maryland.

Methodology

To accomplish our objective, we reviewed applicable Federal laws, regulations, and program guidance and the approved State plan for each of the 14 States. We interviewed State agency officials responsible for identifying and monitoring drug expenditures and rebate amounts, as well as staff responsible for reporting the drug expenditures to CMS. We also interviewed CMS officials responsible for identifying and monitoring drug expenditures and rebate amounts.

Centers for Medicare & Medicaid Services Review

To determine whether CMS had adequate controls over drug expenditures, we reviewed its process for monitoring the drug utilization data that State agencies report to CMS quarterly.

We reviewed CMS guidance associated with terminated drugs and less-than-effective drugs. We also analyzed the effect of CMS delays in including termination dates on the quarterly drug tapes.

Based on our reviews of the 14 State agencies, we also compiled a list of drugs whose costs we had set aside for CMS adjudication because the drug products were not listed on the quarterly drug tapes. From this list, we selected a judgmental sample of the 30 drugs with the largest total expenditures to determine why these drugs were not listed on the quarterly drug tapes. The costs associated with these 30 drugs represented approximately 50 percent of the $68.7 million in Federal expenditures identified for drugs that were not listed on the quarterly drug tapes. We provided this list to CMS for its review.

We discussed the results of our review with CMS officials on September 29, 2010.

State Agencies' Reviews

To determine whether drug expenditures complied with Federal requirements, we obtained a detailed listing of each of the 14 State agencies' drug expenditures for the time periods covered by each review and reconciled these data to the amounts reported on the States' CMS-64 reports.

We then compared the drugs claimed to the quarterly drug tapes to determine whether the drugs were: (1) listed as covered outpatient drugs,[2] (2) dispensed after their termination dates,[3] or (3) listed as less than effective.

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

The 14 selected State agencies' claims for reimbursement of drug expenditures did not always comply with Federal requirements. Of the approximately $41.6 billion in drug expenditures claimed by the 14 State agencies, the unallowable and potentially unallowable drug expenditures totaled $258,791,245 ($166,579,985 Federal share):

- $68,668,509 (Federal share) for drugs not listed on the quarterly drug tapes,
- $58,140,937 (Federal share) for terminated drugs,
- $428,838 (Federal share) for less-than-effective drugs, and
- $39,341,701 (Federal share) for inadequately supported drug expenditures.

For the remaining approximately $41.3 billion (approximately $23.4 billion Federal share), we identified no other drugs that were not included on the quarterly drug tapes or were terminated, less than effective, or inadequately supported.

Neither CMS nor the 14 State agencies had adequate controls to ensure that all drug expenditures complied with Federal requirements. CMS did not always ensure that the quarterly drug tapes listed all covered outpatient Medicaid drugs, nor did it always provide the termination dates to the State agencies before the termination dates became effective. Additionally, CMS reported some unallowable and potentially unallowable drug expenditures to State agencies on quarterly UDRs. However, during our audit period, CMS did not require the State agencies to amend their

[2] For any drugs that were not listed on the quarterly tape, we determined whether the 14 State agencies had verified that the drugs were eligible for Medicaid coverage. If the drugs were compound drugs, we requested supporting documentation that identified the individual drug components. (Compound drugs are created by combining two or more prescription or nonprescription drug products and repackaging them into a new capsule or other dosage form.)

[3] To account for delays in processing data for terminated drugs, we used either the termination date listed on the quarterly tape or the first day of the quarter after the State agency received the tape as the termination date if the termination date was not reported in a timely manner. The audit we performed in Nebraska did not account for these delays in processing data for terminated drugs. To account for this difference in methodology, we have separately identified the questioned amounts associated with terminated drugs.

claimed drug expenditures, nor did it follow up with the State agencies to ensure that they had done so.

The 14 State agencies generally did not use the quarterly drug tapes to determine whether drugs were eligible for coverage and did not contact CMS to determine whether drugs were eligible for coverage if the drugs were not listed on the quarterly drug tapes.

These shortcomings in internal controls adversely affected the efficiency of the Medicaid outpatient prescription drug program. Our audits of the 14 State agencies identified potential cost savings to Medicaid that can be realized through the implementation of our recommendations.

Furthermore, use of terminated or less-than-effective drugs poses potential quality-of-care implications for the beneficiaries for whom they are prescribed.

CLAIMS FOR REIMBURSEMENT OF DRUG EXPENDITURES DID NOT ALWAYS COMPLY WITH FEDERAL REQUIREMENTS

Drugs Not Listed on Quarterly Drug Tapes

Federal Requirements

Section 1927(a)(1) of the Act generally conditions Federal Medicaid reimbursement for covered outpatient drugs on a requirement that manufacturers of those drugs enter into agreements with CMS to pay rebates to the States.[4] CMS requires manufacturers to provide a list of all covered outpatient drugs to CMS quarterly. CMS includes these drugs on the quarterly drug tapes and makes adjustments for any errors.

Section 1927(k)(4) of the Act provides that covered outpatient drugs shall also include drugs that may be sold without a prescription (over-the-counter drugs) if these drugs are approved by the State plan and prescribed by a physician.

According to the CMS Medicaid drug rebate program memorandum to State Medicaid directors, number 130: "… the CMS [quarterly drug tape] is the one to use for ALL data when you are dealing with the drug rebate program…. If [a drug code] that is not on the last CMS [quarterly drug tape] you received is billed to you by a pharmacy … check with CMS to assure that the [drug code] is valid…." Furthermore, the CMS Medicaid drug rebate program memorandum to State Medicaid directors, number 44, provides that: "States must check the [quarterly drug tape] to ensure the continued presence of a drug product…."

In addition, page S-13 of CMS's *Medicaid Drug Rebate Operational Training Guide* states: "If you have paid for [a drug code] that is NOT on [the quarterly drug tape] you should have checked to make sure it was correct. If you paid a pharmacy for utilization on an invalid [drug code], you may have to … recoup your funds."

[4] A State may exempt certain drugs from this requirement if the State has determined that availability of the drug is essential to the health of Medicaid beneficiaries and if certain other conditions are met.

Claims for Drugs Not Listed on Quarterly Drug Tapes

Our audits of the 14 State agencies determined that they claimed $68,668,509 (Federal share) in potentially unallowable expenditures for drug products that were not listed on the quarterly drug tapes. None of the State agencies reviewed contacted CMS to ensure that the drugs were eligible for Medicaid coverage under the Act. As a result, the 14 State agencies did not have evidence that these payments were allowable Medicaid expenditures and were, therefore, eligible for Federal reimbursement.

For our judgmental sample of 30 drugs with the largest total expenditures, CMS provided the following reasons why they were not listed on the quarterly drug tapes:

- Twenty-six drugs had not been reported to CMS in time for CMS to include them on the quarterly drug tape and so were eligible for Federal reimbursement.

- Two drugs were associated with manufacturers that did not participate in the Medicaid drug rebate program and so were not eligible for Federal reimbursement. One manufacturer never participated in the drug rebate program, and the other had been terminated from the drug rebate program on July 1, 2000.

- Two drugs were removed from the quarterly drug tape during the cumulative time periods covered by our reviews of the 14 State agencies. Officials from CMS were unable to explain why these drugs were deleted from the tape. We were unable to determine whether these drugs would have been eligible for Federal reimbursement.

Some of the expenditures for drug products that were not listed on the quarterly drug tapes were not eligible for Federal reimbursement. For the drugs that were eligible for Federal reimbursement, the 14 State agencies may not have known the amounts to invoice the manufacturers for the associated rebates. Consequently, the 14 State agencies may not have appropriately invoiced the manufacturers for these rebates and may have lost the opportunity to earn revenues from these rebates.

Terminated Drugs

Federal Requirements

Pursuant to 21 CFR § 211.137, each drug must have an expiration date to ensure that the drug meets certain standards, including strength and quality, at the time of its use. The expiration date effectively establishes a shelf life for the drug. A drug's termination date is generally defined by CMS as (1) the expiration date of the last batch of a discontinued drug sold by the manufacturer or (2) the date that FDA or the manufacturer withdraws a drug from the market for health and safety reasons or orders such a withdrawal.[5]

[5] *Medicaid Drug Rebate Operational Training Guide*, page F7 (Sept. 2001); *Medicaid Drug Rebate Program Release No. 19*, page 5.

According to the CMS Medicaid drug rebate program memorandum to State Medicaid directors, number 19, the States "… must … assure that claims submitted by pharmacists are not for drugs dispensed after the termination date. These should be rejected as invalid since these drugs cannot be dispensed after this date."

In addition, the CMS Medicaid drug rebate program memorandum to State Medicaid directors, number 130, states that "… the CMS [quarterly drug tape] is the one to use for ALL data when you are dealing with the drug rebate program…." The quarterly drug tapes list the Medicaid-covered drugs' termination dates as reported by the manufacturers.

Claims for Terminated Drugs

Our audits of the 14 State agencies determined that they claimed $58,140,937 (Federal share) in unallowable and potentially unallowable expenditures for drugs dispensed after the termination dates reported by the manufacturers. These terminated drug expenditures had the following issues:

- Our audits identified $16,133,403 (Federal share) in unallowable expenditures for drugs dispensed after the relevant State agencies became aware that the drugs in question had been terminated. For example, one State agency paid for the drug Zocor, which was dispensed on September 15, 2004. Based on the drug code claimed, the termination date for the last batch of this drug was May 31, 2004, according to the tapes beginning with the quarter ended March 31, 2002. The State agency had received information about the drug's termination date 2 years before it was dispensed to a beneficiary and claimed for reimbursement.

- Our audits identified $42,007,534 (Federal share) in potentially unallowable expenditures for drugs dispensed before the relevant State agencies became aware that the drugs in question had been terminated. Because CMS often did not report in a timely manner the termination dates on the quarterly tapes, the State agencies may not have been aware that particular drugs had been terminated. For example, one State agency paid for the drug Lorabid, which was dispensed on March 10, 2003. Based on the drug code claimed, the drug's termination date for the last batch of this drug was July 1, 2002, which was not reported on the tapes until the quarter ended June 30, 2003. The State agency did not receive information about the drug's termination date until almost a year after it had been terminated.

Less-Than-Effective Drugs

Federal Requirements

Section 1903(i)(5) of the Act prohibits Federal Medicaid funding for drug products that are ineligible for Medicare payment pursuant to section 1862(c) of the Act. Section 1862(c) of the Act generally prohibits Federal funding for drug products determined to be less than effective for all conditions prescribed, recommended, or suggested on the products' labels. The quarterly drug tapes identify drugs that have been determined to be less than effective. According to the

CMS Medicaid drug rebate program memorandum to State Medicaid directors, number 130: "… the CMS [quarterly drug tape] is the one to use for ALL data when you are dealing with the drug rebate program…."

Claims for Less-Than-Effective Drugs

Our audits determined that 7 of the 14 State agencies claimed $428,838 (Federal share) in unallowable expenditures because drugs were classified as less than effective on the quarterly drug tapes. For example, one State agency paid for the drug Estratest, which was dispensed on September 23, 2004. However, CMS had reported the drug as less than effective on the tapes beginning with the quarter that ended September 30, 2003. The claimed expenditure was unallowable because the drug was dispensed after CMS had reported it as less than effective.

Inadequately Supported Medicaid Outpatient Drug Expenditures

Federal Requirements

According to the CMS *State Medicaid Manual*, section 2497.1: "Expenditures are allowable only to the extent that, when a claim is filed, you have adequate supporting documentation in readily reviewable form to assure that all applicable Federal requirements have been met." To receive reimbursement for covered outpatient drugs, State agencies must maintain documentation identifying the specific drugs used.

Claims for Inadequately Supported Medicaid Outpatient Drug Expenditures

As discussed in more detail in reports listed in Appendix A, our audits of the 14 State agencies determined that 8 of the 14 claimed $39,341,701 (Federal share) in unallowable drug expenditures because they did not have supporting documentation. The eight State agencies attributed their inadequately supported claims to various reasons, including their inability to identify the individual components of a compound drug, irreconcilable data, and duplicated expenditures.

INADEQUATE CONTROLS TO DETECT UNALLOWABLE CLAIMS FOR MEDICAID OUTPATIENT DRUG EXPENDITURES

Centers for Medicare & Medicaid Services Controls

CMS did not have adequate controls to ensure that all drug expenditures submitted by the 14 State agencies complied with Federal requirements. CMS did not always ensure that the quarterly drug tapes listed all covered outpatient Medicaid drugs, nor did it ensure that the termination dates were provided to the State agencies before the termination dates became effective.

Although it did not receive information for all covered drugs from the drug manufacturers, CMS had not, during the period of our reviews of the 14 State agencies, imposed penalties on the manufacturers to ensure that they provided complete and timely information.

CMS reported some unallowable and potentially unallowable drug expenditures, such as those associated with less-than-effective drugs and drugs that were not listed on the quarterly drug tape, to the State agencies on quarterly UDRs. However, as of September 29, 2010, CMS had not required the 14 State agencies to amend their claimed drug expenditures based on the discrepancies identified, nor did CMS follow up with the 14 State agencies to ensure that they had done so. Further, CMS did not identify utilization of terminated drugs on the quarterly UDRs.

Fourteen State Agencies' Controls

The 14 State agencies did not have adequate controls to ensure that all drug expenditures complied with Federal requirements. The 14 State agencies generally did not use the quarterly drug tape to determine whether a drug was eligible for coverage and did not contact CMS to determine whether a drug was eligible for coverage if the drug was not listed on the quarterly drug tape. As a result, the 14 State agencies claimed reimbursement for some Medicaid outpatient drugs that were not eligible for Federal reimbursement.

EFFECT OF INADEQUATE CONTROLS OVER MEDICAID OUTPATIENT DRUG EXPENDITURES

The 14 selected State agencies' claims for reimbursement of drug expenditures did not always comply with Federal requirements. The unallowable and potentially unallowable expenditures, caused by shortcomings in internal controls at CMS and at the 14 State agencies, totaled $166,579,985 (Federal share). Furthermore, use of terminated or less-than-effective drugs has quality-of-care implications for the beneficiaries for whom these drugs are prescribed. Because terminated drugs have expired or have been pulled from the market for health or safety reasons, they could be weak, ineffective, or detrimental to beneficiaries' health.

Less-than-effective drugs lack substantial evidence of effectiveness for all intended purposes. Although the use of less-than-effective drugs may not cause direct physical harm to beneficiaries, reliance on these drugs could be detrimental when they are used instead of drugs whose effectiveness has been verified.

RECOMMENDATIONS

We recommend that CMS:

- instruct State agencies to develop and implement controls to ensure that claimed drug expenditures comply with all Federal requirements and monitor State agencies to ensure that they institute policies and procedures so that they:

- use the quarterly drug tapes to verify whether their drug expenditures are eligible for Medicaid coverage and notify CMS if drugs are missing from the tapes,

- do not claim expenditures for drugs that have been designated as less than effective, and

- maintain documentation supporting all drug expenditures claimed as required;

- report terminated drug expenditures to State agencies on the quarterly UDRs, require State agencies to use these reports to ensure that their drug expenditures comply with Federal requirements, and follow up as necessary with State agencies to ensure that claimed drug expenditures comply with Federal requirements;

- work with the drug manufacturers and strengthen controls to ensure that the information on the quarterly drug tapes is complete and accurate and take appropriate action against manufacturers if they are not timely in providing information to CMS for all of their covered drugs; and

- develop policies and procedures to inform State agencies immediately when a drug has been terminated, instruct State agencies to claim expenditures only for drugs dispensed before the termination dates, and require State agencies to review and reject all current and prior claims for terminated drugs.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, CMS concurred with our third recommendation, did not concur with our second recommendation, and partially concurred with our other recommendations. CMS also described corrective actions that it has taken or plans to take. A summary of the recommendations with which CMS did not concur and our responses follows. CMS's comments appear in their entirety as Appendix B.

Nothing in CMS's comments has caused us to change our findings or recommendations. As the administrator of the Medicaid program at the Federal level, CMS has the primary responsibility to ensure that the State agencies are administering their Medicaid programs appropriately.

Controls for Ensuring That State Agencies Use the Quarterly Drug Tape

Centers for Medicare & Medicaid Services Comments

CMS stated that a drug's eligibility for Federal reimbursement cannot solely be determined by the quarterly drug tape. CMS also said that it is the manufacturers' responsibility to ensure that they report only rebate-eligible drugs to the Medicaid drug rebate program.

CMS described guidance that it has already issued to manufacturers and said that it will reiterate instructions to the Medicaid State agencies regarding (1) use of the quarterly drug tape to ensure

that the expenditures claimed are appropriate and (2) the way to proceed when drugs are missing from the quarterly drug tape.

Office of Inspector General Response

We agree that the quarterly drug tape has limitations and, as indicated in our report, that there are cases in which the drugs claimed are eligible for reimbursement despite not being listed on the quarterly drug tape. Our recommendation is for CMS to instruct the State agencies to develop and implement controls so that they use the quarterly drug tape to verify whether a drug is eligible for reimbursement. Notwithstanding CMS's statement that it only partially concurred with this part of our first recommendation, the corrective actions described by CMS are consistent with our recommendation.

Controls for Maintaining Documentation Supporting Drug Expenditures

Centers for Medicare & Medicaid Services Comments

CMS stated that we had not sufficiently explained this recommendation or explained what inadequate documentation existed. CMS added that it will follow up with us to get more information regarding this recommendation.

Office of Inspector General Response

This report is a summary of the findings that we discussed in individual reports to the 14 State agencies, as listed in Appendix A. More detailed explanations of the issues that led to this recommendation can be found in those individual reports. We will coordinate with CMS and provide further detail regarding any findings for which sufficient detail does not exist in the individual reports. We continue to recommend that CMS instruct and monitor the State agencies to ensure that they are maintaining adequate documentation supporting all drug expenditures.

Reporting Terminated Drug Expenditures on the Quarterly Utilization Discrepancy Report

Centers for Medicare & Medicaid Services Comments

CMS stated that the UDRs are not intended to inform State agencies of drug product information, such as termination dates. CMS added that the UDRs are sent to State agencies only in response to receipt of quarterly utilization data, "… so this would not adequately correct the issue [of drugs dispensed after their termination dates as reported by manufacturers] from a timing/frequency perspective."

CMS also stated that it has provided the State agencies with "an interface to access the Drug Data Reporting for Medicaid System," which allows State agencies to view appropriate manufacturer product changes, including the changes to termination dates.

Office of Inspector General Response

As stated in our report, CMS compares the utilization data received from the State agencies with the information on the quarterly drug tape and identifies any drugs classified as less than effective or drugs not listed on the tape. CMS reports these discrepancies to each State agency on the quarterly UDRs. However, CMS does not identify utilization of terminated drugs on the UDRs. Furthermore, CMS has not provided the State agencies with guidance on how to proceed when potentially unallowable drug utilization has been identified on the UDRs. Although the Drug Data Reporting for Medicaid System will provide more readily available information to State agencies, the UDRs, which are already in place, allow CMS to monitor, identify, and report back to the State agencies regarding potential problems with their utilization data. Therefore, we continue to recommend that CMS include terminated drugs on the quarterly UDRs and require the State agencies to use these reports to ensure that the State agencies claim only drugs that comply with Federal requirements.

Development of Policies and Procedures Regarding Terminated Drugs

Centers for Medicare & Medicaid Services Comments

CMS did not concur that the State agencies should claim expenditures only for drugs dispensed before the termination date because manufacturers do not report these termination dates properly or in a timely manner. CMS added that it believes that further work is needed to ensure manufacturer compliance and said that it will reiterate to manufacturers and State agencies the requirements regarding terminated drugs.

Office of Inspector General Response

According to the CMS Medicaid drug rebate program memorandum to State Medicaid directors, number 19, the States "…must … assure that claims submitted by pharmacists are not for drugs dispensed after the termination date…. If you find that the manufacturer's termination date is incorrect (e.g., a pharmacist has stock with an expiration date later than what the manufacturer stated), please notify us." Although CMS has already provided guidance to the State agencies to prevent utilization of terminated drugs and has requested the State agencies to monitor these termination dates for accuracy, CMS is not currently requiring State agencies to review and reject their prior drug expenditures for terminated drugs. For this reason, we continue to recommend that CMS develop policies and procedures to ensure that State agencies (1) claim expenditures only for drugs dispensed before the termination dates and (2) review and reject all current and prior claims for terminated drugs, thereby ensuring that all drugs dispensed to Medicaid beneficiaries are safe and effective and that these claims comply with Federal requirements.

APPENDIXES

APPENDIX A: SUMMARY OF UNALLOWABLE AND POTENTIALLY UNALLOWABLE CLAIMS FOR MEDICAID OUTPATIENT DRUG EXPENDITURES

			FEDERAL SHARE					
	Audit Period		Unallowable and Potentially Unallowable Expenditures Reported to State					Claims for Terminated Drugs—Termination Dates Not Timely[1]
State (Report No.)	Start Date	End Date	Claims for Terminated Drugs	Claims for Less-Than-Effective Drugs	Unsupported Drugs	Claims for Drugs Not Listed on Quarterly Drug Tapes	Total	
California (A-09-07-00039)	10/1/2003	9/30/2005	$3,057,929	$0	$21,024,264	$10,926,099	$35,008,292	$9,528,275
Colorado (A-07-07-04113)	10/1/2002	9/30/2004	21,678	0	0	459,604	481,282	84,595
Connecticut (A-01-07-00003)	10/1/2003	9/30/2005	61,732	0	0	9,404,911	9,466,643	962,841
Illinois (A-05-07-00019)	10/1/2003	9/30/2005	108,331	0	0	3,485,893	3,594,224	4,029,689
Iowa (A-07-06-04062)	10/1/2002	9/30/2004	154,245	0	0	1,079,386	1,233,631	254,524
Michigan (A-05-08-00048)	10/1/2003	9/30/2005	61,909	43,709	0	2,937,769	3,043,387	339,675
Missouri (A-07-06-04063)	10/1/2002	9/30/2004	1,985,938	0	951,118	1,887,845	4,824,901	629,141
Montana (A-07-07-04103)	10/1/2001	9/30/2004	11,454	0	980,986	363,210	1,355,650	129,479
Nebraska (A-07-05-04056)	10/1/2002	9/30/2004	28,683	26,635	13,169,719	608,624	13,833,661	120,774
New York (A-02-07-01028)	10/1/2003	9/30/2005	578,321	89,650	568,331	16,189,125	17,425,427	11,568,129
Pennsylvania (A-03-07-00203)	10/1/2003	9/30/2005	1,800,651	145,794	2,451,283	5,900,935	10,298,663	1,069,124
Tennessee (A-04-07-00027)	10/1/2003	9/30/2005	7,925,673	44,607	0	13,224,612	21,194,892	7,709,435
Texas (A-06-07-00092)	10/1/2003	9/30/2005	242,726	77,973	4,209	52,986	377,894	3,660,779
West Virginia (A-03-07-00220)	10/1/2003	9/30/2005	94,133	470	191,791	2,147,510	2,433,904	1,921,074
Total			**$16,133,403**	**$428,838**	**$39,341,701**	**$68,668,509**	**$124,572,451**	**$42,007,534**

[1] The claims were for drugs dispensed before the relevant State agencies became aware that the drugs in question had been terminated. For this reason, these potentially unallowable expenditures were not included in the individual audit reports we issued to the State agencies.

APPENDIX B: CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: MAY 0 4 2011

TO: Daniel R. Levinson
Inspector General

FROM: Donald M. Berwick, M.D.
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Nationwide Review of Centers for Medicare & Medicaid Services Medicaid Drug Expenditure Controls" (A-07-10-06003)

Thank you for the opportunity to review and comment on the subject OIG draft report. The OIG reviewed 14 selected State agencies' claims for reimbursement of Medicaid drug expenditures to determine if they complied with Federal requirements. The OIG used the Medicaid Budget Expenditure System (MBES) data to determine how much States had submitted to the Centers for Medicare & Medicaid Services (CMS) to receive Federal funds for prescription drugs.

The OIG found that the 14 selected State agencies claims for reimbursement did not always comply with Federal requirements. The findings noted that of the approximately $41.6 billion in drug expenditures claimed by the 14 State agencies, the unallowable and potentially unallowable drug expenditures totaled $258,791,245 ($166,579,985 Federal share); of which $68,668,509 (Federal share) was for drugs not listed on the quarterly drug tapes, $58,140,937 (Federal share) was for terminated drugs, $428,838 (Federal share) was for less-than-effective drugs, and $39,341,701 (Federal share) was for inadequately supported drug expenditures. For the remaining approximately $41.3 billion (approximately $23.4 billion Federal share), the OIG identified no deficiencies.

The OIG also found that neither CMS nor the 14 State agencies had adequate controls to ensure that the quarterly drug tapes listed all covered outpatient Medicaid drugs, nor did it always provide the termination dates to the State agencies before the termination dates became effective. Additionally, the OIG stated that CMS reported some unallowable and potentially unallowable drug expenditures to State agencies on quarterly Utilization Discrepancy Reports. However, during the OIG audit period, the OIG found that CMS did not require the State agencies to amend their claimed drug expenditures, nor did CMS follow up with the State agencies to ensure that they had done so.

In addition, the 14 State agencies generally did not use the quarterly drug tapes to determine whether drugs were eligible for coverage and did not contact CMS to determine whether drugs were eligible for coverage if the drugs were not listed on the quarterly drug tapes.

We appreciate the OIG's work in this area. However, for the reasons that follow in response to the OIG recommendations, we do not agree with the OIG's contention that the bulk of the monies the OIG identified as unallowable or potentially unallowable are in fact so absent further work by the OIG to document these claims.

OIG Recommendation

CMS should instruct State agencies to develop and implement controls to ensure that claimed drug expenditures comply with all Federal requirements and monitor State agencies to ensure that they institute policies and procedures so that they use the quarterly drug tapes to verify whether their drug expenditures are eligible for Medicaid coverage and notify CMS if drugs are missing from the tapes.

CMS Response

We partially concur. Please note that it is the manufacturer's responsibility to ensure that they only report rebate-eligible drugs to the Medicaid Drug Rebate Program (MDRP). As we discussed with the OIG at the entrance conference for this report, the MDRP quarterly rebate file can generally be used to determine which drugs the manufacturer represented as rebate-eligible. CMS has issued releases, added language to the Medicaid Drug Rebate Data Guide for Labelers, and continued to update manufacturers on the requirement to submit only rebate-eligible drugs to the MDRP. Finally, we have added language to many standard manufacturer letters requesting that the companies review their list of drugs submitted to the MDRP to ensure that they are rebate-eligible.

While we believe that States can generally rely on the quarterly rebate file to determine whether a covered outpatient drug is correctly included for Federal reimbursement on the MBES 64 reporting form, the larger issue of any drugs' appropriate inclusion by States for Federal reimbursement cannot solely be determined by the MDRP quarterly rebate file. Manufacturers may market drugs between times the MDRP files are sent to the States and those will not appear on the tapes prior to the States claims for reimbursement of these drugs. Also, manufacturers may report their drugs after a reporting period is closed or may have timely product data rejected for formatting issues, but the drug is validly covered by the States. States may also appropriately seek Federal share funds for other non-rebate-eligible drugs as allowed by law and approved State plans.

We will reiterate to States how to use the quarterly rebate file to ensure that expenditure claims for rebate-eligible drugs are appropriately made and will issue guidance to States on how to proceed when drugs are missing on the quarterly file in the Medicaid Drug Rebate Data Guide

for States. We will also discuss with the OIG the appropriateness of assessing civil money penalties (CMPs) on those manufacturers that submit non-rebate-eligible drugs.

OIG Recommendation

CMS should instruct State agencies to develop and implement controls to ensure that claimed drug expenditures comply with all Federal requirements and monitor State agencies to ensure that they institute policies and procedures so that they do not claim expenditures for drugs that have been designated as less than effective.

CMS Response

We concur and will reiterate these requirements in the Medicaid Drug Rebate Data Guide for States. To the extent that drugs that have been determined to be less than effective for all conditions of use prescribed, recommended, or suggested in their labeling have been properly identified to the States, we believe that such expenditures are improper and subject to Federal audit and disallowance.

OIG Recommendation

CMS should instruct State agencies to develop and implement controls to ensure that claimed drug expenditures comply with all Federal requirements and monitor State agencies to ensure that they institute policies and procedures so that they maintain documentation supporting all drug expenditures claimed as required.

CMS Response

We do not concur as we do not believe that the OIG has provided a sufficient explanation of this recommendation and what inadequate documentation existed. We will follow up with the OIG for more information on this recommendation.

OIG Recommendation

CMS should report terminated drug expenditures to State agencies on the quarterly Utilization Discrepancy Reports, require State agencies to use these reports to ensure that their drug expenditures comply with Federal requirements, and follow up as necessary with State agencies to ensure that claimed drug expenditures comply with Federal requirements.

CMS Response

We do not concur with using the Utilization Discrepancy Report to transmit this data field to States. State Utilization Discrepancy reports (SUDRs) are not meant to inform States of labeler updates to drug product information such as termination date inputs and changes. SUDRs are

also only sent to States in response to receipt of utilization data due once per quarter, so this would not adequately correct the issue from a timing/frequency perspective. However, we have provided States with an interface to access the Drug Data Reporting for Medicaid System (DDR) where they may view appropriate manufacturer product changes, including the input or change to the termination date field. Most States have obtained access to DDR and can view termination dates on a regular basis. The States that do not have access to DDR receive the termination date information on the rebate files that are sent to them quarterly.

For labelers that do not comply with accurate and timely reporting of their termination dates, we plan to discuss with the OIG the appropriateness of CMPs.

OIG Recommendation

CMS should work with the drug manufacturers and strengthen controls to ensure that the information on the quarterly drug tapes is complete and accurate and take appropriate action against manufacturers if they are not timely in providing information to CMS for all of their covered drugs.

CMS Response

We concur, and plan to reiterate this rebate requirement in a manufacturer release. Additionally, for labelers that do not comply with accurate and timely reporting of their termination dates, we plan to discuss with the OIG the appropriateness of CMPs.

OIG Recommendation

CMS should develop policies and procedures to inform State agencies immediately when a drug has been terminated, instruct State agencies to claim expenditures only for drugs dispensed before the termination dates, and require State agencies to review and reject all current and prior claims for terminated drugs.

CMS Response

We concur that we should inform States immediately when a drug has been terminated. CMS has enhanced the DDR to provide a State interface, which allows States to view drug termination dates along with other product data prior to receipt of the quarterly rebate file and we are working on further enhancements to that system.

However, we do not concur that we should instruct State agencies to claim expenditures only for drugs dispensed before the termination dates, and require State agencies to review and reject all current and prior claims for terminated drugs. While we believe our guidance in manufacturer and State releases are clear on this point, we do not believe manufacturers properly and timely report such termination dates. We believe further work is needed in this area to assure manufacturer compliance and plan to reiterate to manufacturers and States the requirements

regarding terminated drugs. Absent that, we do not believe it appropriate to disallow expenditures for these claims.

Furthermore, for labelers that do not comply with timely reporting of their termination dates, we plan to discuss with the OIG the appropriateness of the CMP assessment for late reporting of the termination date.

The CMS would again like to thank the OIG for their efforts in reviewing the compliance of States' participation in the Medicaid Drug Rebate Program for the reimbursement of drug expenditures.