DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

NOV 10 2008

TO: Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services

FROM: Joseph E. Vengrin
Deputy Inspector General for Audit Services

SUBJECT: Review of Medicaid Outpatient Drug Expenditures in Tennessee for the Period October 1, 2003, Through September 30, 2005 (A-04-07-00027)

Attached is an advance copy of our final report on Medicaid outpatient drug expenditures in Tennessee for the period October 1, 2003, through September 30, 2005. We will issue this report to the Bureau of TennCare (State agency) within 5 business days.

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 Tennessee, administer their Medicaid prescription drug programs in accordance with the Medicaid drug rebate program. The program generally pays for covered outpatient drugs if the drug manufacturers have rebate agreements with the Centers for Medicare & Medicaid Services (CMS) and pay rebates to the States. Under the drug rebate agreement, CMS provides the States with a quarterly Medicaid drug tape, which lists all covered outpatient drugs and indicates a drug's termination date, if applicable. CMS guidance instructs the States to use the tape to verify coverage of the drugs for which they claim reimbursement.

Our objective was to determine whether the State agency's claims for reimbursement of Medicaid outpatient drug expenditures complied with Federal requirements.

The State agency's claims for reimbursement of Medicaid outpatient drug expenditures for fiscal years 2004 and 2005 did not fully comply with Federal requirements. Of the $4.5 billion ($3 billion Federal share) claimed, $7,970,280 (Federal share) represents expenditures for drug products that were not eligible for Medicaid coverage because they were either terminated drugs for which the termination dates were listed on the CMS quarterly drug tape before the drugs were dispensed or less-than-effective drugs. An additional $13,224,612 (Federal share) represents expenditures for drug products that were not listed on the quarterly drug tapes. Because the State agency did not verify whether the drugs missing from the tapes were eligible for Medicaid coverage, some of the expenditures may not have been allowable for Medicaid reimbursement. For the remainder of the $4.5 billion ($3 billion Federal share) claimed, we identified no other

errors with respect to whether the drugs were (a) terminated, (b) less than effective, or (c) included on the CMS quarterly drug tapes.

The State agency had insufficient controls to ensure that all of its outpatient drug expenditures complied with Federal requirements.

We recommend that the State agency:

- refund $7,970,280 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage;

- work with CMS to determine whether the $13,224,612 in payments for drugs that were not listed on the quarterly drug tapes was eligible for Medicaid coverage; and

- strengthen internal controls to ensure that claimed Medicaid drug expenditures comply with Federal requirements, specifically:

    - claim expenditures only for drugs that are dispensed before the termination dates listed on the quarterly drug tapes,

    - claim expenditures only for drugs that are not listed as less than effective on the quarterly drug tape, and

    - verify whether drugs not listed on the quarterly drug tapes are covered under the Medicaid program and notify CMS when drugs are missing from the tapes.

In written comments on our draft report, the State agency agreed in part with our first recommendation and did not directly address our second and third recommendations. After reviewing the State agency's comments, we continue to support our findings and recommendations.

If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact George M. Reeb, Assistant Inspector General for the Centers for Medicare & Medicaid Audits, at (410) 786-7104 or through e-mail at George.Reeb@oig.hhs.gov or Peter J. Barbera, Regional Inspector General for Audit Services, Region IV, at (404) 562-7800 or through e-mail at Peter.Barbera@oig.hhs.gov. Please refer to report number A-04-07-00027.

Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General
Office of Audit Services

REGION IV
61 Forsyth Street, S.W., Suite 3T41
Atlanta, Georgia 30303

NOV 13 2008

Report Number: A-04-07-00027

Mr. Darin Gordon
Deputy Commissioner
Bureau of TennCare
310 Great Circle Road
Nashville, Tennessee 37243

Dear Mr. Gordon:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled "Review of Medicaid Outpatient Drug Expenditures in Tennessee for the Period October 1, 2003, Through September 30, 2005." 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.

Pursuant to the principles of the Freedom of Information Act, 5 U.S.C. § 552, as amended by Public Law 104-231, OIG reports generally are made available to the public to the extent the information is not subject to exemptions in the Act (45 CFR part 5). Accordingly, this report will be posted on the Internet at http://oig.hhs.gov.

If you have any questions or comments about this report, please do not hesitate to call me, or contact Mark L. Wimple, Audit Manager, at (919) 790-2765, extension 24, or through e-mail at Mark.Wimple@oig.hhs.gov. Please refer to report number A-04-07-00027 in all correspondence.

Sincerely,

Peter J. Barbera
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, Illinois 60601

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF MEDICAID OUTPATIENT DRUG EXPENDITURES IN TENNESSEE FOR THE PERIOD OCTOBER 1, 2003, THROUGH SEPTEMBER 30, 2005

Daniel R. Levinson
Inspector General

November 2008
A-04-07-00027

Office of Inspector General

http://oig.hhs.gov

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Pursuant to the principles of the Freedom of Information Act, 5 U.S.C. § 552, as amended by Public Law 104-231, Office of Inspector General reports generally are made available to the public to the extent the information is not subject to exemptions in the Act (45 CFR part 5).

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 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 Tennessee, TennCare (the State agency) administers its 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 Tennessee, administer their Medicaid prescription drug programs in accordance with the Medicaid drug rebate 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 drug rebate program, CMS provides the States with a quarterly Medicaid drug tape, which lists all covered outpatient drugs and indicates a drug's termination date, if applicable. CMS guidance instructs the States to use the tape to verify coverage of the drugs for which they claim reimbursement.

In Tennessee, the State agency claims Medicaid expenditures on Form CMS-64, "Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program." CMS reimburses the State agency based on the Federal medical assistance percentage for the majority of claimed Medicaid outpatient drug expenditures.

OBJECTIVE

Our objective was to determine whether the State agency's claims for reimbursement of Medicaid outpatient drug expenditures complied with Federal requirements.

SUMMARY OF FINDINGS

The State agency's claims for reimbursement of Medicaid outpatient drug expenditures for fiscal years 2004 and 2005 did not fully comply with Federal requirements. Of the $4.5 billion ($3 billion Federal share) claimed, $7,970,280 (Federal share) represents expenditures for drug products that were not eligible for Medicaid coverage because they were either terminated drugs for which the termination dates were listed on the CMS quarterly drug tape before the drugs were dispensed or less-than-effective drugs. An additional $13,224,612 (Federal share) represents expenditures for drug products that were not listed on the quarterly drug tapes. Because the State agency did not verify whether the drugs missing from the tapes were eligible for Medicaid coverage, some of the expenditures may not have been allowable for Medicaid reimbursement. For the remainder of the $4.5 billion ($3 billion Federal share) claimed, we identified no other

errors with respect to whether the drugs were (a) terminated, (b) less than effective, or (c) included on the CMS quarterly drug tapes.

The State agency had insufficient controls to ensure that all of its outpatient drug expenditures complied with Federal requirements.

RECOMMENDATIONS

We recommend that the State agency:

- refund $7,970,280 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage;

- work with CMS to determine whether the $13,224,612 in payments for drugs that were not listed on the quarterly drug tapes was eligible for Medicaid coverage; and

- strengthen internal controls to ensure that claimed Medicaid drug expenditures comply with Federal requirements, specifically:

    - claim expenditures only for drugs that are dispensed before the termination dates listed on the quarterly drug tapes,

    - claim expenditures only for drugs that are not listed as less than effective on the quarterly drug tape, and

    - verify whether drugs not listed on the quarterly drug tapes are covered under the Medicaid program and notify CMS when drugs are missing from the tapes.

STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, the State agency agreed in part with our first recommendation and did not directly address our second and third recommendations. The State agency's comments appear in their entirety as the Appendix.

After reviewing the State agency's comments, we continue to support our findings and recommendations.

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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 plan. Although the State has considerable flexibility in designing and operating its Medicaid program, it must comply with applicable Federal requirements. In Tennessee, TennCare (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

States offer outpatient prescription drugs to eligible Medicaid beneficiaries. Most States, including Tennessee, administer their Medicaid prescription drug programs in accordance with the Medicaid drug rebate 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 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 a drug's termination date;[2] if applicable, specifies whether the drug is less than effective;[3] and includes information that the States use to claim rebates from drug 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.

[1]The Omnibus Budget Reconciliation Act of 1990 established the Medicaid drug rebate program effective January 1, 1991. The program is set forth in section 1927 of the Act.

[2]The termination date, which the manufacturer submits to CMS, reflects the shelf-life expiration date of the last batch sold for a particular drug code. However, if the drug is pulled from the market for health or safety reasons, the termination date is the date that the drug is removed from the market.

[3]The Food and Drug Administration determines whether drugs are less than effective. Such drugs lack substantial evidence of effectiveness for all conditions of use prescribed, recommended, or suggested in their labeling.

Reimbursement of Medicaid Expenditures

In Tennessee, the State agency claims Medicaid expenditures on Form CMS-64, "Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program" (CMS-64). CMS reimburses the State agency based on the Federal medical assistance percentage (reimbursement rate) for the majority of claimed Medicaid expenditures, including outpatient drug expenditures.

For Federal fiscal years (FY) 2004 and 2005, Tennessee's Federal reimbursement rate for Medicaid expenditures varied from 64.40 to 67.54 percent.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether the State agency's claims for reimbursement of Medicaid outpatient drug expenditures complied with Federal requirements.

Scope

The audit scope included $4.5 billion ($3.0 billion Federal share) in Medicaid outpatient drug expenditures that the State agency claimed for FYs 2004 and 2005. We limited our testing of these expenditures to determining compliance with specific Federal requirements and guidance related to whether the drugs were (a) terminated, (b) less than effective, and (c) included on the CMS quarterly drug tapes.

We limited our internal control review to the State agency's procedures for determining whether the outpatient drugs were eligible for Medicaid coverage and were accurately claimed for Federal reimbursement. We did not review the accuracy or completeness of the quarterly Medicaid drug tapes.

We conducted fieldwork at the State agency's offices in Nashville, Tennessee, from February through October 2007.

Methodology

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

We used the quarterly drug tapes for the period October 1, 1999, through June 30, 2006. We reconciled the amounts that the State agency reported on its CMS-64s to a detailed list of the State agency's outpatient drug expenditures. We also used the detailed list of drug expenditures to determine whether the expenditures complied with Federal requirements. Specifically, we determined whether the drugs for which the State agency claimed reimbursement were dispensed after the termination dates listed on the quarterly drug tape. In addition, we determined whether CMS had included the termination dates on the quarterly drug tape in a timely manner—that is,

before terminated drugs could be dispensed. To account for reasonable delays in processing data for terminated drugs, we used the first day of the quarter after the State received the tape as the termination date if the termination dates were provided to the States retroactively.

We also determined whether the drugs claimed for reimbursement were listed on the applicable quarterly drug tape. If the drugs were not listed on the tape, we determined whether the State agency had verified whether the drugs were eligible for Medicaid coverage. If the drugs were compound drugs, we requested supporting documentation that identified the individual drug components.[4]

We calculated the Federal share of the expenditures using the lowest percentage (64.40 to 67.54 percent) applicable for each quarter. We did not reduce the questioned drug expenditures by the rebate amounts that the State received.

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 State agency's claims for reimbursement of Medicaid outpatient drug expenditures for FYs 2004 and 2005 did not fully comply with Federal requirements. Of the $4.5 billion ($3 billion Federal share) claimed, $7,970,280 (Federal share) represents expenditures for drug products not eligible for Medicaid coverage because they were either terminated drugs for which the termination dates were listed on the CMS quarterly drug tape before the drugs were dispensed or less-than-effective drugs. An additional $13,224,612 (Federal share) represents expenditures for drug products not listed on the quarterly drug tapes. Because the State agency did not verify whether the drugs missing from the tapes were eligible for Medicaid coverage, some of the expenditures may not have been allowable for Medicaid reimbursement. For the remainder of the $4.5 billion ($3 billion Federal share) claimed, we identified no other errors with respect to whether the drugs were (a) terminated, (b) less than effective, or (c) included on the CMS quarterly drug tapes.

The State agency had insufficient controls to ensure that all of its outpatient drug expenditures complied with Federal requirements.

[4]Pharmacists create compound drugs by combining two or more prescription or nonprescription drug products and then repackaging them into a new capsule or other dosage form.

CLAIMS FOR 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 product. The termination date equals the expiration date of the last batch sold, except in cases when the product is pulled from the market. In those cases, the termination date may be earlier than the expiration date.

According to the CMS Medicaid drug rebate program release 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." (Emphasis in original.)

The CMS Medicaid drug rebate program release 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 drug manufacturers.

For FYs 2004 and 2005, the State agency claimed $12,381,981 ($7,925,673 Federal share) in expenditures for drugs that, according to the State's records, were dispensed after the termination dates shown on the quarterly drug tapes. For example, the State continued to pay for the drug Zocor, which was dispensed for 16 months after the drug's termination date of May 31, 2004. The quarterly drug tapes listed the termination date beginning with the quarter that ended March 31, 2002. The claimed expenditures were unallowable because they occurred after the drug's termination date, which was listed on the quarterly drug tape at the time the State agency made the expenditures.

CLAIMS FOR LESS-THAN-EFFECTIVE DRUGS

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) prohibits Federal funding for drug products determined to be less than effective for all conditions prescribed, recommended, or suggested on the product's label. According to the CMS Medicaid drug rebate program release 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." The quarterly drug tapes identify drugs that have been determined to be less than effective.

For FYs 2004 and 2005, the State agency claimed $68,798 ($44,607 Federal share) in expenditures for drugs classified as less than effective on the quarterly drug tapes. For example, the State paid for the drug Novacort, which was dispensed for 9 months after the drug's less-than-effective date of January 1, 2005. However, CMS reported the drug as less than effective on the tapes beginning with the quarter that ended September 30, 2004. The claimed expenditure was unallowable because the drug was dispensed after CMS reported it as less than effective.

CLAIMS FOR DRUGS NOT LISTED ON QUARTERLY DRUG TAPES

Section 1927(a)(1) of the Act generally conditions Medicaid reimbursement for covered outpatient drugs on a requirement that manufacturers of those products enter into rebate agreements with CMS under which they pay rebates to the States.[5] The rebate agreements require 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. According to the CMS Medicaid drug rebate program release 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 release to State Medicaid directors, number 44, provides that "States must check the [quarterly drug tape] to ensure the continued presence of a drug product . . . ."

For FYs 2004 and 2005, the State agency claimed $20,281,121 ($13,224,612 Federal share) in expenditures for drug products not listed on the quarterly drug tapes. The State agency did not contact CMS to ensure these drugs were eligible for Medicaid coverage under the Act. As a result, the State agency did not have conclusive evidence that these payments were allowable Medicaid expenditures.

INSUFFICIENT CONTROLS TO DETECT UNALLOWABLE AND POTENTIALLY UNALLOWABLE CLAIMS FOR DRUG EXPENDITURES

The State agency did not have sufficient controls to ensure that all Medicaid drug expenditures complied with Federal requirements or to detect unallowable and potentially unallowable claims for reimbursement. The State agency did not check the quarterly drug tapes to ensure that the drugs were eligible for Medicaid coverage.

REIMBURSEMENT OF UNALLOWABLE AND POTENTIALLY UNALLOWABLE CLAIMS FOR DRUG EXPENDITURES

The State agency claimed Federal reimbursement for certain drugs not eligible for Medicaid coverage because they were terminated. As a result, for FYs 2004 and 2005, the State agency claimed unallowable expenditures totaling $12,381,981 ($7,925,673 Federal share) for these drugs. In addition, the State agency claimed Federal reimbursement for certain drugs not eligible for Medicaid coverage because they were less than effective. For these drugs, the State agency claimed unallowable expenditures totaling $68,798 ($44,607 Federal share).

The State agency also claimed Federal reimbursement for drug products not listed on the quarterly drug tapes. For these drugs, we set aside potentially unallowable expenditures totaling $20,281,121 ($13,224,612 Federal share) for CMS adjudication because the State agency did not determine whether the drugs were covered by Medicaid.

[5]Pursuant to section 1927(a)(3) of the Act, a State may exempt certain drugs from the requirement to be covered by a drug rebate agreement 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.

RECOMMENDATIONS

We recommend that the State agency:

- refund $7,970,280 to the Federal Government for drug expenditures not eligible for Medicaid coverage;

- work with CMS to determine whether the $13,224,612 in payments for drugs not listed on the quarterly drug tapes was eligible for Medicaid coverage; and

- strengthen internal controls to ensure claimed Medicaid drug expenditures comply with Federal requirements, specifically:

    - claim expenditures only for drugs that are dispensed before the termination dates listed on the quarterly drug tapes,

    - claim expenditures only for drugs that are not listed as less than effective on the quarterly drug tape, and

    - verify whether drugs not listed on the quarterly drug tapes are covered under the Medicaid program and notify CMS when drugs are missing from the tapes.

STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, the State agency agreed in part with our first recommendation and did not directly address our second and third recommendations. The State agency concurred with our finding regarding claims for less-than effective drugs ($44,607 Federal share) but disagreed with our finding regarding claims for terminated drugs ($7,925,673 Federal share). The State agency made additional comments but did not provide evidence to refute our finding that terminated drugs were claimed. The State agency's comments appear in their entirety as the Appendix.

After reviewing the State agency's comments, we continue to support our findings and recommendations.

APPENDIX

State of Tennessee
Department of Finance and Administration
Bureau of TennCare
310 Great Circle Road
Nashville, Tennessee 37243

Phil Bredesen
Governor

M. D. Goetz, Jr.
Commissioner

September 2, 2008

Mr. Peter J. Barbera
Regional Inspector General
For Audit Services
Department of Health and Human Services
Office of Inspector General
Office of Audit Services
Region IV
61 Forsyth Street, SW, Suite 3T41
Atlanta, Georgia 30303

RE: Review Of Medicaid Outpatient Drug Expenditures in Tennessee For The Period October 1, 2003, Through September 30, 2005

Dear Mr. Barbera:

I want to sincerely apologize for the lateness of our response to this review. Please find attached our written comments to the Review of Medicaid Outpatient Drug Expenditures in Tennessee for the Period October 1, 2003 through September 30, 2005 as it relates to "Terminated Drugs" and "Less Than Effective".

Again, please accept my apology for the lateness of our response.

Sincerely,

Scott C. Pierce
Chief Financial Officer

Attachment

Scp:mt

Terminated Drugs:

We concur in part. While the Bureau of TennCare understands the ramifications of reimbursing for terminated drugs, we do not agree with the amounts for the terminated drug list at $7,925,673 federal share. TennCare utilizes a Pharmacy Benefits Manager (PBM) which relies on data from the nationally recognized expert First Data Bank to acquire and update any drug termination dates, pricing, NDC updates, etc, in the PBM's point of sale network. TennCare's policy was to allow for a 365-day "run-out" of drugs from pharmacy inventory after the termination date has been announced. This policy has since been retracted and at the first notification of a drug's termination date, the NDC is no longer a valid drug eligible for TennCare reimbursement through our PBM's point of sale network.

After researching the dates of termination for the drug Zocor (five Zocor NDCs on the terminated list comprise 91.98% of the federal questioned dollars) it was determined that the termination dates of the various strengths of Zocor were entered into First Data Bank's system between two and four months after the termination date. Using the run-out policy from the termination date, the vast majority of this drug's questioned costs would fall in that 365-day span for run-out. Additionally, this specific NDC is only for a certain sized container of the drug (60-count bottle) and the drug itself is still a currently produced and dispensed drug. The drug itself was never taken off the market, only the package size was discontinued.

In regards to the quarterly drug tapes, the information contained on them has been proven to be less than reliable. According to CMS regulations, a pharmaceutical company is supposed to report to CMS every quarter its qualifying drugs and the rebates associated with them. Some apparently report only on an annual or semi-annual basis. The quarterly tapes are therefore nonsensical in the exceptions for reported drugs: one quarter a drug is allowable, the next unallowable, the next quarter it is allowable. The drug has not terminated because of this, but instead the company only reports every six months to CMS its qualifying drug list and rebates. Merck, the creator of Zocor, reimbursed TennCare over $4.5 million for its applicable drug rebates for the very same NDCs that are in question and that were on the quarterly drug tapes. This was for more than 109 thousand prescriptions dispensed.

Less Than Effective:

We concur. Drugs that have been deemed less than effective by CMS should not be reimbursed by TennCare to the PBM.