



DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF AUDIT SERVICES
233 NORTH MICHIGAN AVENUE
CHICAGO, ILLINOIS 60601

REGION V
OFFICE OF
INSPECTOR GENERAL

JUN - 5 2009

Report Number: A-05-08-00048

Ms. Janet Olszewski
Director
Michigan Department of Community Health
Capital View Building
201 Townsend Street
Lansing, Michigan 48913

Dear Ms. Olszewski:

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 Michigan for the Period October 1, 2004, 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.

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If you have any questions or comments about this report, please do not hesitate to call me, or contact David Markulin, Audit Manager, at (312) 353-1644 or through e-mail at David.Markulin@oig.hhs.gov. Please refer to report number A-05-08-00048 in all correspondence.

Sincerely,

Marc Gustafson
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 MICHIGAN
FOR THE PERIOD
OCTOBER 1, 2004, THROUGH
SEPTEMBER 30, 2005**



Daniel R. Levinson
Inspector General

June 2009
A-05-08-00048

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

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 Michigan, the Department of Community Health (the State agency) administers Medicaid.

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 Michigan, 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, indicates a drug's termination date if applicable, and specifies whether the Food and Drug Administration has determined the drug to be less than effective. CMS guidance instructs the States to use the tape to verify coverage of the drugs for which they claim reimbursement.

In Michigan, 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 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 year 2005 did not fully comply with Federal requirements. Of the \$987 million (\$560 million Federal share) claimed, \$105,618 (Federal share) represented expenditures for drug products that were not eligible for Medicaid coverage because they were either (1) terminated drugs for which the termination dates were listed on the CMS quarterly drug tape before the drugs were dispensed or (2) drugs listed on the CMS quarterly drug tape as less than effective. An additional \$2,937,769 (Federal share) represented 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, these drug expenditures may not have been allowable for Medicaid reimbursement.

The State agency improperly claimed other Medicaid services totaling \$395,185 (Federal share) as drug expenditures on the CMS-64. During our audit, the State agency reclassified the expenditures and adjusted the CMS-64, resulting in no net effect to the claimed Federal reimbursement. For the remainder of the \$987 million (\$560 million Federal share) claimed, we identified no errors with respect to whether the drugs were terminated, less than effective, included on the CMS quarterly drug tapes, or supported with adequate documentation.

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

RECOMMENDATIONS

We recommend that the State agency:

- refund \$105,618 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage;
- work with CMS to resolve \$2,937,769 in payments for drugs that were not listed on the quarterly drug tapes and that may not have been 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 tapes;
 - 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; and
 - implement review and reconciliation procedures to ensure that Medicaid drug expenditures reported on the CMS-64 are accurate, supportable, and in compliance with all applicable requirements.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency concurred with our first and second recommendations. The State agency also described corrective actions it had taken to strengthen its internal controls to ensure that claimed Medicaid drug expenditures comply with Federal requirements.

The State agency's comments are included in their entirety as the Appendix.

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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 Michigan, the Department of Community Health (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 Michigan, 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 date² 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.

¹The 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. Arizona is the only State that does not participate in the program.

²The 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.

³The 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 Michigan, 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 year (FY) 2005, Michigan’s Federal reimbursement rate for Medicaid expenditures was 56.71 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 \$987 million (\$560 million Federal share) in Medicaid outpatient drug expenditures that the State agency claimed for FY 2005. We limited our testing of these expenditures to determining compliance with specific Federal requirements and guidance related to whether the drugs were (1) terminated, (2) less than effective, (3) included on the CMS quarterly tapes, and (4) supported with adequate documentation.

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 performed fieldwork from July through November 2008 at the State agency’s offices in Lansing, Michigan.

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 or were listed as less than effective on

the 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.

We calculated the Federal share of the expenditures using the reimbursement rate (56.71 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 FY 2005 did not fully comply with Federal requirements. Of the \$987 million (\$560 million Federal share) claimed, \$105,618 (Federal share) represented expenditures for drug products that were not eligible for Medicaid coverage because they were either (1) terminated drugs for which the termination dates were listed on the CMS quarterly drug tape before the drugs were dispensed or (2) drugs listed on the CMS quarterly drug tape as less than effective. An additional \$2,937,769 (Federal share) represented 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, these drug expenditures may not have been allowable for Medicaid reimbursement.

The State agency improperly claimed other Medicaid services totaling \$395,185 (Federal share) as drug expenditures on the CMS-64. During our audit, the State agency reclassified the expenditures and adjusted the CMS-64, resulting in no net effect to the claimed Federal reimbursement. For the remainder of the \$987 million (\$560 million Federal share) claimed, we identified no errors with respect to whether the drugs were terminated, less than effective, included on the CMS quarterly drug tapes, or supported with adequate documentation.

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

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 the 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 FY 2005, the State agency claimed \$109,167 (\$61,909 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 agency paid for the drug Butalbital, which was dispensed on April 4, 2005. However, the drug’s termination date was August 31, 2004, according to the tapes beginning with the quarter that ended December 31, 2003. The claimed expenditure was unallowable because it occurred after the drug’s termination date, which was listed on the quarterly drug tape at the time the State agency made the expenditure.

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 FY 2005, the State agency claimed \$77,075 (\$43,709 Federal share) in expenditures for drugs classified as less than effective on the quarterly drug tapes. For example, the State agency paid for the drug Bellaspas, which was dispensed on August 14, 2005. However, CMS reported the drug as less than effective on the tapes beginning with the quarter that ended December 31, 2003. 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.⁴ 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: “States must check the [quarterly drug tape] to ensure the continued presence of a drug product”

The CMS “Medicaid Drug Rebate Operational Training Guide,” page S-S13, 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.”

For FY 2005, the State agency claimed \$5,180,336 (\$2,937,769 Federal share) in expenditures for drug products that were not listed on the quarterly drug tapes. The State agency did not contact CMS to ensure that 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.

CLAIMS FOR INADEQUATELY SUPPORTED DRUG EXPENDITURES

Section 1927 of the Act generally defines which covered outpatient drugs are allowable for Federal reimbursement under the Medicaid program. To receive reimbursement for covered drugs, States must maintain documentation identifying the specific drugs used. 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.”

The State agency improperly claimed Medicaid services related to Title V (Maternal and Child Health Services) totaling \$395,185 (Federal share) as drug expenditures on the CMS-64.⁵ The State agency indicated that these expenditures were not drug related. During our audit, the State agency reclassified and reported these services on the CMS-64 for the quarter that ended June 30, 2008, resulting in no net effect to the claimed Federal reimbursement. These errors occurred because the State agency did not sufficiently review and reconcile drug expenditures reported on the CMS-64 to ensure that the amounts claimed were accurate, supported by documentation, and in compliance with Medicaid requirements.

⁴Pursuant 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.

⁵We did not determine whether the services were actually provided or represented allowable expenditures to be claimed on the CMS-64.

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

The State agency did not have adequate controls to ensure that all claims for Medicaid drug expenditures complied with Federal requirements or to detect unallowable and potentially unallowable claims for reimbursement. The State agency also 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 that were not eligible for Medicaid coverage because they were terminated or less than effective. As a result, for FY 2005, the State agency claimed unallowable expenditures totaling \$186,242 (\$105,618 Federal share) for these drugs. The State agency also claimed Federal reimbursement for drug products that were not listed on the quarterly drug tapes. For these drugs, we set aside potentially unallowable expenditures totaling \$5,180,336 (\$2,937,769 Federal share) for CMS adjudication because the State agency did not determine whether the drugs were covered by Medicaid.

RECOMMENDATIONS

We recommend that the State agency:

- refund \$105,618 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage;
- work with CMS to resolve \$2,937,769 in payments for drugs that were not listed on the quarterly drug tapes and that may not have been 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 tapes;
 - 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; and
 - implement review and reconciliation procedures to ensure that Medicaid drug expenditures reported on the CMS-64 are accurate, supportable, and in compliance with all applicable requirements.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency concurred with our first and second recommendations. The State agency also described corrective actions it had taken to strengthen its internal controls to ensure that claimed Medicaid drug expenditures comply with Federal requirements.

The State agency's comments are included in their entirety as the Appendix.

APPENDIX



JENNIFER M. GRANHOLM
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF COMMUNITY HEALTH
LANSING

JANET OLSZEWSKI
DIRECTOR

April 15, 2009

Mr. Marc Gustafson
Regional Inspector General for Audit Services
Department of Health and Human Services
Office of Audit Services
233 North Michigan Avenue
Chicago, Illinois 60601

Re: Report Number (A-05-08-00048)

Dear Mr. Gustafson:

Enclosed is the Michigan Department of Community Health's response to the draft report entitled "Review of Medicaid Outpatient Drug Expenditures in Michigan" that covered the period October 1, 2004 through September 30, 2005.

We appreciate the opportunity to review and comment on the report before it is released. If you have any questions regarding this response, please refer them to Pam Myers at (517) 373-1508.

Sincerely,

Janet Olszewski
Janet Olszewski
Director

JO:kk

Enclosure

cc:



Review of Medicaid Outpatient Drug Expenditures in Michigan
for the period October 1, 2004 through September 30, 2005
(A-05-08-00048)

Finding

The State agency claimed Federal reimbursement for certain drugs that were not eligible for Medicaid coverage because they were terminated or less than effective. As a result, for FY 2005, the State agency claimed unallowable expenditures that were totaling \$186,242 (\$105,618 Federal share) for these drugs. The State agency also claimed Federal reimbursement for drug products that were not listed on the quarterly drug tapes. For these drugs, we set aside potentially unallowable expenditures totaling \$5,180,336 (\$2,937,769 Federal share) for CMS adjudication because the State agency did not determine whether the drugs were covered by Medicaid.

Recommendations

We recommend that the State agency:

- refund \$105,618 to the Federal government for drug expenditures that were not eligible for Medicaid coverage
- work with CMS to resolve \$2,937,769 in payments for drugs that were not listed on the quarterly drug tapes and that may not have been 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 tapes
 - 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; and
 - implement review and reconciliation procedures to ensure that Medicaid drug expenditures reported on the CMS-64 are accurate, supportable, and in compliance with all applicable requirements.

Review of Medicaid Outpatient Drug Expenditures in Michigan
for the period October 1, 2004 through September 30, 2005
(A-05-08-00048)

DCH Response

The Department:

- concurs with the recommendation and will refund \$105,618 to the Federal government for drug expenditures for terminated and less-than-effective drugs
- will work with CMS to resolve any questionable payments for drugs not listed on the quarterly drug tapes, but believes these claims were appropriately covered and that the suggested financial penalties are not warranted.
- has strengthened its internal controls to ensure that claimed Medicaid drug expenditures comply with Federal requirements by:
 - implementing additional pharmacy claim adjudication functionality and rules on 9/25/2008 and 10/15/2008 to ensure that terminated drugs are not covered
 - implementing revised less-than-effective drug coverage coding on 5/30/2007 based on CMS clarification and reviewing and updating, when necessary, the coding upon receipt of CMS notices of less-than-effective drug changes
 - Pharmacy Services Section staff and the Department's contracted rebate invoicing vendor reviewing the quarterly CMS utilization discrepancy report and notifying CMS when drugs covered under the Medicaid program are missing from the quarterly drug tapes; and
 - implementing review and reconciliation procedures October 2008 to ensure that Medicaid drug expenditures reported on the CMS-64 are accurate, supportable, and in compliance with all applicable requirements.

ADDITIONAL DETAILS

Prior to and during the audit period, the industry standard for pharmacy claim adjudication has been on-line real time processing. Real time processing requires up-to-date drug reference and pricing information from independent data sources, like First DataBank, so that *new* medically necessary products can be covered for Medicaid beneficiaries. Several years ago, CMS (formerly called HCFA) recognized this industry standard in its published *Best Practices Under the Medicaid Drug Rebate Program* stating "...many State Medicaid programs and pharmacy providers utilize drug data from independent data sources such as Medispan, First DataBank, and Redbook. For this

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reason, Manufacturers **should** provide basic product information for all NDCs (e.g., product description, product indication, AWP, unit type, package size, etc.) to independent data sources.” The CMS quarterly rate tapes are available up to 45 days after the rebate quarter ends (i.e. after claims have already been adjudicated). Our State program has therefore relied upon the drug data, including termination dates, less-than-effective and rebate status from an independent data source, the First DataBank drug file, to determine coverage.

CLAIMS FOR TERMINATED DRUGS

We agree with the analysis as presented to us in this document related to Terminated Drugs. In accordance with industry standards, the Department historically utilized an independent data source to determine drug coverage. During the audit period, our processing system used the termination or obsolete dates from the independent drug file. Our policy previously allowed for coverage no more than 365 days post manufacturer reported obsolete date because it was discovered that termination dates were not always reported by the manufacturers.

The Department would not expect differences between the HCFA termination date on the drug file and the CMS quarterly drug tape. However, a recent Pharmacy Benefits Management (PBM) system upgrade implemented September 25, 2008 now allows for rules that incorporate dates from both data sources. To prevent any data discrepancies in the future, the Department has taken advantage of the system upgrade and the CMS quarterly drug tape date will be used in claim adjudication when appropriate. Additionally, October 15, 2008, the Department began creating drug exclusion lists to be used during claim adjudication to accommodate CMS email notifications of newly terminated drugs in between the quarterly drug tapes. The independent data source is still needed in online real-time processing until the drug product shows up on the CMS quarterly tape and/or if the drug is excluded from the rebate program all together but was determined to be medically necessary for the beneficiary.

CLAIMS FOR LESS-THAN-EFFECTIVE DRUGS

We agree with the analysis as presented to us in this document related to Less-Than-Effective drugs. As a result of recent CMS clarification on DESI classifications, the Department’s pharmacy processing system rules were enhanced 5/30/2007 to more accurately screen less-than-effective drugs. The rules were implemented retroactively to address claims submitted for dates of service back to 7/5/1999.

CLAIMS FOR DRUGS NOT LISTED ON QUARTERLY DRUG TAPES

The Department’s PBM claim processing system adjudicates claims in accordance with our published policy and approved State Plan. The State Plan language we previously provided allows our Program to cover medications when medically necessary regardless

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of rebate status. In addition, there are some claims submitted through our PBM system that are excluded from the CMS rebate requirements. The Department feels compelled to document, that upon review of the audit preliminary conclusions, we found:

- 1) The majority of the questionable expenditures were for rebatable products of which manufacturers made CMS rebate payments on during the audit period. The Department attempted to collect rebates on all NDCs that were reimbursed during the specified time periods by sending rebate invoices to manufacturers enrolled in the CMS program. Once manufacturers receive an invoice, they have the responsibility to process the utilization and pay using the appropriate rate if applicable and also calculate and pay any interest that might be due the Department. Fentanyl patches alone accounted for \$2,953,724.16 of the \$5,196,568.44 questionable expenditures. The Department has documentation of CMS rebate payments collected for the Fentanyl patches during the audit period.
- 2) Many of the remaining questionable expenditures were for medical supply products or family planning supplies (e.g. condoms) that were covered as a pharmacy benefit in accordance with our Medicaid policy and approved State Plan. Both are normally excluded from rebate requirements because they do not meet the definition of an outpatient drug.
- 3) Last but not least, as mentioned above, our approved State Plan allows pharmacy coverage of medically necessary products regardless of rebate status. We've reviewed and believe the remaining questionable expenditures were covered appropriately for medical necessity.

Due to the Department financial penalties suggested for failure to utilize the quarterly CMS rebate tapes, the Department suggests that CMS automate the transmittal of the rebate data to align with current industry standards (e.g. secure FTP). In addition to the mode of transmittal, the frequency of transmittal should be increased so it aligns with the CMS rebate emails requiring drug coverage changes, sometimes as often as daily. The automation and increased frequency would provide States with the drug rebate details needed in real-time processing to eliminate improper coverage of products, prevent beneficiary medication access issues, and reduce unnecessary purchase and maintenance of the hardware used to support the old CMS rebate tape cartridges.

CLAIMS FOR INADEQUATELY SUPPORTED DRUG EXPENDITURES

The Department's Bureau of Accounting, Grants Management Section implemented procedures in October 2008 pertaining to recommendations from the audit. One procedure will perform reconciliations of the Michigan Administrative Information Network (MAIN) expenditures with the DCH Accounting/Budget drug invoice tracking spreadsheet on an annual basis. Also, reconciliation procedures have been implemented for the drug rebates. This includes verifying beginning and ending balances and

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comparing individual lines of the CMS-64.9R for each quarter, to the Department's CMS 64.9R Report (rebate invoicing and collection data report) so that the rebate totals reconcile to MAIN and what is submitted on the CMS 64.9R (i.e. line 7a1, Drug Rebate). The procedures will ensure the Medicaid drug expenditures reported on the CMS-64 are accurate, supportable, and in compliance with all applicable requirements.