Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

ACCURACY OF DRUG CATEGORIZATIONS FOR MEDICAID REBATES

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EXECUTIVE SUMMARY

OBJECTIVE

To determine whether the drug categorizations used to calculate Medicaid rebates are consistent with the categorizations listed in national compendia.

BACKGROUND

Medicaid is a health insurance program for certain low-income and medically needy people, jointly funded by Federal and State governments. Currently, all 50 States and the District of Columbia offer prescription drug coverage as part of their Medicaid benefit packages. In 2007, Medicaid expenditures for prescription drugs totaled $22 billion.

For Federal payments to be available for covered outpatient drugs provided under Medicaid, sections 1927(a)(1) and (b)(1) of the Social Security Act (the Act) require drug manufacturers to (1) enter into rebate agreements with the Secretary of the Department of Health and Human Services and (2) pay quarterly rebates to State Medicaid agencies. In addition, covered outpatient drugs must be approved by the Food and Drug Administration (FDA) for safety and effectiveness, with certain exceptions, to qualify for Federal payments. As set forth in section 1927(b)(3) of the Act, manufacturers must provide the Centers for Medicare & Medicaid Services (CMS) with the average manufacturer price (AMP), by national drug code (NDC), for each of their covered outpatient drugs.

The rebate amount for a drug is based in part on whether it is categorized as an innovator or a noninnovator product. For rebate purposes, innovators include both single-source (typically a brand-name product that has no available generic versions) and innovator multiple-source (typically a brand-name product that has available generic versions) products. Noninnovators are typically generic versions of multiple-source drugs. Manufacturers provide CMS with the drug categorizations for the NDCs of their covered outpatient drugs in conjunction with AMP data. Innovator products are generally subject to higher rebates than noninnovator products.

We compared drug categorizations in CMS's fourth-quarter 2007 AMP file (AMP file) to drug categorizations in two national compendia for more than 17,000 NDCs. National drug compendia are databases

compiled by private companies using data from such sources as drug manufacturers and FDA. We then conducted a manual review of the drug categorizations for 75 nonmatching NDCs associated with high Medicaid expenditures, using information obtained from FDA's Drug Information directories, FDA staff, and manufacturer Web sites. Further, we determined the percentage of NDCs with Medicaid utilization in the fourth quarter of 2007 that were not included in that quarter's AMP file.

FINDINGS

Most AMP file drug categorizations matched the categorizations in two national compendia. For 90 percent of the 17,121 NDCs in our comparison, the drug categorizations in the fourth-quarter 2007 AMP file were the same as the categorizations in the national compendia. However, drug categorizations did not match for 1,730 NDCs. Overall, these nonmatching NDCs were associated with just 3 percent of total fourth-quarter 2007 Medicaid expenditures for the NDCs under review.

A manual review of 75 of the 1,730 nonmatching NDCs found that 35 of the 75 nonmatching NDCs included in the manual review appear to have been correctly categorized in the AMP file under Medicaid rebate program requirements. This means that the drugs' innovator status in the AMP file matched the drugs' innovator status found in FDA's Drug Information directories.

Another 8 of the 75 drugs were associated with NDCs that appear to have been incorrectly categorized in the AMP file. These drugs were categorized as noninnovators in the AMP file but had been approved through new drug applications by FDA. It appears that under Medicaid rebate program requirements, these NDCs should have been categorized by their manufacturers as innovators. Because manufacturers pay smaller rebates for noninnovator drugs, States may not be receiving the rebates to which they are entitled for these eight NDCs. Fourth-quarter 2007 Medicaid expenditures for the drugs represented by these eight NDCs totaled nearly $14 million.

The remaining 32 nonmatching NDCs in the manual review were for drugs not listed in FDA's Drug Information directories. According to FDA, none of the drugs associated with these NDCs had been approved. Medicaid paid $20 million for these drugs in the fourth quarter of 2007.

A substantial number of NDCs were excluded from the drug categorization comparison, primarily because of missing data. We were unable to compare drug categorizations for 42 percent (12,557 of 29,678) of NDCs with fourth-quarter 2007 Medicaid utilization for several reasons: (1) the NDCs were not listed in the AMP file, (2) the NDCs were not listed in one or both of the two national drug compendia, or (3) the NDCs had drug categorization that differed in the two national compendia. These NDCs accounted for less than 10 percent of total Medicaid reimbursement for prescription drugs in the fourth quarter of 2007.

We excluded 65 percent (8,101 of 12,557) of these NDCs from the comparison of drug categorizations because data were missing from the AMP file. Over half of these NDCs were also not listed in the previous quarter's AMP file. For the remaining NDCs excluded from this comparison, 24 percent (3,031 of 12,557) were not listed in one or both of the national compendia. An additional 11 percent (1,425 of 12,557) of these NDCs were excluded because their innovator status in one compendium did not match their innovator status in the other.

RECOMMENDATIONS

We found that for the purposes of Medicaid drug rebates, manufacturers typically categorize their drugs in the same way as national compendia. Based on our review, most drug categorizations used to calculate Medicaid rebates appear to be correct. However, our manual review identified (1) a potential problem with Medicaid payment for drugs that do not have FDA approval and (2) instances in which certain drugs appear to have been categorized incorrectly in the AMP file, potentially resulting in a loss of rebates for States. Because we were able to identify these specific problems only for drugs that were included in our manual review of 75 nonmatching NDCs, it is likely that our findings understate the number of drugs that fit into each category. We will provide CMS with a list of the drugs that we identified as being unapproved or potentially miscategorized.

Finally, we were not able to compare drug categorizations for a large number of NDCs, primarily because AMP data were missing. The absence of AMP data would likely inhibit CMS from calculating unit rebate amounts in a timely manner. In these cases, it is the States' responsibility to collect any amounts that are owed.

To address these issues, we recommend that CMS:

Work closely with FDA to identify any potentially problematic Medicaid payments for drugs that have not been approved by FDA.

Work with manufacturers to determine the correct categorizations of the drugs that we identified as being potentially miscategorized in the AMP file and assist States in collecting any unpaid rebates that they are owed.

Continue to explore and undertake a range of efforts to ensure that drug manufacturers are submitting the required AMP data in a timely manner, including collaborating with the Office of Inspector General on administrative remedies for noncompliance.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In its comments on the draft report, CMS did not indicate whether it concurred with OIG's three recommendations. However, CMS did note that it has taken and will continue to take steps related to each of OIG's recommendations.

CMS responded to our recommendation on potentially unapproved drugs by stating that it has worked and will continue to work closely with FDA to identify potentially problematic Medicaid payments for drugs that do not meet the definition of a covered outpatient drug. In its response to our recommendation on potentially miscategorized drugs, CMS stated that it is contacting the manufacturers for which OIG identified a potential problem with drug categorizations. CMS responded to our recommendation on timely reporting of AMP data by stating that it will continue to ensure that drug manufacturers are submitting the required AMP data in a timely manner.

We ask that CMS indicate in its final management decision whether it concurs with each of our recommendations. Ongoing OIG work will further evaluate CMS's and FDA's ability to identify and remove drugs that may not be eligible for coverage under the Medicaid drug rebate program. In addition, OIG is exploring potential actions against manufacturers that fail to provide AMP data in a timely manner.

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INTRODUCTION

OBJECTIVE

To examine whether the drug categorizations used to determine Medicaid rebates are consistent with the categorizations listed in national compendia.

BACKGROUND

Medicaid Prescription Drug Coverage

Medicaid is a health insurance program for certain low-income and medically needy people, jointly funded by Federal and State governments. Individual States establish eligibility requirements, benefit packages, and payment rates for their Medicaid programs under broad Federal standards. Currently, all 50 States and the District of Columbia offer prescription drug coverage as part of their Medicaid benefit packages. In 2007, Medicaid expenditures for prescription drugs totaled nearly $22 billion.[1]

Medicaid Drug Reimbursement

Medicaid beneficiaries typically receive covered drugs through pharmacies, which are reimbursed for these drugs by State Medicaid agencies. Generally, covered outpatient drugs must be approved by the Food and Drug Administration (FDA) for safety and effectiveness, with certain exceptions, to qualify for Federal payments.[2] Reimbursement for covered outpatient prescription drugs is based on national drug codes (NDC), which are 11-digit identifiers that indicate the manufacturer, dosage form, and package size of each drug product. Federal regulations require, with certain exceptions, that each State's reimbursement for a drug not exceed the lower of its estimated

[1] Centers for Medicaid & Medicare Services (CMS), "State Drug Utilization Data." Available online at http://www.cms.hhs.gov/MedicaidDrugRebateProgram/SDUD/list.asp. Accessed on June 16, 2008. The figure does not include any rebates collected by States through the Medicaid drug rebate program.

[2] Exceptions include drugs which were commercially used or sold in the United States before the date of the enactment of the Drug Amendments of 1962; drugs for which the Secretary has determined there is a compelling justification for their medical need; drugs for which the Secretary has not issued a notice of an opportunity for a hearing on a proposed order of the Secretary to withdraw approval of an application because the Secretary has determined that the drug is less than effective; and drugs that have not been subject to a final determination that they are new drugs.

acquisition cost plus a reasonable dispensing fee or the provider's usual and customary charge to the public.[3]

CMS allows States flexibility when defining estimated acquisition cost. Each State is required to submit a Medicaid State plan to CMS describing its reimbursement methodology for covered drugs. States use a variety of mechanisms when setting drug reimbursement amounts. Currently, most States base their calculations of estimated acquisition cost on a drug's average wholesale price (AWP) discounted by a certain percentage or its wholesale acquisition cost plus a certain percentage.[4] For some multiple-source drugs, States also use the Federal upper limit and/or State maximum allowable cost programs in determining reimbursement amounts.[5]

Medicaid Drug Rebate Program

For Federal payments to be available for covered outpatient drugs provided under Medicaid, sections 1927(a)(1) and (b)(1) of the Social Security Act (the Act) require drug manufacturers to enter into rebate agreements with the Secretary of the Department of Health and Human Services and pay quarterly rebates to State Medicaid agencies. Under these rebate agreements and pursuant to section 1927(b)(3) of the Act, manufacturers must provide CMS with the average manufacturer price (AMP) by NDC for each of their covered outpatient drugs. As defined in section 1927(k)(1) of the Act, the AMP is the average price paid to the manufacturer of the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade. The AMP is determined without regard to customary prompt pay discounts extended to wholesalers.

The AMP is calculated as a weighted average of prices for all of the manufacturer's package sizes of a drug sold during a given time period and is reported for the lowest identifiable quantity of the drug

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[3] 42 CFR § 447.512.

[4] CMS, "Medicaid Prescription Reimbursement Information by State—Quarter Ending March 2008." Available online at http://www.cms.hhs.gov/MedicaidDrugRebateProgram/downloads/RxReimbursementRateMarch2008.pdf. Accessed on June 13, 2008.

[5] States use the Federal upper limit and/or State maximum allowable cost programs to establish ceiling prices for certain multiple-source drugs. CMS has established Federal upper limit amounts for more than 500 drugs. Individual States determine the types of drugs included in their maximum allowable cost programs and the methods by which the maximum allowable cost for a drug is calculated.

(e.g., 1 milligram, 1 milliliter, 1 tablet, 1 capsule). Currently, manufacturers submit AMP data on monthly and quarterly bases, with submissions due 30 days after the end of the rebate period.

In the Medicaid drug rebate program, drugs are generally categorized as one of three types: single-source, innovator multiple-source, or noninnovator multiple-source. Manufacturers provide CMS with the drug category for each of their NDCs in conjunction with AMP data. Generally, pursuant to section 1927(k)(7)(A) of the Act and 42 CFR § 447.502, (1) a single-source drug is a covered outpatient drug produced or distributed under an original new drug application approved by FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application; (2) an innovator multiple-source drug is a multiple-source drug that was initially marketed under an original new drug application approved by FDA; and (3) a noninnovator multiple-source drug is a multiple-source drug that is not an innovator multiple-source drug.[6] [7]

In general terms, a single-source drug would typically be a brand-name product with no available generic versions. An innovator multiple-source drug would typically be a brand-name product that has available generic versions. A noninnovator multiple-source drug would simply be a generic version of any multiple-source product.

In addition to AMP, section 1927(b)(3) of the Act requires manufacturers of single-source and innovator multiple-source drugs to provide CMS with the best price available for each of its covered outpatient drugs. Best price is generally defined as the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, with certain exceptions.[8] Manufacturers of noninnovator multiple-source

[6] The regulation (42 CFR § 447.502) also generally provides that for drugs that entered the market in 1962 or later, a noninnovator multiple-source drug is a drug marketed under an abbreviated new drug application; for drugs that entered the market before 1962, it is a drug not originally marketed under an original new drug application.

[7] Pursuant to 42 CFR § 447.502, single-source and innovator multiple-source drugs also include covered outpatient drugs approved under product license approvals, establishment license approvals, or antibiotic drug approvals. Single-source drugs also include covered outpatient drugs approved under a biological license application.

[8] Section 1927(c)(1)(C)(i) of the Act.

drugs are not required to provide their best price. CMS maintains AMP and best price data as part of its quarterly AMP files (AMP file).

Medicaid Drug Rebate Calculations

The amount of rebates owed by manufacturers to State Medicaid agencies for a drug is determined by two figures: (1) the unit rebate amount of the drug and (2) the number of units of the drug reimbursed by the State in a given quarter. Pursuant to section 1927(c) of the Act, the formula used to determine the unit rebate amount depends on the drug category reported by the manufacturer. Under Medicaid rebate law, unit rebate amounts for single-source and innovator multiple-source drugs are calculated using the same formula. Therefore, for the purposes of this report, both single-source and innovator multiple-source drugs are hereinafter referred to as "innovator" products, while noninnovator multiple-source drugs are referred to as "noninnovators." For innovator drugs, the unit rebate amount equals the greater of 15.1 percent of the AMP or the difference between the AMP and best price.[9] For noninnovator drugs, the unit rebate amount is 11 percent of the AMP.[10]

At the end of every quarter, CMS calculates a unit rebate amount for each NDC included in the Medicaid drug rebate program and provides this amount to State Medicaid agencies. To determine total rebates due from manufacturers, the unit rebate amount is multiplied by the total number of units of the NDC reimbursed by the State during the quarter.

In some cases, States may have reimbursed for drugs that do not have AMPs reported by the manufacturers in the given quarter. As a result, CMS is unable to calculate unit rebate amounts for the affected NDCs. However, States are still owed rebates for these drugs. CMS has instructed States to include the NDCs that have unit rebate amounts of zero because AMP data are missing or have been rejected as part of the quarterly rebate statement sent to manufacturers, listing the number of units of the NDC reimbursed by the State in the quarter.[11] The

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[9] Section 1927(c)(1)(A) of the Act.

[10] Section 1927(c)(3) of the Act.

[11] CMS, "Medicaid Drug Rebate Program Bulletin for Participating Drug Manufacturers," Release Number 69. Available online at http://www.cms.hhs.gov/MedicaidDrugRebateProgram/03_DrugMfrReleases.asp. Accessed on December 12, 2008.

manufacturers calculate their own unit rebate amounts for the NDCs according to Medicaid drug rebate program rules and determine the total rebates owed based on the utilization provided.[12] However, according to CMS staff, manufacturers do not always follow through with this process, causing States to expend substantial efforts to recoup the unpaid amounts.[13] [14]

Drug Compendia

Drug compendia are databases compiled by private companies using data from such sources as drug manufacturers and FDA. National drug compendia are references for health care professionals that provide access to drug-pricing and drug category data. Two commonly used drug compendia on the market today are the Red Book (published by Thomson Healthcare) and the First DataBank National Drug Data File (First DataBank) (published by the Hearst Corporation).

FDA Drug Information Directories

FDA publishes information via several sources regarding drugs that it has approved. For example, FDA's "National Drug Code Directory" (NDC Directory) is supposed to list the application numbers for NDCs associated with drugs approved by FDA.[15] [16] However, previous OIG work has found the NDC Directory to be incomplete, primarily because of insufficient reporting by drug manufacturers.[17] In addition, FDA

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[12] CMS, "Medicaid Drug Rebate Program Bulletin for Participating Drug Manufacturers," Release Number 38. Available online at http://www.cms.hhs.gov/MedicaidDrugRebateProgram/03_DrugMfrReleases.asp. Accessed on October 24, 2008.

[13] Because States are responsible for tracking collections and reporting those amounts to CMS, the responsibility falls on States to collect the rebates owed to them when manufacturers do not follow through with this process.

[14] Previous Office of Inspector General (OIG) work found that many States do not receive all possible drug rebates from manufacturers because of missing AMP data.

[15] Available online at http://www.fda.gov/cder/ndc/index.htm. Accessed on October 10, 2008.

[16] FDA inputs the NDC and the information submitted as part of the listing process into a database known as the Drug Registration and Listing System (DRLS). Several times a year, FDA extracts some of the information from the DRLS database (currently, properly listed marketed prescription drug products and insulin) and publishes that information in the NDC Directory.

[17] OIG, "The Food and Drug Administration's National Drug Code Directory," OEI-06-05-00060, August 2006.

recently stated that the NDC directory is neither fully accurate nor complete.[18]

The NDC Directory does not indicate whether the application numbers are for new drug applications (i.e., represent innovator drugs) or abbreviated new drug applications (i.e., represent noninnovator drugs). The FDA Approved Drug Products directory (Drugs@FDA) provides each drug's approval history, including whether it was approved under a new drug application or an abbreviated new drug application; however, it does not list any of this information by NDC.[19] Drugs@FDA is searchable by application number, proprietary drug name, and active ingredient; therefore, with information gathered from FDA's NDC Directory, Drugs@FDA can be used to identify NDCs as innovators or noninnovators.

METHODOLOGY

Scope and Data Collection

Scope. We reviewed only NDCs with Medicaid utilization in the fourth quarter of 2007 (October 1 to December 31). There were 29,678 NDCs with Medicaid utilization in the quarter under review. We were able to compare drug categorizations only if NDCs were present in all data sources. Therefore, any NDCs that were not listed in the fourth-quarter 2007 AMP file or either of the two national drug compendia (Red Book and First DataBank) were excluded from our comparison. In addition, we excluded drugs whose drug categorizations differed in the two national compendia (i.e., drugs that were considered innovators in Red Book and noninnovators in First DataBank or vice versa). As a result of these steps, our comparison of drug categorizations included 17,121 NDCs. These 17,121 NDCs accounted for 91 percent ($4.9 billion of $5.4 billion) of total Medicaid reimbursement for prescription drugs in the fourth quarter of 2007.

Data collection. We identified all NDCs with Medicaid reimbursement in the fourth quarter of 2007 using CMS's National Drug Utilization Database, which contains the Medicaid utilization and expenditures by

[18] FDA response to Representative Edward J. Markey. Available online at http://www.ascp.com/medicarerx/upload/FDAltrMerkey.pdf. Accessed on November 17, 2008.

[19] FDA, "Drugs@FDA: Frequently Asked Questions." Available online at http://www.fda.gov/cder/drugsatfda/FAQ.htm. Accessed on September 22, 2008.

NDC.[20] In February 2008, we obtained the Medicaid drug rebate fourth-quarter 2007 AMP file from CMS. We obtained variables that identify drug categorizations from fourth-quarter 2007 versions of two national drug compendia (Red Book and First DataBank). We also obtained information from FDA's Drug Information directories (NDC Directory and Drugs@FDA) for use during our manual review of drug categorizations.

Data Analysis

Compendia data. Drug compendia do not contain individual drug category variables that identify NDCs as single-source, innovator multiple-source, or noninnovator multiple-source drugs, as defined by Medicaid drug rebate law. Therefore, we developed our own variable based on a combination of other variables contained in the compendia. For both compendia, we used the variable that identifies NDCs as brand-name or generic in conjunction with a variable that identifies NDCs as single-source or multiple-source to create our comparison variable. We used the following criteria for our categories:

1. NDCs categorized as brand-name and single-source were considered single-source and therefore innovators for purposes of this analysis.
2. NDCs categorized as brand-name and multiple-source were considered innovator multiple-source and therefore innovators for purposes of this analysis.
3. NDCs categorized as generic and multiple-source were considered noninnovator multiple-source and therefore noninnovators for purposes of this analysis.

As previously stated, to avoid potential confusion, NDCs for which drug categorizations differed in the two national compendia were excluded from further analysis of drug categorizations.[21]

Comparison of drug categorizations. We compared the drug categorizations listed in national compendia to the drug categorizations in the AMP file for the 17,121 NDCs under review. We placed NDCs for

[20] CMS, "State Drug Utilization Data." Available online at http://www.cms.hhs.gov/MedicaidDrugRebateProgram/SDUD/list.asp. Accessed on May 20, 2008.

[21] We excluded 1,425 NDCs from our analysis because the drug categorizations in Red Book did not match the drug categorizations in First DataBank.

which the rebate categorizations in the AMP file did not match the compendia categorizations into one of two groups:

1. NDCs categorized as noninnovator drugs in the AMP file but categorized as innovator drugs in drug compendia.
2. NDCs categorized as innovator drugs in the AMP file but categorized as noninnovator drugs in drug compendia.

We determined the potential effect of miscategorizations by calculating (1) the percentage of NDCs and (2) the percentage of total Medicaid reimbursement in the fourth quarter of 2007 associated with each group (i.e., innovators in the AMP file, noninnovators in drug compendia, and vice versa).

Manual review. In addition to comparing Medicaid rebate categorizations to the two drug compendia, we conducted a manual review of 75 high-expenditure, nonmatching NDCs to address concerns that neither the AMP file nor drug compendia are completely accurate and reliable sources of drug category data. These 75 NDCs consisted of the 50 NDCs categorized as noninnovators in the AMP file (but innovators in compendia) and the 25 NDCs categorized as innovators in the AMP file (but noninnovators in compendia) with the highest expenditures in the fourth quarter of 2007.

We identified reasons for any differences in drug categorizations by examining drug approval status and drug categorization data in FDA's Drug Information directories. For each of the 75 NDCs included in our manual review, we used a two-step method to determine the correct drug category. First, we used FDA's NDC Directory to search for the product's application number. Because the application number alone does not identify an NDC as innovator or noninnovator, we then used the Drugs@FDA directory to identify whether the application numbers belonged to drugs that were approved under new drug applications (i.e., innovators) or abbreviated new drug applications (i.e., noninnovators). We considered the drug categorization in the AMP file to be correct only when its drug category corresponded to the appropriate approval status in the FDA directories.[22] A small number

[22] Generally, under the Medicaid drug rebate program, drugs categorized as innovators have new drug applications and drugs categorized as noninnovators have abbreviated new drug applications (with certain exceptions). Section 1927(k)(7)(A) of the Act and 42 CFR § 447.502.

of drugs associated with the 75 NDCs under review were not listed in FDA's NDC Directory but were listed in Drugs@FDA. Although Drugs@FDA does not list drugs by NDC, we were able to verify the approval status of these NDCs using a combination of product and manufacturer data from the database.[23]

For some of the NDCs included in our manual review, we were unable to locate information in any of FDA's online sources. Therefore, a third step was necessary. We provided FDA staff with a list of these NDCs and obtained further information about the approval status and categorization for each of the associated drugs. We also obtained information about these NDCs from their manufacturers' Web sites.

Drugs not included in the AMP file and/or compendia. For some NDCs, we were unable to compare the Medicaid drug categorizations to those in the national compendia because the data were missing from at least one of the files. First, we calculated the percentage of NDCs with Medicaid utilization in the fourth quarter of 2007 that were not included in that quarter's AMP file.[24] We also determined whether any of the NDCs with missing fourth-quarter 2007 AMPs did not appear in the third-quarter 2007 AMP file. Then, we calculated the percentage of NDCs with Medicaid utilization in the fourth quarter of 2007 that were missing from one or both of the national compendia. Finally, we calculated the percentage of NDCs with Medicaid utilization in the fourth quarter of 2007 that were listed in both compendia, but the drug categorizations differed in each source.

Limitations

The editorial policies of national drug compendia permit submission of data from manufacturers, distributors, Government publications, internal research, and medical literature as sources of drug information. However, publishers of compendia do not perform formal data reviews for every new release. We did not verify the accuracy of data provided by First DataBank or Red Book. In addition, we did not verify the accuracy of the data provided by CMS or FDA. More current AMP data may have become available after we completed our analysis. For

[23] Drugs@FDA is searchable by application number, proprietary drug name, or active ingredient.

[24] According to CMS Drug Rebate Program Release No. 69, individual State Medicaid agencies are responsible for collecting rebates for NDCs with Medicaid utilization that are not included in the AMP file.

example, the fourth-quarter 2007 AMP file provided to us by CMS on February 2, 2008, may have been updated after our analysis was completed.

The eligibility for Medicaid payments of the unapproved drugs identified by our manual review is beyond the scope of this study. We did not determine whether any Federal funds were used to pay for drugs that were not approved by FDA.

Standards

This study was conducted in accordance with the "Quality Standards for Inspections" issued by the President's Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency (now the Council of the Inspectors General on Integrity and Efficiency).

Most AMP file drug categories matched the drug categories in two national compendia

For 90 percent of the 17,121 NDCs in our comparison, the drug categorizations in the fourth-quarter 2007 AMP file were the same as the categorizations in the national compendia. Drugs with matching categorizations accounted for 97 percent of Medicaid expenditures for the NDCs under review. In the AMP file, 29 percent of the 17,121 NDCs under review were categorized as innovators, and 71 percent were categorized as noninnovators.

However, as shown in Table 1, there were 1,730 NDCs (10 percent of NDCs in our comparison) whose drug categorizations in the AMP file did not match the drug categorizations in the national compendia. The nonmatching NDCs represented 12 percent of the NDCs categorized as innovators in the AMP file and 9 percent of the NDCs categorized as noninnovators in the AMP file. Overall, these nonmatching NDCs were associated with 3 percent ($146 million of $4.9 billion) of the total fourth-quarter 2007 Medicaid expenditures for the NDCs under review.

Table 1. Comparison of Drug Categorizations in the AMP File and Two National Drug Compendia

AMP Drug Categorization	Number of NDCs That Matched Compendia Drug Categorization	Number of NDCs That Did Not Match Compendia Drug Categorization	Total Number of NDCs by AMP File Drug Categorization
Innovator (single-source, innovator multiple-source)	4,389	585	4,974
Noninnovator	11,002	1,145	12,147
Total	**15,391**	**1,730**	**17,121**

OIG analysis of data contained in AMP file, Red Book, First DataBank.

A manual review of 75 of the 1,730 nonmatching NDCs indicates that many drugs identified as such in Table 1 may have been correctly categorized for rebate purposes.[25] As Table 2 illustrates, several factors contributed to nonmatching drug categorizations in the AMP file and national compendia, including (1) questionable categorizations in compendia (i.e., correct categorizations in the AMP file),[26] (2) incorrect

[25] Our manual review comprised the top 50 nonmatching NDCs (by total Medicaid expenditures in the fourth quarter of 2007) categorized as noninnovators in the AMP file and the top 25 nonmatching NDCs (by total Medicaid expenditures in the fourth quarter of 2007) categorized as innovators in the AMP file.

[26] Because compendia are not required to categorize drugs according to Medicaid rebate law, it would be erroneous to refer to these cases as "incorrect" in the compendia.

categorizations in the AMP file, and (3) the presence of unapproved drugs in the AMP and Medicaid reimbursement files.

Table 2. Reasons for Nonmatching Drug Categorizations Between AMP File and National Compendia

AMP Drug Categorization	Questionable in Compendia (Correct in AMP File)	Incorrect in AMP File	Unapproved Drugs	Total Nonmatching NDCs Reviewed
Innovator (single-source, innovator multiple-source)	25	0	0	25
Noninnovator	10	8	32	50
Total	**35**	**8**	**32**	**75**

OIG analysis of data contained in AMP file, Red Book, First DataBank, Drugs@FDA, and NDC Directory.

Nearly half of nonmatching NDCs that we reviewed appear to have been categorized correctly in the AMP file

Thirty-five of the seventy-five nonmatching NDCs that underwent manual review appear to have been correctly categorized in the AMP file according to Medicaid drug program requirements (i.e., categorizations in the compendia were questionable). This number includes all 25 nonmatching NDCs categorized as innovators in the AMP file (but noninnovators in the compendia). Each of the drugs represented by these NDCs had been approved through a new drug application according to Drugs@FDA.

Further, 10 of 50 nonmatching NDCs categorized as noninnovators in the AMP file (but innovators in the compendia) had been approved through abbreviated new drug applications, according to Drugs@FDA. According to Medicaid drug program requirements, it appears that these NDCs were also categorized correctly in the AMP file.

A small number of nonmatching NDCs that we reviewed resulted from apparent incorrect drug categorizations in the AMP file

Eight of seventy-five NDCs that underwent manual review appear to have been incorrectly categorized in the AMP file. All eight of these NDCs were categorized as noninnovators in the AMP file but had been approved through new drug applications according to Drugs@FDA. It appears that under Medicaid drug program requirements, these NDCs should have been categorized by their manufacturers as innovators. Because manufacturers pay smaller rebates for noninnovator drugs, States may not be receiving the amount of rebates to which they are entitled for these eight NDCs. Fourth-quarter 2007 Medicaid

expenditures for the drugs represented by these eight NDCs totaled nearly $14 million.

Over 40 percent of nonmatching NDCs that we reviewed were for drugs not approved by FDA

Thirty-two of the seventy-five NDCs (43 percent) that underwent manual review corresponded to drugs not listed in FDA's Drug Information directories. Each of these nonmatching NDCs was categorized as a noninnovator in the AMP file and an innovator in the compendia. According to FDA, none of the drugs associated with these NDCs had been approved. Based on information obtained from FDA staff and manufacturer Web sites, the unapproved drugs indentified by our manual review were enzyme-replacement products awaiting new drug application approvals, multivitamins (prenatal or otherwise), cough suppressants, antihistamines, or hydrating lotions. Medicaid paid $20 million for drugs associated with these 32 NDCs in the fourth quarter of 2007.[27]

A substantial number of NDCs were excluded from the drug category comparison, primarily because of missing data

We were unable to compare drug categorizations for 42 percent (12,557 of 29,678) of NDCs with fourth-quarter 2007 Medicaid utilization for several reasons: (1) the NDCs were not listed in the AMP file, (2) the NDCs were not listed in one or both of the two national drug compendia, or (3) the NDCs had drug categorizations that differed in the two national compendia. NDCs in these three groups accounted for less than 10 percent of total Medicaid reimbursement for prescription drugs in the fourth quarter of 2007.

Lack of data in the AMP file accounted for most of the excluded NDCs

We excluded 65 percent (8,101 of 12,557) of the NDCs from the comparison of drug categorizations because data were missing from the AMP file. Fourth-quarter 2007 payments for these NDCs totaled $338 million. More than half of these NDCs were also not listed in the previous quarter's AMP file. According to CMS staff, States sometimes face difficulty in obtaining the rebates owed for products with late or missing AMP data.

[27] Generally, for Medicaid Federal financial participation to be available, most covered outpatient drugs must be approved by FDA for safety and effectiveness, with certain exceptions.

For the remaining NDCs excluded from this comparison, 3,031 (24 percent of excluded NDCs) were not listed in one or both of the national compendia.[28] These NDCs accounted for $60 million in Medicaid payments in the fourth quarter of 2007. An additional 1,425 NDCs (11 percent of excluded NDCs) were excluded because their innovator status in one compendium did not match their innovator status in the other. These NDCs accounted for $99 million in Medicaid payments in the fourth quarter of 2007. Table 3 provides a statistical breakdown of the reasons we excluded NDCs from our comparison of drug categorizations.

Table 3. Reasons for Exclusion of NDCs From the Drug Categorization Comparison

Reason for Exclusion From Analysis	Number of NDCs Excluded	Medicaid Expenditures in the Fourth Quarter of 2007
NDC missing from AMP file	8,101	$338,017,282
NDC not listed in one compendium or both compendia	3,031	$59,823,807
NDC's drug categorization differed in the two national compendia	1,425	$99,353,525
Total	**12,557**	**$497,194,614**

OIG analysis of data contained in AMP file, Red Book, First DataBank, and Medicaid's fourth-quarter 2007 National Utilization File.

Note: Medicaid expenditures are rounded to the nearest dollar.

[28] Of the 3,031 NDCs excluded from our comparison because compendia data were missing, 2,916 were listed in one of the two national compendia. Only 115 of the NDCs were missing from both.

RECOMMENDATIONS

For this review, we compared drug categorizations in the fourth-quarter 2007 AMP file to those in two national drug compendia. Because each drug's innovator status determines the rebate amount paid by the manufacturer to State Medicaid agencies, incorrect drug categorizations could reduce Medicaid drug rebates paid to States. We found that for the purposes of Medicaid drug rebates, manufacturers typically categorize their drugs in the same way as national compendia. In other words, most drug categorizations used to calculate Medicaid rebates appear to be correct.

However, in our manual review of 75 nonmatching NDCs, we identified a potential problem involving unapproved drugs: Medicaid paid $20 million in the fourth quarter of 2007 for 32 drugs that were not approved by FDA. These products may not be currently eligible for Federal payment under Medicaid because of their FDA approval status. According to FDA, unapproved drugs pose a significant health risk because they may not meet modern standards for safety, effectiveness, quality, and labeling. Further, FDA has noted that many health care providers may be prescribing unapproved drugs because they are unaware of the drugs' approval status.

Our manual review of 75 NDCs revealed eight instances in which certain drugs appear to have been categorized incorrectly in the AMP file, potentially resulting in a loss of rebates for States. Although total Medicaid expenditures for these eight NDCs were relatively small ($14 million in one quarter), manufacturers may still owe States that reimbursed for these products higher rebates than the amounts that States collected.

In both cases, the figures presented in our findings were limited to drugs included in our manual review of 75 high-expenditure nonmatching NDCs and are therefore likely to understate the actual amount spent on all drugs that fit into each category. We will provide CMS with a list of the drugs that we identified as being unapproved or potentially miscategorized.

Finally, we were not able to compare categorizations for a large number of NDCs, primarily because AMP data were missing. The lack of AMP data would likely inhibit CMS from calculating unit rebate amounts in a

timely manner. In these cases, States are responsible for collecting any amounts that are owed.

To address the issues raised in this report, we recommend that CMS:

Work closely with FDA to identify any potentially problematic Medicaid payments for drugs that have not been approved by FDA.

Work with manufacturers to determine the correct categorizations of the drugs that we identified as being potentially miscategorized in the AMP file and assist States in collecting any unpaid rebates that they are owed.

Continue to explore and undertake a range of efforts to ensure that drug manufacturers are submitting the required AMP data in a timely manner, including collaborating with OIG on administrative remedies for noncompliance.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In its comments on the draft report, CMS did not indicate whether it concurred with OIG's three recommendations. However, CMS did note that it has taken and will continue to take steps related to each of OIG's recommendations.

CMS responded to our recommendation on potentially unapproved drugs by stating that it has worked and will continue to work closely with FDA to identify potentially problematic Medicaid payments for drugs that do not meet the definition of a covered outpatient drug for the purposes of the Medicaid drug rebate program. CMS explained that FDA provides it with information on unapproved drugs that may be ineligible for coverage under the Medicaid drug rebate program. CMS reviews that information and determines whether action should be taken to remove these drugs from the list of covered drugs.

In its response to our recommendation on potentially miscategorized drugs identified in the AMP file, CMS stated that it is contacting the manufacturers for which OIG identified a potential problem with drug categorizations. If CMS determines that a manufacturer has miscategorized a drug and additional rebates are due, it will work with that manufacturer to ensure that a revised categorization is submitted so that the manufacturer can pay States appropriate rebates. CMS also noted that it has been working with

manufacturers to correctly categorize drugs that manufacturers themselves have identified as being misreported.

CMS responded to our recommendation on timely reporting of AMP data by stating that it will continue to ensure that drug manufacturers are submitting the required AMP data in a timely manner. To that end, after each quarter, CMS contacts drug manufacturers that have failed to submit timely AMP data to remind them of their responsibilities and request that their data be submitted immediately. In addition, on a quarterly basis, CMS provides OIG with a list of drug manufacturers that have failed to report timely data for two or more quarters in a four-quarter period for further investigation and/or review. CMS states that OIG may impose civil monetary penalties for manufacturers that appear on this quarterly report and indicated that issuing these penalties would assist in ensuring that drug manufacturers submit their required pricing data in a timely manner.

We ask that CMS indicate in its final management decision whether it concurs with each of our recommendations. Ongoing OIG work will further evaluate CMS's and FDA's ability to identify and remove drugs that may not be eligible for coverage under the Medicaid drug rebate program. In addition, OIG is exploring potential actions against manufacturers that fail to provide AMP data in a timely manner.

The full text of CMS's comments is provided in Appendix A.

APPENDIX ~ A

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

200 Independence Avenue SW
Washington, DC 20201

RECEIVED
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OFFICE OF INSPECTOR GENERAL

MAY 18 2009

DATE:

TO: Daniel R. Levinson
Inspector General

FROM: Charlene Frizzera
Charlene Frizzera
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Accuracy of Drug Categorizations for Medicaid Rebates" (OEI-03-08-00300)

Thank you for the opportunity to review and comment on the OIG Draft Report entitled "Accuracy of Drug Categorizations for Medicaid Rebates" (OEI-03-08-00300). The purpose of this report was to determine whether the drug categorizations used to calculate Medicaid rebates are consistent with the categorizations listed in national compendia.

The OIG report presents findings that compare drug categorizations used to determine Medicaid rebates to drug categorizations in two widely used national compendia. The rebate amount for a drug is based on whether the drug is categorized as a single-source, innovator multi-source, or non-innovator multiple-source drug product.

Drug categorizations in the fourth-quarter 2007 average manufacturer price (AMP) file were compared to drug categorizations in two national compendia for more than 17,000 national drug codes (NDCs). A manual review was conducted of the drug categorizations for 75 non-matching NDCs associated with high Medicaid expenditures, using information obtained from the Food and Drug Administration's (FDA) Drug Information directories, FDA staff, and manufacturer Web sites. The report also determined the percentage of NDCs with Medicaid utilization in the fourth-quarter of 2007 that were not included in that quarter's AMP file.

For 90 percent of NDCs, it was found that the drug categorizations in the fourth-quarter 2007 AMP file were the same as the categorizations in the national compendia. Drug categorizations did not match for 10 percent of NDCs. Overall, these non-matching NDCs were associated with 3 percent of total fourth-quarter 2007 Medicaid expenditures for the NDCs under review. A manual review of 75 high-expenditure non-matching NDCs revealed that 32 NDCs were for drugs that had not been approved by the FDA.

OIG Recommendation

The Centers for Medicare & Medicaid Services (CMS) should work closely with the Food and Drug Administration (FDA) to identify any potentially problematic Medicaid payments for drugs that have not been approved by the FDA.

CMS Response

The CMS has been and will continue to work closely with the FDA to identify potentially problematic Medicaid payments for drugs that do not meet the definition of a covered outpatient drug for purposes of the Medicaid Drug Rebate Program (MDRP). FDA provides CMS with information on unapproved drugs that may be ineligible for coverage under the MDRP, CMS reviews that information and determines whether action should be taken to remove the drug. CMS also works with the FDA to identify similar drugs that might also be ineligible for coverage under the MDRP. The FDA generally identifies a drug based on pharmaceutical ingredients, and CMS identifies NDCs in the MDRP that may contain those ingredients. Subsequently, these products are also removed from the list of covered drugs in the MDRP and CMS notifies States and the affected labelers of this action.

OIG Recommendation

CMS should work with manufacturers to determine the correct categorizations of the drugs that we identified as being potentially miscategorized in the AMP file and assist States in collecting any unpaid rebates that they are owed.

CMS Response

We are pleased that the OIG found that almost all drugs were correctly classified. Nevertheless, we want to ensure that manufacturers correctly report their drug classification, and we are in the process of contacting those manufacturers where the OIG has identified a potential problem. If we determine that a manufacturer has miscategorized a drug and additional rebates are due, we will work with the manufacturer to ensure that a revised classification is submitted so that manufacturers can pay States the appropriate rebates. We note that it is the manufacturer's responsibility to submit data to CMS that reflects the FDA's approval process for the drug and not to rely solely on other information such as that in the compendia.

We have also been working with manufacturers to correctly categorize drugs that have been misreported. When a manufacturer identifies that a product has been miscategorized, we review the product and determine whether the manufacturer has identified the correct drug product category. If the drug is miscategorized, CMS requests that the manufacturer provide information in support of a specific drug category, the effective date of the change, and the financial impact as a result of this change. CMS will then use the FDA databases to determine the correct drug category based on the FDA drug application number and verify that the NDC is listed in the FDA National Drug Code Directory.

OIG Recommendation

CMS should continue to explore and undertake a range of efforts to ensure that drug manufacturers are submitting the required AMP data in a timely manner, including collaborating with the OIG on administrative remedies for noncompliance.

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CMS Response

The CMS will continue to ensure that drug manufacturers are submitting the required AMP data in a timely manner, including collaborating with the OIG to notify them of instances of manufacturer noncompliance with respect to timely data submission. Currently, after each quarterly data submission deadline, CMS contacts drug manufacturers that have failed to submit timely pricing data to remind them of their data submission responsibilities and request that their data be submitted immediately.

The CMS also includes data reporting status information in the Drug Data Reporting System application so that, upon logging into the application, labelers may identify what the next reporting due dates are and how much data the labeler has submitted and certified (i.e., whether or not the labeler is out of compliance with their data reporting requirements). In addition, on a quarterly basis, CMS reports to the OIG the drug manufacturers that have failed to report timely data for two or more quarters in a four-quarter period for further investigation and/or review. It is our understanding that the OIG may impose civil monetary penalties for the manufacturers that appear on this quarterly report, and CMS believes that the issuance of such penalties would assist further in ensuring that drug manufacturers submit their required pricing data timely.

The CMS would, again, like to thank the OIG for their efforts in reviewing the accuracy of drug categorizations for Medicaid rebates. CMS will continue to work closely with the FDA to ensure that manufacturers have correctly reported their drug classifications and that drug manufactures are submitting the required AMP data in a timely manner. We have received the list of manufacturers from the OIG and are in the process of planning to contact those manufacturers regarding potential drug miscategorizations. Furthermore, we will continue to collaborate with the OIG regarding administrative remedies for noncompliance. CMS is committed to ensuring the accuracy of drug categorizations and all Medicaid rebate data.

ACKNOWLEDGMENTS

This report was prepared under the direction of Robert A. Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office, and David E. Tawes, Director, Prescription Drug Pricing Unit.

Roman Strakovsky served as the lead analyst for this study. Other principal Office of Evaluation and Inspections staff from the Philadelphia regional office who contributed to the report include Edward Burley; other central office staff who contributed include Lyn Killman.