

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**POTENTIAL MISCLASSIFICATIONS
REPORTED BY DRUG MANUFACTURERS
MAY HAVE LED TO \$1 BILLION IN LOST
MEDICAID REBATES**



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Why OIG Did This Review

Manufacturers with rebate agreements are required to report all of their covered outpatient drugs to the Medicaid Drug Rebate Program (Medicaid rebate program). The Centers for Medicare & Medicaid Services (CMS) calculates rebate amounts using manufacturer-reported pricing and classification data. Congress asked the Office of Inspector General (OIG) to evaluate the accuracy of manufacturer-reported data in the Medicaid rebate program, and CMS's oversight of that data.

The Food and Drug Administration's (FDA's) marketing categories, which also are manufacturer-reported, can be used to help determine whether a drug is classified as an innovator, e.g., brand-name, or noninnovator, e.g., generic, product, for the purposes of calculating Medicaid rebates. Innovator products are generally subject to higher base rebate amounts. Manufacturers are required to pay an additional, inflation-adjusted rebate if a drug's price increases faster than inflation. When information provided by manufacturers is incorrect or missing, State Medicaid agencies may not be able to collect all appropriate rebates.

How OIG Did This Review

We compared manufacturer-reported classifications for drugs in the Medicaid rebate program to drug information in FDA files. We determined the Medicaid drug classifications that matched FDA's, and those that did not match, i.e., were potentially misclassified, in 2016. We then estimated the rebate amounts that Medicaid may have lost from 2012 to 2016 for the 10 potentially-misclassified drugs with the highest total reimbursement in 2016. Finally, we reviewed CMS's policies and procedures for ensuring appropriate oversight of data submitted to the Medicaid rebate program.

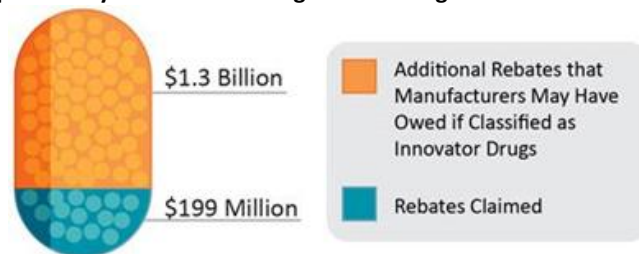
Potential Misclassifications Reported by Drug Manufacturers May Have Led to \$1 Billion in Lost Medicaid Rebates

What OIG Found

The vast majority of the approximately 30,000 drugs in the Medicaid rebate program were classified appropriately. However, we found that manufacturers may have misclassified 885 of these drugs (3 percent) in 2016. We found that from 2012 to 2016, Medicaid may have lost \$1.3 billion in base and inflation-adjusted rebates for 10 potentially-misclassified drugs with the highest total reimbursement in 2016.

When CMS determines that information reported by manufacturers may be incorrect, it requests that manufacturers change the data. CMS does not have the explicit legal authority to require manufacturers to change their classification data. CMS did report that when it identifies potential errors in classification data, it works with manufacturers to assist them in correcting the errors. However, CMS does not track or maintain a central database of these potential errors or their resolutions. Therefore, we had no way to determine which drugs CMS identified as potentially-misclassified, or what steps, if any, CMS took to address these potential misclassifications.

Exhibit 1: Manufacturers may have owed an additional \$1.3 billion for 10 potentially-misclassified drugs with the highest total reimbursement in 2016



Source: OIG analysis of Medicaid and FDA drug classification data, 2016.

What OIG Recommends

We recommend that CMS (1) follow up with manufacturers associated with potentially-misclassified drugs identified in this report to determine whether current classifications are correct, (2) improve its Drug Data Reporting for Medicaid System to minimize inconsistent data submissions and track potential classification errors for followup, and (3) pursue a means to compel manufacturers to correct inaccurate classification data reported to the Medicaid rebate program. CMS concurred with all three recommendations.

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OBJECTIVES

1. To determine whether manufacturers potentially misclassified drugs in the Medicaid Drug Rebate Program (Medicaid rebate program) in 2016, and how much Medicaid may have lost in rebates as a result of these potential misclassifications from 2012 to 2016.
2. To determine the extent to which the Centers for Medicare & Medicaid Services (CMS) has policies and procedures in place to identify incorrect drug classification data.

BACKGROUND

Manufacturers with rebate agreements are required to report all of their covered outpatient drugs (hereinafter referred to as drugs) to the Medicaid rebate program. As part of their rebate agreements, Federal law generally requires drug manufacturers to pay quarterly rebates to State Medicaid agencies. CMS calculates unit rebate amounts (URAs) using manufacturer-reported drug pricing and product data, such as drug classifications. If manufacturers do not provide accurate pricing and classification data to CMS, rebates may not be calculated appropriately and State Medicaid agencies may not invoice the manufacturers for the total rebates owed for these drugs.

Previous Office of Inspector General (OIG) work found that manufacturers may have misclassified some drugs in the Medicaid rebate program as innovator (brand-name), or noninnovator (generic) products.¹ As a result, manufacturers may not have paid the appropriate rebate amounts for these drugs. In September 2016, Congress asked OIG to evaluate the accuracy of manufacturer-reported drug classification data in the Medicaid rebate program, and the extent to which CMS oversees drug classification data submitted by manufacturers. In response to the congressional request, this study evaluates drug classification data submitted to the Medicaid rebate program and CMS's policies and procedures to ensure appropriate oversight of this data.

Medicaid Payment for Drugs

Medicaid provides medical assistance for low-income individuals and families. Medicaid is administered by States and financed using State and Federal funds. State Medicaid agencies reimburse pharmacies for drugs dispensed to Medicaid beneficiaries. Reimbursement for drugs is based

¹ OIG, *Accuracy of Drug Categorizations for Medicaid Rebates* (OEI-03-08-00300), July 2009.

on national drug codes (NDCs), which are 11-digit identifiers that indicate the manufacturer, product code, and package size of each drug product. Medicaid paid \$60.5 billion for drugs in 2016.

The Medicaid Rebate Program

For Federal payments to be available for covered outpatient drugs provided under Medicaid, manufacturers are generally required to enter into rebate agreements with the Secretary of Health and Human Services and pay quarterly rebates to the States.² As part of the rebate agreements, manufacturers must provide CMS with the average manufacturer price (AMP) and best price, if applicable, for each of their covered outpatient drugs.^{3, 4}

Manufacturers also must provide CMS with drug classification data that indicates whether each drug is (1) an innovator, i.e., a single-source or an innovator multiple-source product, or (2) a noninnovator multiple-source product. Manufacturers report and must certify this drug classification data in the Drug Data Reporting for Medicaid System (reporting system) and CMS publishes the reported information in the Medicaid rebate drug product file.⁵

Medicaid Rebate Calculations. The calculation of the rebate amount for a drug depends on whether the drug manufacturer classifies it as an innovator or noninnovator product. The current base URA for innovator drugs is usually either 23.1 percent of AMP (17.1 percent of AMP if it is exclusively pediatric or a clotting factor) or the difference between AMP and best price, whichever is greater. The URA for noninnovator drugs is equal to 13 percent of AMP. However, if the AMP for a drug has risen faster than inflation, manufacturers are required to pay an additional, inflation-adjusted rebate amount.⁶

² Section 1927(a)(1) & (b)(1) of the Social Security Act (the Act)

³ AMP is defined as the average price paid to a manufacturer of a drug in the United States by a wholesaler for drugs distributed to retail community pharmacies and by retail community pharmacies that purchase drugs directly from the manufacturer, with certain exclusions. 42 CFR § 447.504.

⁴ Best price is defined in § 1927(c)(1)(C)(i) of the Act as essentially the lowest price available from the manufacturer during the rebate period to any purchaser in the United States, with certain exceptions. Manufacturers are required to report best price only for their innovator products because best price is used only in the calculation of rebates for innovator products.

⁵ CMS, *Medicaid Drug Rebate Data Guide for Labelers*, January 2017.

⁶ Before January 2017, only innovator products were subject to the inflation-adjusted rebate amount (see § 1927(c)(2) of the Act). However, the Bipartisan Budget Act of 2015 (P.L. 114-74) expanded this rebate to apply to noninnovator drugs, beginning January 1, 2017.

At the end of every quarter, CMS calculates a URA for each drug included in the Medicaid rebate program and makes this data available to State Medicaid agencies. States then invoice manufacturers to collect the rebates owed for drugs reimbursed by Medicaid. However, manufacturers are ultimately responsible for calculating URAs and paying the correct rebates to States.

Food and Drug Administration Approval

With certain exceptions, drugs must be approved by the Food and Drug Administration (FDA) for safety and effectiveness to qualify for Federal payments under Medicaid. Manufacturers are generally required to provide FDA with a list of all the drugs that they manufacture, prepare, propagate, compound, or process for commercial distribution.⁷ FDA maintains this information in directories that include drugs’ names, NDCs, manufacturers, and application types, which are listed as marketing categories.

FDA marketing categories are one factor used to determine whether a drug is an innovator or noninnovator product for the purposes of calculating Medicaid rebates. Exhibit 2 provides a list of FDA marketing categories that directly correspond to Medicaid drug classifications.

Exhibit 2: Selected FDA Marketing Categories that Correspond to Medicaid Classifications

FDA Marketing Category	Description	Corresponding Medicaid Classification
New Drug Application (NDA)	Product that was approved for marketing as a new drug	Innovator Product: Single-Source or Innovator Multiple-Source
Biologic License Application (BLA)	Product that was approved for marketing as a biologic, e.g., allergenics and gene therapies	
Authorized Generic	Product approved as a brand-name drug that is marketed without the brand-name label	
Abbreviated New Drug Application (ANDA)	Product that was approved for marketing as a generic drug	Noninnovator Product

Source: FDA, *Drugs @FDA Glossary of Terms*, 2017 and *FDA List of Authorized Generic Drugs*, 2017.

CMS Oversight of Medicaid Rebate Data

It is the drug manufacturers’ responsibility to ensure that classification data is reported accurately to the Medicaid rebate program. When information provided by manufacturers is incorrect or missing, State Medicaid agencies may not be able to collect all appropriate drug rebates. For example, if manufacturers incorrectly classify their drugs as innovator or noninnovator products, this may result in incorrect rebate calculations

⁷ 21 U.S.C. § 360.

for these drugs. As a result, manufacturers may not pay the appropriate rebate amounts, as required under the rebate agreement.

CMS reports that it routinely seeks to identify potential misclassifications and takes action when they are identified. To identify potential misclassifications, CMS compares Medicaid drug classifications reported by manufacturers to FDA data on a quarterly basis. If CMS identifies any errors in manufacturer-reported data, CMS stated that it typically contacts the manufacturer to request that the manufacturer correct the reported information. CMS may terminate a manufacturer from participation in the Medicaid rebate program for good cause.⁸ If a manufacturer does not correct errors in reported data, CMS could potentially determine that the manufacturer is subject to termination for good cause.

In February 2016, CMS issued the Covered Outpatient Drug final rule with comment period. In this rule, CMS recognized there could be limited circumstances in which it might be appropriate to treat a drug approved under an NDA as if it were approved under an ANDA and classified as a noninnovator product. CMS established a process through which manufacturers of innovator drugs could apply for this narrow exception that would allow them to pay noninnovator rebate amounts.⁹ Under this process, manufacturers had until March 31, 2017 to submit applications and supporting materials to request this exception. CMS will respond to the manufacturers in writing to confirm or deny the narrow exception request.¹⁰

⁸ Section 1927(b)(4)(B) of the Act.

⁹ 81 Fed. Reg. 5169 (February 1, 2016).

¹⁰ CMS does not provide a comprehensive list of narrow exceptions, but has provided examples of which drugs may qualify. For example, these narrow exceptions may apply to drugs approved under a paper NDA before 1984, or drugs approved under certain types of literature-based approvals after 1984. 81 Fed. Reg. 5169, 5191 (February 1, 2016).

METHODOLOGY

Data Collection and Analysis

Medicaid Classifications. We obtained fourth-quarter 2016 drug classifications for 30,469 NDCs, i.e., drugs, included in the Medicaid rebate program.¹¹ As shown in Exhibit 3, we compared the Medicaid classifications reported to CMS for these drugs to marketing categories from FDA files. We determined the number and percentage of drugs with Medicaid classifications that matched the FDA marketing categories and considered these drugs to be appropriately classified. We also determined the number and percentage of drugs with Medicaid classifications that contradicted the FDA marketing categories, i.e., they were potentially misclassified.¹² For the purposes of this study, we considered each 11-digit NDC to be an individual drug. Therefore, our list of potentially-misclassified drugs could include different package sizes of the same drug product.

Exhibit 3: OIG Classification Determinations for Drugs in the Medicaid Rebate Program, 2016

OIG Classification Determination	Medicaid Classification	FDA Marketing Category
Appropriately Classified	Single-Source or Innovator Multiple-Source	NDA, BLA, Authorized Generic
	Noninnovator Multiple-Source	ANDA
Potentially Misclassified	Single-Source or Innovator Multiple-Source	ANDA
	Noninnovator Multiple-Source	NDA, BLA, Authorized Generic

Source: OIG analysis of Medicaid and FDA Classification data, 2016.

We were unable to determine whether certain drugs were appropriately classified because not all FDA marketing categories directly correspond to a Medicaid classification. We identified the number and percentage of drugs with FDA marketing categories that did not directly correspond to a Medicaid classification and categorized these as unable to determine. In addition, some drugs were not listed in the FDA files. We categorized these drugs as missing from FDA files and identified the number and percentage of these drugs.

We also compared Medicaid classifications to drug compendia classifications for drugs that were potentially misclassified. Drug

¹¹ We did not include terminated drugs or drugs categorized by Medicaid as over-the-counter, unapproved, or less-than-effective.

¹² To be conservative, we considered a drug to be classified appropriately if the marketing category in at least one of the two FDA files reviewed corresponded to the drug's Medicaid classification.

compendia are private information repositories that maintain and provide information about drug prices, drug classifications, and manufacturers. These resources are often updated daily and can be used by State Medicaid agencies and providers to obtain recent information about drugs. We used the Redbook and First Databank drug compendia, which include variables that identify a drug's classification.

Rebate Calculations. To provide some indication of the potential lost rebates to Medicaid as a result of misclassifications, we selected 10 potentially-misclassified drugs with the highest total reimbursement in 2016 to calculate additional rebates that could have been collected. We estimated the base and inflation-adjusted rebates that Medicaid may have lost due to potential misclassifications for these drugs from 2012 to 2016.

CMS Oversight. We reviewed and summarized CMS's policies and procedures for ensuring the accuracy of drug classification data.

Appendix A provides a detailed methodology for our analysis.

Limitations

We use the term "potentially misclassified" and describe rebates that "may have" been lost in this report because CMS has not completed its review of the narrow exception requests submitted by manufacturers. If CMS grants a manufacturer's request for a narrow exception for any of the drugs identified as potentially misclassified in this report, this determination could affect our list of potentially-misclassified drugs and any associated lost rebates.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.





FINDINGS

Drug manufacturers may have misclassified a small percentage of drugs in the Medicaid rebate program

Medicaid classifications for 95 percent of drugs in the Medicaid rebate program matched FDA data in 2016. This means that most drugs classified as innovator products in the Medicaid file had innovator marketing categories in the FDA files, and most drugs classified as noninnovator in the Medicaid file had noninnovator marketing categories in the FDA files.¹³ These appropriately classified drugs accounted for 98 percent of the \$59.7 billion in Medicaid reimbursement in 2016 for the drugs reviewed.

Of the remaining drugs, 3 percent had classifications that contradicted FDA data, i.e., they were potentially misclassified in 2016.¹⁴ As shown in Exhibit 4, Medicaid reimbursement for potentially-misclassified drugs totaled \$813 million in 2016.¹⁵ The vast majority (93 percent) of the 885 drugs that were potentially misclassified according to FDA were also potentially misclassified according to at least 1 of the 2 drug compendia reviewed.¹⁶

Exhibit 4: Classification Determinations for Drugs in the Medicaid Rebate Program in 2016

	Classification Determination	Number of Drugs	Percentage of Drugs	Medicaid Reimbursement
	Appropriately Classified	28,945	95%	\$58,690,484,856
	Potentially Misclassified	885	3%	\$813,324,981
	Unable to Determine	339	1%	\$139,138,150
	Missing from FDA files	300	1%	\$19,049,845
	Total	30,469	100%	\$59,661,997,832

Source: OIG analysis of Medicaid and FDA classification data, 2016.

¹³ One drug had conflicting marketing categories across the two FDA files; this drug had an ANDA marketing category in one FDA file, but an NDA marketing category in the other FDA file. The drug was classified as a noninnovator product in the Medicaid file. Because the Medicaid classification matched the marketing category in one FDA file, we considered this drug to be classified appropriately.

¹⁴ One percent of drugs had FDA marketing categories that did not directly correspond to a Medicaid classification. Therefore, we were unable to determine whether these drugs were classified appropriately. Another 1 percent of drugs were missing from both FDA files.

¹⁵ There was no Medicaid reimbursement for 266 of the 885 potentially-misclassified drugs in 2016.

¹⁶ The remaining 7 percent of potentially-misclassified drugs were either missing from both compendia, or they had compendia classifications that matched the Medicaid classifications.

The vast majority (97 percent) of the potentially-misclassified drugs were classified as noninnovator products in the Medicaid file but as innovator products in FDA data. Manufacturers would have paid a lower base rebate amount (using the noninnovator calculation instead of the innovator calculation) for these drugs in 2016. In addition, manufacturers would not have paid additional inflation-adjusted rebates, when applicable, for these innovator drugs in 2016.

Four manufacturers were associated with more than half of the potential misclassifications

Manufacturers are responsible for reporting accurate drug classification data to CMS. Potential misclassifications were associated with 54 different manufacturers in 2016. However, just four manufacturers were responsible for over half (54 percent) of the potential misclassifications.

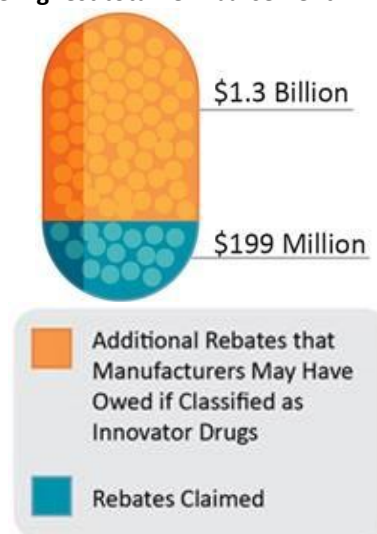
Over the past 5 years, Medicaid may have lost \$1.3 billion in rebates for 10 potentially-misclassified drugs

Manufacturers may have owed an additional \$1.3 billion in rebates from 2012 to 2016 for the 10 potentially-misclassified drugs with the highest total reimbursement in 2016. The top 10 drugs accounted for 68 percent of Medicaid reimbursement for potentially-misclassified drugs in 2016. Most (90 percent) of these potentially-lost rebates were associated with only two drugs.

All 10 of these drugs were classified as noninnovator products in the Medicaid file, but as innovator products in FDA data. As a result, manufacturers paid lower base noninnovator rebates and did not pay any inflation-adjusted rebates for these drugs. As shown in Exhibit 5, Medicaid claimed \$199 million in base noninnovator rebates for these drugs from 2012 to 2016.

If manufacturers had classified the 10 drugs differently, i.e., according to their listed FDA marketing category, manufacturers may have owed an additional \$1.3 billion in higher innovator base rebates and

Exhibit 5: Manufacturers may have owed an additional \$1.3 billion for 10 potentially-misclassified drugs with the highest total reimbursement in 2016



Source: OIG analysis of Medicaid and FDA drug classification data, 2016.

inflation-adjusted rebates over the 5 years.¹⁷ This \$1.3 billion in potentially-lost rebates is equivalent to 87 percent of the \$1.5 billion in total Medicaid reimbursement for these 10 drugs from 2012 to 2016.

CMS has modified its procedures to oversee classification data in the Medicaid rebate program, but opportunities remain for improvement

CMS identified several enhancements to its reporting system that have improved its ability to oversee manufacturer-reported data. CMS reported that it has developed new methods to ensure that manufacturers provide accurate information, but the agency stated that there are limitations to CMS's authority to correct classification data.

CMS provides ongoing training to help staff effectively oversee classification data in the Medicaid rebate program. Training is provided when there is a legislative change to the program, or as needed. The training varies, as appropriate, on the basis of the staff's assigned areas of responsibility. However, these training sessions are not regularly scheduled.

CMS reported that it identified potential errors in classification data reported to the Medicaid rebate program during the past 5 years. It also reported that it reached out to manufacturers to provide instructions on how to correct the potential errors. However, CMS did not provide the specifics or the results of the outreach to these manufacturers. CMS also stated that manufacturers had identified incorrect reporting, and CMS worked with these manufacturers to correct their classifications.

When asked to provide a list of manufacturers and the drugs associated with these potential misclassifications, CMS explained that it does not maintain a database of identified potential errors. CMS also could not provide specific actions that it took to address potential errors. Therefore, we could not determine what steps CMS might have taken to address any identified misclassifications or whether manufacturers voluntarily submitted corrected data.

CMS improved its reporting system, but inconsistencies remain in the Medicaid drug rebate product file

In 2014 and 2016, CMS added new variables and modified the reporting system to better detect the submission of inconsistent manufacturer-reported classification data. For example, CMS added a

¹⁷ If the remaining 875 potentially-misclassified drugs had been classified differently in 2016, manufacturers could have owed an additional \$25 million in base rebates from 2012 to 2016.

“covered outpatient drug status” field, in which manufacturers report to CMS their drugs’ FDA marketing categories, in addition to reporting their drugs’ innovator and noninnovator classifications.

CMS stated that it modified the reporting system so manufacturers would no longer be able to enter a new drug classification that did not correspond to the drug’s FDA marketing category that manufacturers report to CMS. Specifically, CMS reported that only single-source or innovator multiple-source classifications can be selected when manufacturers report to CMS that a drug was approved under an NDA, and only a noninnovator classification can be selected when manufacturers report to CMS that a drug was approved under an ANDA.

CMS has implemented system changes to improve the internal consistency of manufacturer-reported data. However, the system did not review NDCs that were entered prior to these changes, and we found 695 drugs with inconsistent classification data. In all of these cases, manufacturers entered their drugs’ classifications as noninnovator, but in the same reporting system they reported that the drugs had been filed under NDAs.

Some of the potentially-misclassified drugs we identified could be the subject of narrow exception requests submitted by manufacturers. CMS may approve narrow exceptions, which, if granted, would enable manufacturers of innovator drugs to pay lower, noninnovator rebate amounts in a limited number of circumstances. CMS staff also reported that they do not have a method to compile a list of drugs, from CMS’s data system, that were granted narrow exceptions.

CMS does not have the authority to compel manufacturers to correct inaccurate classification data

CMS reported that it performs a quarterly match of manufacturer-reported classification data against FDA’s data to identify potential discrepancies. If CMS’s review identifies a potential misclassification, CMS reported that it contacts the manufacturer requesting an update to the reported data.

When manufacturers are made aware of a potential misclassification and choose not to submit corrected data, CMS does not have explicit authority to compel manufacturers to change their data. CMS could potentially determine that a manufacturer’s refusal to change its drug classification gives rise to good cause for termination from the Medicaid rebate program. However, CMS staff stated that if manufacturers were terminated for misclassifications, this action would have significant repercussions and could cause disruptions to beneficiaries’ access to drugs.

CONCLUSION AND RECOMMENDATIONS

Although the vast majority of drugs in the Medicaid rebate program were classified appropriately, manufacturers may have misclassified 3 percent of drugs in 2016. Medicaid may have lost \$1.3 billion in base and inflation-adjusted rebates for 10 potentially-misclassified drugs between 2012 and 2016.

When CMS determines that information reported by manufacturers may be incorrect, it can request that the manufacturer change its data or work with the manufacturer to resolve the potential errors. However, CMS does not have the explicit legal authority to require manufacturers to change their classification data. CMS did report that it identified potential errors in classification data, but does not maintain a database of these identified potential errors. Therefore, we were unable to determine which drugs CMS identified as potentially misclassified, and whether these potential misclassifications were addressed.

CMS implemented edits to prevent internal inconsistencies in its reporting system. However, the system did not review NDCs that were entered prior to these changes and we found 695 drugs with inconsistent Medicaid classification data in 2016. CMS staff also reported that they do not have a method to compile a list of drugs, from CMS's data system, that were granted narrow exceptions. Therefore, there is no clear way to differentiate drugs that may have inaccurate classification data from drugs that might have qualified for a narrow exception in the Medicaid file.

We recommend that CMS:

Follow up with manufacturers associated with potentially-misclassified drugs identified in this report to determine whether current classifications are correct

Manufacturers may have misclassified 885 drugs in the Medicaid rebate program in 2016. These potential misclassifications may have resulted in lost rebates for Medicaid. We will provide CMS with the drugs that were potentially misclassified, drugs that were missing from FDA files, and the drugs for which we were unable to determine an appropriate classification.

There are limited circumstances that may have allowed some of these drugs to qualify for an exception from innovator rebates. Manufacturers needed to apply for these narrow exceptions by March 31, 2017. CMS should review its files to determine whether any drugs we identified as potentially misclassified are subject to a narrow exception. To the extent they are not, CMS should follow up with the manufacturers of the remaining potentially-misclassified drugs.

Improve its Drug Data Reporting for Medicaid System to minimize inconsistent data submissions and track potential classification errors for followup

CMS stated that it implemented edits to prevent manufacturers from reporting inaccurate classification data for new drugs; however, we identified 695 drugs with internal inconsistencies in data reported by manufacturers to the Medicaid reporting system. Therefore, CMS should review and improve its existing edits to ensure that there is no inconsistent classification data for any drugs, unless an exception has been granted.

CMS stated that it is continuing to make improvements to its reporting system. As part of these improvements, we recommend that CMS add a variable to indicate whether a drug has been granted a narrow exception. This would allow CMS to more easily identify innovator drugs for which manufacturers are appropriately paying a noninnovator rebate. In addition, it would enable CMS to distinguish these from drugs that may be potentially misclassified.

CMS could not provide us with a list of potential drug misclassifications that it identified or the manufacturers associated with these potentially-misclassified drugs. Because CMS does not track instances in which manufacturers may have reported incorrect classification data, it may not be able to effectively monitor its activities to follow up with manufacturers about potential errors in their reported classification data. Therefore, CMS should add another variable in its system to identify drugs that may be misclassified. A new variable may help CMS identify manufacturers that may be paying inaccurate rebate amounts for potentially-misclassified drugs. CMS also should maintain records of all attempts to follow up with manufacturers that submitted potentially inaccurate classification data. CMS also should use this information to track any cases in which the manufacturer refused to change its classification data.

Pursue a means to compel manufacturers to correct inaccurate classification data reported to the Medicaid rebate program

When CMS staff identify potential errors in data submitted to the Medicaid rebate program, they indicated that they notify manufacturers to correct the data. While this engagement with manufacturers may be sufficient in many instances, it may not always be sufficient. In the instances in which voluntary engagement does not result in accurate classification data, CMS does not have the legal authority to compel manufacturers to correct classification data. CMS could potentially determine that a manufacturer's refusal to change its drug classification

constitutes good cause for termination from the Medicaid rebate program. However, CMS also stated that terminating a manufacturer from the program could limit access for beneficiaries. If manufacturers do not update their classification data, they may continue to pay the wrong rebate amounts and Medicaid may not receive the appropriate rebate amounts for potentially-misclassified drugs.

CMS could consider the following options to compel manufacturers to correct inaccurate classification data: (1) CMS could seek legislative authority, e.g., an A-19, to compel manufacturers to submit accurate data and/or enhance its enforcement authority and (2) CMS also could determine whether it has the authority to suspend potentially-misclassified drugs from participation in the Medicaid rebate program until the manufacturer corrects all inaccurate information.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with all three of our recommendations.

In response to our first recommendation, CMS stated that it will review the drugs OIG identified as potentially misclassified. CMS also stated it previously identified potentially-misclassified drugs and communicated with manufacturers to make them aware of the incorrect reporting.

In response to our second recommendation, CMS noted that it is developing a new Medicaid Drug Program system which it believes will help identify and reduce inconsistent data submissions.

Finally, in response to our third recommendation, CMS stated that it will consider methods to improve agency efforts to compel manufacturers to correct inaccurate drug classification data. Additionally, CMS stated that it shares a joint responsibility with OIG to oversee manufacturers' compliance with data reporting, and encouraged OIG to use its enforcement authority in this area. CMS operates the Medicaid rebate program and is ultimately responsible for overseeing the accuracy of drug classification reporting by manufacturers. The Medicaid rebate statute authorizes civil monetary penalties in certain circumstances, and authority to pursue such penalties has been delegated to OIG. Consistent with the scope of the statute, OIG will continue to pursue penalties against manufacturers where appropriate. However, OIG believes it lacks legal authority to affirmatively pursue penalties for the submission of inaccurate drug classification data.

We appreciate CMS's efforts to address potential drug misclassifications in the Medicaid rebate program and we look forward to working with CMS on these issues in the future. Appendix B contains the full text of CMS's comments.

APPENDIX A

Detailed Methodology

Data Collection

Medicaid Data. We obtained 2016 drug classification data from the Medicaid rebate drug product file (the Medicaid file), which is publicly available on Medicaid.gov. We removed NDCs, i.e., drugs, from the Medicaid file that were:

- categorized as over-the-counter,
- terminated and not reactivated before January 1, 2016,
- listed with the covered outpatient drug status of “unapproved,” or
- considered to be less than effective.¹⁸

We evaluated classifications for the remaining 30,469 covered outpatient prescription drugs in the fourth-quarter 2016 Medicaid file.¹⁹ For the drugs under review, we obtained Medicaid reimbursement and utilization data for 2012 through 2016 from Medicaid.gov.²⁰ We also obtained CMS’s quarterly AMP data to estimate potentially-lost rebates from 2012 to 2016.

For the 10 potentially-misclassified drugs with the highest reimbursement in 2016, we obtained the total rebate amounts claimed and the number of units reimbursed from 2012 to 2016 from the Medicaid Drug Rebate system.

FDA Data. We collected information from the NDC Directory and the NDC Structured Product Labeling Data Elements File (available on FDA’s website) to obtain the marketing categories reported by FDA for NDCs in our review.

Compendia Data. We obtained drug classification data from two national drug compendia, First Databank and Redbook. We used the First Databank “innovator” variable and the Redbook “product category” variables to determine the compendia classifications for drugs.

Inflation Data. We obtained consumer price index for urban consumers (CPI-U) data from the Bureau of Labor Statistics. We used this data to estimate additional inflation-adjusted rebates for the

¹⁸ Certain Drug Efficacy Study Implementation drugs are considered to be less than effective. These drugs are not eligible for coverage under the Medicaid rebate program.

¹⁹ We included drugs that had classification data in the fourth-quarter 2016 to ensure that we accounted for the most recent classification data reported by manufacturers.

²⁰ Not all drugs that were in the Medicaid file had reimbursement amounts in 2016.

10 potentially-misclassified drugs with the highest reimbursement in 2016. For the analysis of the top 10 drugs, we included only drugs that were potentially misclassified according to all sources reviewed.

CMS Policies and Procedures. We requested information from CMS on its policies and procedures for reviewing drug classifications in the Medicaid rebate program. We asked CMS to describe any training or guidance provided to staff to assist them in overseeing classification data submitted to the Medicaid rebate program. We also asked CMS how it identifies and addresses instances in which drugs are potentially misclassified in the Medicaid file. We asked CMS to list all instances in which it identified potential misclassifications, and the actions taken in response to these potential misclassifications over the past 5 years.

Data Analysis

Drug Classifications. We determined the number and percentage of drugs that were classified as innovator and noninnovator in the fourth-quarter 2016 Medicaid file. We checked for internal inconsistencies in the Medicaid file by determining whether a drug's classification corresponded to its covered outpatient drug status, which identifies the drug's marketing category.

We then compared these drugs' classifications to the marketing categories in the FDA files and determined the number and percentage of drug classifications that matched, as well as the number and percentage of drugs that did not match.²¹ We considered the nonmatching drugs to be potentially misclassified. Specifically, drugs with innovator classifications in the Medicaid file should correspond to NDA, BLA, or authorized generic marketing categories in the FDA files, and noninnovator drugs in the Medicaid file should correspond to ANDA marketing categories in the FDA files.

We also calculated the number and percentage of drugs with Medicaid classifications for which we were unable to determine whether the Medicaid classification matched the FDA marketing category, and the number and percentage of drugs that were missing from the FDA files.

We identified drug compendia classifications for drugs that were potentially misclassified. We compared these classifications across all files, i.e., the Medicaid file, FDA files, and both drug compendia, to determine the number and percentage of drugs that were classified as innovator and noninnovator in each data source.

²¹ We compared drugs, using the 11-digit NDCs provided by manufacturers to CMS and FDA.

We calculated 2016 Medicaid reimbursement for the potentially-misclassified drugs, drugs for which we could not determine whether the Medicaid classification matched FDA data, and drugs missing from FDA files. We also determined which manufacturers were associated with the greatest number of potential misclassifications in 2016.

Rebates. To provide some indication of the potential lost rebates to Medicaid as a result of misclassifications, we selected 10 potentially-misclassified drugs with the highest total reimbursement in 2016 to calculate additional rebates that could have been collected from 2012 to 2016. Specifically, we determined Medicaid reimbursement for all potentially-misclassified drugs in 2016. We then selected 10 potentially-misclassified drugs with the highest total reimbursement that year and estimated the amounts that Medicaid may have received in additional rebates for these drugs from 2012 to 2016. All 10 of these drugs were classified as noninnovator products in the Medicaid file but classified as innovator or brand-name products in the FDA and compendia files.

We estimated the (1) base rebates (based on calculating 23.1 percent of AMP) and (2) inflation-adjusted rebates manufacturers would have owed if these drugs had been classified as innovator products. We followed statutory guidance on calculating the inflation-adjusted rebate amounts. We used CPI-U and AMP data to determine the inflation-adjusted rebates for the NDCs under review for each quarter from 2012 to 2016.²² We summed the base and inflation-adjusted rebates and then multiplied this total by the number of units reimbursed for each NDC in each quarter. We subtracted the total Medicaid rebate amounts actually claimed each quarter from our calculated total to estimate the rebates that Medicaid may have lost due to potential misclassifications for these 10 drugs over the 5-year period.

We calculated Medicaid reimbursement for these 10 drugs from 2012 to 2016. We then determined the total lost base and inflation-adjusted rebates as a percentage of Medicaid reimbursement across the 5 years.

We also estimated the base rebates that Medicaid would have collected from 2012 to 2016 if the remaining 875 potentially-misclassified drugs had been classified differently in 2016.²³ For this analysis, we calculated

²² When a drug is purchased or acquired from another manufacturer, the NDC for that drug may change. However, the inflation-adjusted rebate amount is calculated on the basis of the market date of the original NDC. We identified the original NDCs for the top 10 drugs to estimate the inflation-adjusted rebates for these drugs.

²³ We used the classification data available in the fourth-quarter 2016. We did not determine which drugs were potentially misclassified from 2012 to 2016.

an estimate of the base rebates manufacturers owed for each of these 875 drugs by multiplying each drug's quarterly utilization by its URA. We then calculated an estimate of the base rebate amounts for each of these drugs had they been classified differently by multiplying the estimated base rebate amount (either 13 percent of AMP or 23.1 percent of AMP) by the quarterly utilization. We then subtracted the base rebates under the 2016 classification from the estimated base rebates had the drugs been calculated differently to determine potentially-lost rebates. We did not calculate the additional inflation-adjusted rebates for these drugs.

CMS Policies and Procedures. We reviewed and summarized CMS's responses about its policies and procedures for ensuring the accuracy of drug classification data.

Limitations

We did not verify the completeness or accuracy of the drug pricing or classification data from CMS, FDA, or the compendia.

We use the term "potentially misclassified" and describe rebates that "may have" been lost in this report because CMS has not completed its review of the narrow exception requests submitted by manufacturers. If CMS grants a manufacturer's request for a narrow exception for any of the drugs identified as potentially misclassified in this report, this determination could affect our list of potentially-misclassified drugs and any associated lost rebates.

FDA files and compendia data can be updated daily and therefore could have changed during the timeframe under review. We used the drug classifications from the fourth quarter of 2016 and downloaded the FDA files and compendia data in the first quarter of 2017. We did not determine whether Medicaid drug classifications changed in the quarters following the fourth quarter of 2016.

Base rebate amounts for innovator drugs are usually calculated as the difference between AMP and best price, or 23.1 percent of AMP, whichever is greater. All 10 of the potentially-misclassified drugs with the highest total reimbursement were classified as noninnovator products, and manufacturer-reported best price information was not available for these drugs. Therefore, we estimated the base rebate amounts using only the 23.1 percent of AMP formula.

All of the top 10 drugs had market dates on or before September 30, 1990. To calculate the inflation-adjusted rebates for these drugs, we used the earliest AMP data available, which was often from the first quarter of 1991.

APPENDIX B

Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

200 Independence Avenue SW
Washington, DC 20201

DATE: SEP 22 2017

TO: Daniel R. Levinson
Inspector General
Office of the Inspector General

FROM: Seema Verma *S.V.*
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Potential Misclassifications Reported by Drug Manufacturers May Have Led to \$1 Billion in Lost Medicaid Rebates (OEI-03-17-00100)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report on drug classification reporting. CMS takes seriously its responsibility to oversee the Medicaid Drug Rebate Program.

The Medicaid Drug Rebate Program is a partnership between CMS, State Medicaid Agencies, and participating drug manufacturers that helps to offset the federal and state costs of most outpatient prescription drugs dispensed to Medicaid patients. The program requires a drug manufacturer to enter into, and have in effect, a Medicaid National Drug Rebate Agreement with the Secretary of the Department of Health and Human Services (HHS) in exchange for state Medicaid coverage of most of the manufacturer's drugs. Manufacturers are required to report all of their covered outpatient drugs to the Medicaid Drug Rebate Program. Manufacturers are then responsible for paying a rebate on those drugs for which payment was made under the state plan. These rebates are paid by drug manufacturers on a quarterly basis to states and are shared between the states and the Federal government.

While it is the responsibility of the manufacturers, under current statute, to properly report all of their drug product information, CMS requires manufacturers that have a rebate agreement to provide product data, including drug category, on the drugs the manufacturers report to the Medicaid Drug Rebate Program. CMS has provided subregulatory guidance and regulatory guidance on these issues to ensure manufacturers are meeting their responsibility, under current statute, to properly report the classification of its drugs and the required pricing data, as well as to pay the proper rebate amounts. In February 2016, CMS published the Covered Outpatient Drugs Final Rule with comment period (Final Rule), which implemented Medicaid Drug Rebate Program revisions made by the Patient Protection and Affordable Care Act. Among other things, the Final Rule clarifies many of the changes made to the program by the Patient Protection and Affordable Care Act and provides drug manufacturers with regulatory guidance to ensure proper calculation and reporting of drug product and pricing information. More specifically, it reiterates

prior guidance concerning the regulatory definitions for "single source drug," "innovator multiple source drug," "noninnovator multiple source drug," and "average manufacturer price," among other definitions.

In October 2016, CMS began development of a new Medicaid Drug Rebate Program system that will update the existing information systems and enhance the agency's capacity to oversee the more than 23,000 drug classifications and other information pertaining to the Medicaid Drug Rebate Program. The new system will match manufacturer-reported data to the Food and Drug Administration data in order to verify manufacturer submissions, receive state drug utilization data via online submission, process the rebate agreement electronically, and automate some of the current process for better data validations.

Finally, in November 2016, CMS published a proposed notice announcing updates to the National Drug Rebate Agreement, which clarifies the responsibilities of manufacturers participating in the Medicaid Drug Rebate Program and of CMS in administering it. CMS is proposing to update the National Drug Rebate Agreement to incorporate legislative and regulatory changes that have occurred since the National Drug Rebate Agreement was last published on February 21, 1991. The proposed updates include modifications to the definitions section, the manufacturer's responsibilities section, the dispute resolution section, and the nonrenewal and termination section.

Despite these efforts, CMS's authority to act if a manufacturer improperly classifies a drug is limited. If it comes to CMS's attention that the manufacturer's drug classification is incorrect for rebate purposes, CMS notifies the manufacturer and attempts to reach an agreement. This occurs as a regular component of the oversight of the program. The statute does not expressly provide the Secretary of HHS with the authority to compel a manufacturer that has incorrectly reported a drug to change that classification or to issue civil monetary penalties in such a case. However, CMS will continue to do as much as current authority allows to increase oversight of manufacturer compliance with the Medicaid Drug Rebate Program requirements.

CMS and OIG share a joint responsibility to provide oversight over manufacturers' compliance on the data reported to the Medicaid Drug Rebate Program. OIG has the authority to conduct audits of manufacturers' reported data classification and report their findings to CMS.

OIG's recommendations and CMS's response are below.

OIG Recommendation

CMS should follow up with manufacturers associated with potentially misclassified drugs identified in this report to determine if current classifications are correct.

CMS Response

CMS concurs with this recommendation. CMS will begin review of the potentially misclassified drugs identified in the report once CMS receives the list of identified National Drug Codes from the OIG. As the OIG notes in their report, some of these manufacturers may have applied for a "narrow exception" request to continue to classify a drug approved under a New Drug Application as a non-innovator drug as permitted under the 2016 Final Rule.

CMS has already identified numerous National Drug Codes that are potentially misclassified and contacted these manufacturers. Over the years, CMS has communicated frequently with manufacturers who may have misclassified one or more of its drugs to encourage the manufacturers to review their data and take appropriate action with CMS.

In addition, since late 2015, CMS specifically communicated with manufacturers that reported drugs approved under a New Drug Application as “noninnovator” drugs to make them aware of the incorrect reporting. Manufacturers that did not take action were informed that the potentially misclassified National Drug Codes were being put into an “out of compliance” status in the system. This prevents the manufacturer from reporting their monthly and quarterly pricing data to the Drug Data Reporting system, which is required by section 1927(b)(3) of the Social Security Act.

OIG Recommendation

CMS should improve its Drug Data Reporting for Medicaid system to minimize inconsistent data submissions and track potential classification errors for follow-up.

CMS Response

CMS concurs with this recommendation. The agency is in the process of developing a new Medicaid Drug Program system. CMS believes these efforts will help to identify and reduce inconsistencies in data submissions as well as position the agency to be proactive in identifying potential classification errors for follow-up.

Additionally, CMS has implemented system edits to prevent manufacturers from submitting new drugs with an incorrect classification and is utilizing current existing capabilities to identify potentially misclassified drugs for follow-up with the manufacturer.

OIG Recommendation

CMS should pursue a means to compel manufacturers to correct inaccurate classification data reported to the Medicaid rebate program.

CMS Response

CMS concurs with this recommendation. CMS and OIG share a joint responsibility to provide oversight of manufacturers’ compliance with data reported to the Medicaid Drug Rebate Program. CMS will consider methods to improve the agency efforts to compel manufacturers to correct inaccurate drug classification data. CMS also encourages OIG to use its oversight and enforcement authority to compel manufacturers to correct inaccurate drug classification data reported to the Medicaid drug rebate program.

CMS thanks OIG for their efforts on this issue and looks forward to working with OIG on this and other issues in the future.

ACKNOWLEDGMENTS

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This report was prepared under the direction of Linda Ragone, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office, and Edward K. Burley, Deputy Regional Inspector General.

To obtain additional information concerning this report or to obtain copies, contact the Office of Public Affairs at Public.Affairs@oig.hhs.gov.

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