

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICAID DRUG REBATE
DISPUTE RESOLUTION COULD
BE IMPROVED**



**Suzanne Murrin
Deputy Inspector General for
Evaluation and Inspections**

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EXECUTIVE SUMMARY: Medicaid Drug Rebate Dispute Resolution Could Be Improved

OEI-05-11-00580

WHY WE DID THIS STUDY

The Medicaid drug rebate program is a significant source of savings for States and the Federal government. Between 2011 and 2013, the rebate program saved Medicaid an average of \$17.5 billion annually—an amount that will grow as a result of changes made by the Affordable Care Act. Sometimes, however, States and drug manufacturers do not agree on the amount of money that manufacturers owe in rebates. In such cases, the manufacturer and the State may enter into a dispute. Disputes are a matter of concern because they can lead to inefficient use of resources and lost money for States and the Federal Government.

HOW WE DID THIS STUDY

We requested data from 31 States to determine the extent to which rebate amounts were disputed. We also surveyed 12 States (including 6 from the group of 31) in more depth to determine the causes of the most frequent types of disputes and the challenges associated with resolving them. We interviewed relevant staff from these States, five manufacturers, and the Centers for Medicare & Medicaid Services (CMS) to determine the measures that each has taken to prevent and resolve disputes.

WHAT WE FOUND

Twenty-nine of thirty-one States that could provide data estimated that only a small percentage of rebate dollars were disputed. The 12 selected States indicated that within this small percentage, certain types of disputes occur frequently. These States reported that poor-quality claims data lead to disputes regarding unit-of-measure conversions and physician-administered drugs. In addition, States reported that poor-quality data regarding ineligible drugs lead to disputes about drugs purchased at a discount under the 340B Drug Pricing Program and terminated drugs.

The 12 selected States reported that once disputes are initiated, they struggle to provide the data necessary to resolve them. States reported difficulties in providing claims data or source data to help resolve disputes. Finally, the selected States and manufacturers expressed interest in greater CMS involvement in preventing and resolving disputes.

WHAT WE RECOMMEND

We recommend that to help prevent and resolve drug rebate disputes, CMS (1) work with States to improve the quality of claims data submitted by providers and pharmacies, (2) help States obtain better data on ineligible drugs, (3) facilitate States' submission of standardized claims data, and (4) establish a stronger role in dispute resolution. CMS concurred with our first three recommendations and partially concurred with our fourth recommendation.

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OBJECTIVES

To determine:

1. the extent to which rebates are disputed under the Medicaid drug rebate program,
2. the causes of frequently occurring types of disputes,
3. challenges that States face in resolving disputes,
4. the measures that States and drug manufacturers believe will help prevent or resolve disputes.

BACKGROUND

The Medicaid drug rebate program is a significant source of savings for States and the Federal government. Between 2011 and 2013, the rebate program saved Medicaid an average of \$17.5 billion annually. This amount is likely to grow due to changes made by the Affordable Care Act (ACA).

Drug manufacturers (hereinafter referred to as manufacturers) may dispute the number of prescription drug units for which States are requesting rebates. Disputes are a matter of concern because they can lead to inefficient use of resources and lost money for States and the Federal Government. In some cases, States and manufacturers spend significant time investigating and addressing disputes. In addition, States may not be receiving all of the rebates they are owed because of vulnerabilities in the dispute-resolution process. Previous Office of Inspector General (OIG) reports have found that some States were not resolving disputes in a timely manner, potentially leading to a loss of rebate revenue.¹

Medicaid Drug Rebate Program

Congress created the Medicaid drug rebate program to reduce State and Federal Medicaid expenditures for prescription drugs.² Manufacturers of covered outpatient drugs (i.e., rebate-eligible drugs) are generally required

¹ OIG, *Multistate Review of Medicaid Drug Rebate Programs*, A-06-03-00048, July 2005; OIG, *Nationwide Rollup Report for Medicaid Drug Rebate Collections*, A-06-10-00011, August 2011.

² The Omnibus Budget Reconciliation Act of 1990, § 4401, codified at 42 U.S.C. § 1396r-8. Social Security Act § 1927.

to enter into rebate agreements with the Secretary of Health and Human Services and pay quarterly rebates to States.³

Most drugs covered under Medicaid are self-administered products (e.g., tablets) dispensed by pharmacies. However, Medicaid also covers physician-administered drugs, which include both injectable and noninjectable drugs that are typically administered by medical professionals in physicians' offices, clinics, or hospitals.⁴

Medicaid Drug Rebate Process

Rebates are calculated using two kinds of data: (1) pricing data submitted by manufacturers and (2) utilization data (i.e., the total number of rebate-eligible units for each drug) compiled by States.⁵ Each quarter, manufacturers send pricing data to the Centers for Medicare & Medicaid Services (CMS), which then calculates an unofficial unit rebate amount (URA). CMS makes a URA for each national drug code (NDC) available to States in the Drug Data Reporting (DDR) system for Medicaid.^{6, 7} Each State determines the rebate amount that a manufacturer owes by multiplying the URA for each of the manufacturer's NDCs by the corresponding number of rebate-eligible units. Manufacturers are ultimately responsible for calculating an official URA and paying rebates to States.

Rebate collection for physician-administered drugs. In contrast to drugs dispensed by pharmacies, which are billed for using NDCs, physician-administered drugs are typically billed for using Healthcare Common Procedure Coding System (HCPCS) codes.⁸ Unlike NDCs, HCPCS codes do not identify the manufacturer responsible for paying a rebate. To assist States in collecting rebates for physician-administered drugs, the DRA essentially required the States to provide for the gathering of data (including NDCs) necessary to collect rebates for all single-source

³ Generally speaking, to be eligible to receive Federal payment for covered outpatient drugs provided under Medicaid, manufacturers must enter into rebate agreements and pay rebates to the State Medicaid programs. Sections 1927(a)(1) and (b)(1) of the Social Security Act .

⁴ See, e.g., §§ 1927(k)(2) and (a)(7) of the Social Security Act (as added by the Deficit Reduction Act of 2005 (DRA), P.L. No. 109-171).

⁵ See, generally, Social Security Act §§ 1927(b)(3)(A) and 1927(c)(1).

⁶ An NDC is an 11-digit identifier for prescription drugs that represents a specific manufacturer, product, and package size.

⁷ The DDR is a Web-based application for all drug data collection. Manufacturers must submit information on their drugs to the DDR. States can request access to view select Medicaid drug rebate data.

⁸ A HCPCS code identifies the drug's name, route of administration, and dosage size.

physician-administered drugs and the 20 multiple-source physician-administered drugs with the highest dollar volume.⁹

Rebate exception for 340B-purchased drugs. Drugs purchased through the 340B Drug Pricing Program (340B program) are not subject to rebates under the Medicaid drug rebate program. The 340B program requires manufacturers to sell covered outpatient drugs to eligible health care organizations, known as covered entities, at significantly reduced prices.¹⁰ Drugs purchased under the 340B program (340B-purchased drugs) are not subject to Medicaid rebates because to do so would subject manufacturers to a duplicate discount on these drugs.¹¹

However, covered entities may choose to purchase drugs outside of the 340B program for their Medicaid patients. States may invoice manufacturers for rebates for such drugs.

The Medicaid Exclusion File, maintained by the Health Resources and Services Administration (HRSA), indicates whether covered entities dispense 340B-purchased drugs to their Medicaid patients. States use this information to exclude 340B-purchased drugs from the invoices they use to collect rebates.

Drug Rebate Disputes

When a manufacturer, in good faith, does not believe that a State's utilization data for a particular NDC accurately represent the total number of rebate-eligible units, the manufacturer may dispute the invoiced amount.¹² To initiate a rebate dispute, the manufacturer communicates the number of units for each NDC that it is disputing (i.e., the number of units that it believes not to be rebate-eligible) to the State and indicates the reason it believes this number is incorrect. When a manufacturer initiates a dispute, it can withhold payment only for the disputed numbers of units; for all nondisputed numbers of units, the manufacturer is expected to pay rebates in a timely manner.

Manufacturers may initiate disputes at any point in the process. In fact, some manufacturers review old data and initiate disputes on previously

⁹ Section 1927(a)(7) of the Social Security Act (as added by the DRA, P.L. No. 109-171).

¹⁰ See <http://www.hrsa.gov/opa/index.html>. The 340B program was established by the Veterans Health Care Act of 1992, P.L. No. 102-585 § 602 and codified at 42 U.S.C. §§ 256b.

¹¹ 42 U.S.C. § 256b(a)(5). See also 58 Fed. Reg. 27293 (May 7, 1993).

¹² CMS, *Sample Drug Rebate Agreement*, § V(b). Accessed at <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/SampleRebateAgreement.pdf> on April 23, 2014.

paid rebates.¹³ As of fiscal year (FY) 2014, there was no Federal requirement establishing a time limit to prevent manufacturers from initiating disputes on claims that were paid years ago. However, the President's budget for FY 2015 includes a proposal to limit to 12 quarters the timeframe for which manufacturers can dispute drug rebate amounts.

Resolving Drug Rebate Disputes

To resolve a dispute, States and manufacturers must come to an agreement on the disputed units. If States can prove to manufacturers' satisfaction that the utilization data they invoiced was correct, manufacturers should pay rebates for any disputed units.¹⁴ If States find errors in the utilization data that they invoiced, they should adjust the number of units accordingly.¹⁵ If States cannot provide evidence to manufacturers, it is possible that the dispute will remain unresolved and manufacturers will not pay rebates for the disputed units.

No time limit exists for resolving disputes. In fact, previous OIG reports indicated that States may have disputes dating back many years.¹⁶ Although the rebate agreement says that States and manufacturers should strive to resolve disputes within 60 days, this does not always happen.¹⁷ States have indicated that they generally try to resolve disputes within 1 year of paying providers' claims for disputed units.

CMS involvement in dispute resolution. CMS has a voluntary dispute-resolution program that provides facilitation and mediation assistance to States and manufacturers during rebate disputes. CMS previously sponsored conferences at which manufacturers and States could meet to resolve disputes, but has not done so since 2009. States can contact the regional CMS staff member assigned to dispute resolution or submit questions by email.

¹³ States can also review old data and previous invoices. If a State finds that it was underpaid because a drug was invoiced using the wrong type of unit, resulting in an incorrect number of units, the State can request an adjustment from the manufacturer.

¹⁴ CMS, *Best Practices for States*, § II6, and *Best Practices for Drug Manufacturers*, § II5. Accessed at <http://www.medicare.gov/Medicare-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicare-Drug-Rebate-Program-Dispute-Resolution.html> on April 29, 2014.

¹⁵ Ibid.

¹⁶ OIG, *Review of the Medicaid Drug Rebate Program in California*, A-09-03-00038, December 2003; OIG, *Follow-Up Review of the Medicaid Drug Rebate Program in Florida*, A-04-07-00022, April 2008; OIG, *Review of the Medicaid Drug Rebate Program in Illinois*, A-05-08-00011, July 2008; OIG, *Follow-up Review of the Medicaid Drug Rebate Program in Michigan*, A-05-08-00014, July 2008.

¹⁷ CMS, *Sample Drug Rebate Agreement*, § V(c). See footnote 12 for URL.

In addition to having the voluntary dispute-resolution program, CMS has issued documents to assist States and manufacturers with dispute resolution. Among these documents are several “program releases” on the topic, as well as documents with best practices for resolving disputes.

Related Reports

Previous OIG reports have indicated concerns about States’ ability to properly invoice manufacturers, resolve disputes, and collect all rebates owed to them. In 2005, OIG found that many States lacked adequate assurance that all drug rebates owed to them were properly recorded or collected, and that CMS did not have reliable billing and collection information to properly monitor the drug rebate program.¹⁸ Specifically, this study found that 15 States had inadequate processes for dispute resolution and rebate collection.¹⁹ A 2011 followup study found that 6 States (including 2 of the original 15) had inadequate processes for dispute resolution and rebate collection.²⁰

METHODOLOGY

This review presents information collected from selected States and manufacturers related to preventing and resolving disputes. In addition, we collected information from CMS on its role in helping States prevent and resolve disputes. See Appendix A for a detailed methodology.

Sample

State selection. To determine the extent to which rebates are disputed under the Medicaid drug rebate program, we collected data from 31 States. These States indicated that they had the capability to provide all of the data that the OIG planned to request.

Initially, we surveyed all States and the District of Columbia (hereinafter referred to as States) about their ability to provide data such as the amount of money ever in dispute, the amount of money currently in dispute, and the total amount of money invoiced since the rebate program began. Thirty-one States indicated that they could provide all of the requested information, and 20 States indicated that they could not.

To address the other evaluation objectives, we purposively selected a sample of 12 States for more in-depth review. We selected 6 States from

¹⁸ OIG, *Multistate Review of Medicaid Drug Rebate Programs*, A-06-03-00048, July 2005.

¹⁹ *Ibid.*

²⁰ OIG, *Nationwide Rollup Report for Medicaid Drug Rebate Collections*, A-06-10-00011, August 2011.

the 31 States that indicated they could provide the requested data and 6 States from the 20 States that indicated they could not. We purposively selected States this way to include States with different levels of sophistication in their dispute-tracking systems, so as to represent variation among States in their capacity to track and address disputes. In addition, to maximize our coverage of Federal funds invested in the rebate program, we selected these 12 States from those with the highest drug expenditures.

Manufacturer selection. To determine which manufacturers to select, we used information provided from all States as to which manufacturers worked more cooperatively to resolve disputes in a timely manner and which did not. We purposively selected manufacturers using these criteria to obtain a broad perspective of how manufacturers handle dispute resolution. The five manufacturers we interviewed included two that States most often reported as more cooperative and three that States most often reported as less cooperative.

Data Collection

Data request. In May 2013, we sent a data request to the 31 States that indicated they could provide OIG's requested data. We received responses from all 31 States. The data request focused on quantifying the amount of money that States had in dispute at the time of our data request.

State survey and structured interviews. Also in May 2013, we sent a survey to the 12 selected States. We received survey responses from all 12 States. In June 2013, we conducted followup structured interviews with each of these States.²¹

Limitations

The results of this report cannot be extrapolated nationally (i.e., across all States), nor can they be extrapolated across all manufacturers.

All data were self-reported by States and manufacturers and represent their perspectives on Medicaid drug disputes.

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.

²¹ In some cases, States use a contractor for drug rebate functions. Some States invited their contractors to attend the interviews.

FINDINGS

Twenty-nine of thirty-one States that could provide data estimated that only a small percentage of rebate dollars were disputed

Twenty-nine of thirty-one States that could provide data estimated that, of the amount of money they invoiced for rebates in calendar year (CY) 2012, 6 percent or less was in dispute. Specifically, 24 of these 29 States reported 2 percent or less of the money from CY 2012 rebate invoices in dispute. Of the two States that reported that *more* than 6 percent was in dispute, one reported that 14 percent of the money it invoiced was in dispute, and the other reported 25 percent.²²

While the percentage of money in dispute appears to be small, it still represents millions of dollars. Six of the thirty-one States provided dollar amounts for their estimated percentages of money in dispute from CY 2012 rebate invoices; these disputed amounts totaled \$5.2 million. This represents 2 percent or less of the money invoiced in these States. The remaining 25 States could not provide estimates that distinguished between invoice amounts that were disputed and those that were unpaid for other reasons.

Because disputes can be resolved in favor of the State or manufacturer, the entirety of the estimated money in dispute is likely not owed to the State or Federal government. However, the entirety of the money represents unresolved disputes that parties are expending resources to monitor and resolve.

Poor-quality data is a primary cause of frequent rebate disputes in 12 selected States

Within the small percentage of money in dispute, certain types of disputes occur frequently. These disputes are typically associated with (1) drugs with complicated unit-of-measure conversions, (2) physician-administered drugs, (3) 340B-purchased drugs, and (4) terminated drugs.²³

²² The State that reported the figure of 14 percent indicated that this percentage was associated with retroactive rebate invoices for drugs dispensed by Medicaid managed care organizations. These invoices dated back to 2010, and the State found that disputes were higher for those retroactive rebate invoices. The State that reported a figure of 25 percent indicated that only 2 percent was for mandated Medicaid rebates. The remaining 23 percent in dispute was for additional rebates that the State negotiated with manufacturers.

²³ A terminated drug is a drug that is no longer manufactured.

States struggle with preventing these disputes because of poor-quality data. States reported receiving poor-quality claims data from providers and pharmacies. In addition, States reported challenges in obtaining accurate data from other sources to remove drugs that are ineligible for rebates. See Table 1 for the relationship between the type of dispute and the related data problems that States reported.

Table 1: Causes of Frequent Types of Rebate Disputes

Type of Dispute	Cause Reported by States	Number of States
Unit-of-measure conversions	Poor-quality claims data from providers and pharmacies	10
Physician-administered drugs		
340B-purchased drugs	Poor-quality data as to which drugs are ineligible for rebates	7
Terminated drugs		

Source: OIG analysis of survey responses, 2013.

Ten of the twelve selected States reported that poor-quality claims data lead to disputes regarding unit-of-measure conversions and physician-administered drugs

Ten of the twelve selected States reported that poor-quality Medicaid claims data from providers and pharmacies can result in disputes regarding drugs with complex unit-of-measure conversions (i.e., drugs delivered as liquids, creams, or aerosols) and physician-administered drugs. The five selected manufacturers also said that these types of disputes were frequent.

Unit-of-measure conversions. Nine of the ten States reported that one way they receive inaccurate claims data is when providers or pharmacies submit the wrong number of units. Three of these ten States reported that physician-administered drugs, which are typically liquid injectable drugs, are especially prone to unit-of-measure mistakes. The five selected manufacturers also indicated that unit-of-measure issues continue to cause frequent disputes.

Determining the correct units to bill is not always straightforward, particularly for drugs in nontablet form (e.g., liquid-filled syringes or creams). For example, 1 dose of albumin is 12.5 grams per 240 milliliters. Solutions, injectable liquids, and drugs measured by volume should be billed as the number of milliliters, not grams. With such drugs, the provider or pharmacy would have to calculate the correct number of milliliters and include that number of units on the claim. For example, if 2 doses of albumin were administered, the units to be billed to Medicaid would be 480 units, not 25 units.

Physician-administered drugs. Three of the ten States reported that another way they receive inaccurate data is when providers include the wrong NDC on claims for physician-administered drugs. One State noted that it sometimes receives NDCs for a completely different drug or for a different drug within the same “product line.” In some cases, the HCPCS codes that providers use to bill for physician-administered drugs cover many NDCs representing different manufacturers.

States have limited ability to determine whether the NDC listed on the claim from the provider is correct. In the case of an NDC for a completely different drug, States may be able to catch this error if they have access to a “crosswalk” that indicates which NDCs are linked to the HCPCS code on the claim. In the case of an NDC for a different drug within the same product line—i.e., one of the NDCs associated with a given HCPCS code—there is little States can do to determine whether the provider billed for the correct NDC, short of requesting medical records or talking directly to the provider. Because of these limitations, States may invoice manufacturers for the wrong drug, leading to disputes.

Seven of the twelve selected States reported that poor-quality data regarding ineligible drugs lead to disputes associated with 340B-purchased drugs and terminated drugs

Seven of the twelve selected States reported that the data they need to exclude ineligible drugs from rebate invoices are of poor quality. This occurs primarily with 340B-purchased drugs and terminated drugs.

340B-purchased drugs. States reported that it can be difficult to ensure that all drugs that receive an upfront discount under the 340B program are excluded from the rebate invoice. Four of the twelve selected States reported that disputes related to 340B-purchased drugs occurred frequently. Four of the five selected manufacturers agreed.

States reported problems with the Medicaid Exclusion File, the official list of covered entities that dispense 340B-purchased drugs to Medicaid patients. Specifically, States noted that the file sometimes was not up to date or was inaccurate. Without accurate data on which covered entities dispense 340B-purchased drugs to Medicaid patients, States cannot effectively program their systems to identify claims for 340B-purchased drugs and exclude them from rebate invoices.

Terminated drugs. Three States reported that another way that ineligible drugs are invoiced for rebates is when States lack updated or complete information needed to remove terminated drugs from rebate invoices.

One State noted that it receives updated information about terminations from CMS only on a quarterly basis.²⁴ Another State reported that the information from CMS may not indicate all terminated drugs because manufacturers do not always report drug terminations in a timely way. This State reported that some manufacturers do not report a drug's termination until years after the fact.

Selected States Struggle To Provide the Data Necessary To Resolve Disputes

All 12 selected States reported that they struggle to provide data needed to resolve disputes. First, States had difficulties providing claims data to manufacturers. Second, when claims data are insufficient to resolve disputes, States struggle to provide source data, particularly if the disputes are about old claims.²⁵

Four of the twelve selected States reported difficulties in providing claims data to manufacturers

Four of the twelve selected States reported that it was difficult to provide claims data to manufacturers. States and manufacturers agreed that, despite potential inaccuracies with claims data, reviewing these data is a helpful first step in pinpointing the cause of disagreement.

States reported that providing claims data is time consuming, especially if records are on paper or require manual review. One State reported that it has a spreadsheet with multiple pages and thousands of lines to review prior to sending claims data to manufacturers. Another mentioned that it had to review claims data to remove confidential beneficiary information before sharing with manufacturers.

In addition, all five selected manufacturers reported problems in efficiently using claims data received from States, which delays dispute resolution. For example, two manufacturers reported that necessary information, such as provider number or provider name, is missing from some States' claims data. As a result, manufacturers must go back to the States for the additional information, which delays resolution.

Additionally, all five manufacturers reported that receiving nonstandardized data from States is a problem. Manufacturers must reformat nonstandardized data, which also delays resolution.

²⁴ CMS staff reported that if they choose, all States have the ability to access the DDR system, which provides real-time drug status.

²⁵ Source data is documentation of the drug provided, maintained in the records of providers and pharmacies.

Four of the twelve selected States reported difficulties in obtaining source data when claims data are insufficient to resolve disputes

Four of the twelve selected States reported difficulties in obtaining source data to resolve disputes. States need source data when manufacturers suspect that claims data are inaccurate and request further proof to resolve disputes.

However, source data can be challenging for States to obtain because it can be hard to reach providers and pharmacies. For example, three States reported that when they contact a provider or pharmacy, the person they reach may be an administrative or billing staff member who does not know specifics as to what drugs were used or why they were used. Such an individual would be able only to provide information listed on a medical record, and would not be able to tell if there was an error in a record. Further, because of providers' clinical responsibilities, reaching the provider can be difficult or time consuming.

All of the 12 selected States reported difficulties in obtaining data for disputes about old claims

The 12 selected States reported difficulties in obtaining information for disputes about old claims. Two States reported that they have trouble reviewing their own claims data before a certain year because system upgrades have made accessing old data difficult or impossible. Additionally, States reported that they have trouble verifying the accuracy of older claims with providers or pharmacies. Providers or pharmacies may no longer be enrolled in Medicaid when States attempt to contact them, in which case States cannot compel them to provide the source data needed to resolve the dispute. Even when States are able to contact providers or pharmacies, data needed may be past the statute of limitations for medical records retention and therefore unavailable.²⁶

Selected States and Manufacturers Are Interested In Greater CMS Involvement in Preventing and Resolving Disputes

According to the 12 selected States and 5 selected manufacturers, greater CMS involvement in preventing and resolving disputes could be helpful. States reported that they want more general involvement from CMS in both preventing and resolving disputes.

²⁶ Among the 12 selected States, the statute of limitations for medical records retention ranged between 3 and 10 years.

All 12 selected States would like help from CMS in preventing disputes

All 12 selected States wanted help from CMS in preventing disputes. Five of them suggested additional guidance that CMS could provide. Nine of them had specific suggestions as to how CMS could help with disputes related to drugs that are ineligible for rebates.

Five of the twelve selected States suggested that additional guidance from CMS could help prevent a variety of disputes. For example, one State requested that CMS issue guidance defining when it is acceptable for a manufacturer to initiate a dispute. The State noted that there is no disincentive for a manufacturer to initiate a dispute, because the burden is on the State to prove the dispute is not valid. This State recounted difficulties with a manufacturer that disputed any prescription dosage over the average dose, even for doses within the manufacturer's own recommended dosage range (listed on the drug's package insert). Another State also faced this problem and suggested that to avoid this type of dispute, CMS should establish a range of reasonable values to be used when manufacturers review invoices.

Nine States also made suggestions as to how CMS could assist with frequent disputes related to drugs that are ineligible for rebates. States said that to help them exclude 340B-purchased drugs, CMS should (1) work with HRSA to improve the accuracy of the Medicaid Exclusion File and (2) encourage States to require pharmacies to identify 340B-purchased drugs on claims. States said that to help them exclude terminated drugs, CMS should (1) require manufacturers to report termination dates in a timely manner and (2) update termination information weekly, not quarterly.

Eleven of the twelve selected States suggested that active CMS involvement could help resolve disputes

States suggested that greater CMS involvement could assist in dispute resolution. States noted that CMS is the legal party to the rebate agreement with manufacturers and has more influence over manufacturers than they do.²⁷ For example, eight States reported that when CMS became involved, formerly nonresponsive manufacturers became responsive.

Four States suggested that greater CMS involvement would increase efficiency for all parties. For example, if multiple States have the same

²⁷ Technically, the Secretary is the legal party to the rebate agreement with manufacturers. However, CMS has been designated by the Secretary to administer the Medicaid drug rebate program.

type of dispute with the same manufacturer, CMS could facilitate a single conversation between the manufacturer and the group of States, eliminating the need for multiple separate conversations.

Additionally, three States noted that the past CMS-sponsored conferences on dispute resolution were helpful and two of the three specifically suggested that CMS resume these conferences. One of the three States reported that these conferences were helpful because (1) a State could talk to many manufacturers over the course of the conference, and (2) the conferences helped reveal to CMS and manufacturers that multiple States were having the same problems. Two manufacturers agreed that previous CMS-sponsored meetings had been helpful.

Two of the twelve selected States and all five of the selected manufacturers suggested that CMS could improve dispute resolution by helping States provide standardized data

Two of the twelve selected States and all five of the selected manufacturers suggested that to improve dispute resolution, CMS could help States resolve their problems in providing claims data. First, States and manufacturers said that they would like help from CMS in facilitating the electronic transmission of claims data—for example, by developing a central repository for States and manufacturers to use to transmit claims data. They suggested that a central repository in one format would reduce the time it takes to request and reformat data from States. Second, manufacturers would like CMS to encourage that claims data be standardized. Some suggested that CMS could specify what data elements should be provided and require that the data be in a universal format.

Nine of the twelve selected States suggested that CMS establish a statute of limitations for initiating disputes

Nine states suggested that CMS could minimize disputes that are challenging to resolve by establishing a statute of limitations regarding manufacturers' ability to initiate a dispute (e.g., manufacturers could not open a dispute more than 3 years after an invoice was submitted). This would increase the likelihood that States would have access to the data needed to verify the accuracy of the claims data.

CONCLUSION AND RECOMMENDATIONS

Within the small percentage of rebate money in dispute, certain types of disputes occur frequently in the 12 selected States. These States struggle with preventing these disputes because of poor-quality data, including claims data from providers and pharmacies and data needed to effectively remove drugs that are ineligible for rebates.

States and manufacturers reported that disputes can be difficult to resolve. To resolve a dispute, a State must prove that a rebate is owed for the disputed number of units. This typically involves providing claims data to manufacturers and may also require obtaining source data from providers and pharmacies. Both activities are time consuming for States and are particularly difficult for disputes about old claims.

We recommend that to help prevent and resolve drug rebate disputes, CMS:

Work with States to improve the quality of claims data submitted by providers and pharmacies

CMS should work with States to improve data that States receive from providers and pharmacies. CMS should work with States to educate providers and pharmacies on (1) how to accurately calculate units on claims for drugs with complicated unit-of-measure conversions and (2) the importance of submitting the correct NDC on claims for physician-administered drugs. Improving the quality of claims data will increase the accuracy of rebate invoices that States send to manufacturers, thus reducing disputes.

Help States obtain better data on ineligible drugs

CMS should help States obtain accurate and up-to-date data on ineligible drugs. CMS should inform States of the option for them to identify, at the claim level, 340B-purchased drugs that are ineligible for rebates. States can instruct covered entities to use the industry-accepted standard to identify Medicaid claims for 340B-purchased drugs. However, when OIG asked States about this method in 2010, only nine States reported that they instruct covered entities to identify 340B-purchased drugs on Medicaid claims.²⁸

CMS should also work to ensure that data about terminated drugs are accurate and up to date. CMS could accomplish this by working with

²⁸ OIG, *State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs*, OEI-05-09-00321, June 2011.

States to learn which manufacturers may be delayed in submitting termination data. Then, CMS could conduct one-one-one outreach to these manufacturers or send a targeted reminder to these manufacturers about their responsibility to report termination dates in a timely manner.

Facilitate States' submission of standardized claims data

Although it is not mandatory for States to submit claims data to manufacturers, some States do so to help resolve disputes and clarify manufacturers' questions. To make this data exchange more useful and efficient, CMS could work with States and manufacturers to develop a core set of variables that States could transmit to manufacturers. Additionally, CMS could work with States and manufacturers to develop a recommended standardized format for this core set of variables.

Establish a stronger role in dispute resolution

CMS, as the delegate of the Secretary (who is the legal party to the rebate agreement), should be more engaged in dispute resolution. CMS involvement could help States and manufacturers reach agreement more quickly, enforce agreements, or bring multiple issues to the forefront at once.

CMS should provide more opportunities for States and manufacturers to interact and work on dispute resolution. For example, CMS could reestablish the CMS-sponsored conferences on dispute resolution. Alternatively, CMS could consider regional conferences, or the agency could host a videoconference or teleconference with a different manufacturer each quarter.

In addition, CMS should provide additional opportunities for States to collaborate on dispute resolution. CMS could do this by creating an online forum for States to obtain technical assistance, either from CMS or from each other.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with our first three recommendations and partially concurred with our fourth recommendation. CMS described ongoing activities in support of our recommendations, and it listed topics for which it is considering issuing additional guidance. OIG acknowledges CMS's planned activities and encourages CMS to take the additional steps necessary to address our recommendations.

For the first recommendation, CMS stated that it will consider issuing additional guidance to States and manufacturers about accurately calculating units on claims for drugs with complicated unit-of-measure conversions and about the importance of submitting the correct NDC on claims for physician-administered drugs. OIG encourages CMS to issue this guidance and suggests that CMS guidance to States also address improving the quality of Medicaid claims data submitted by providers and pharmacies.

For the second recommendation, CMS addressed ineligible 340B-purchased drugs and terminated drugs. For 340B-purchased drugs, CMS indicated that it is working with HRSA regarding guidance on such drugs. OIG encourages CMS to continue working with HRSA to finalize the guidance and ensure that the guidance addresses how to flag claims for 340B-purchased drugs. Regarding terminated drugs, CMS reiterated that States can view current drug data in the Drug Data Reporting (DDR) system for Medicaid and indicated that it has added a new field for identifying when a termination date was reported. CMS also indicated that it is considering issuing additional guidance to manufacturers about the need to provide accurate information to the DDR regarding a drug's termination date. OIG encourages CMS to take the steps necessary to issue this guidance.

For the third recommendation, CMS stated that it will offer technical assistance to States that require help in identifying methods to improve the quality of claims data, and that it will consider additional guidance to States on best practices for submitting claims data. The actions to which CMS commits are excellent steps to respond to our first recommendation, and we encourage CMS to implement them. However, we wish to clarify that the third OIG recommendation refers to the claims data that States submit *to manufacturers* to help resolve rebate disputes, not the claims data that providers and pharmacies send *to States* to be reimbursed for dispensing drugs to Medicaid patients. To respond to the third recommendation, CMS should work with States to develop a standard set

of variables that States could transmit to manufacturers to help resolve disputes more efficiently.

For the fourth recommendation, CMS indicated that it would take some actions to reinforce dispute resolution, but it did not agree to take a more active role. CMS indicated that it plans to issue dispute-resolution guidance to reiterate best practices both for States and manufacturers. CMS also indicated that its staff, including regional office coordinators of the dispute resolution program, will continue to respond to State and manufacturer inquiries. These efforts will be helpful and OIG encourages them, but we continue to believe that disputes could be resolved more efficiently and quickly if CMS took a more active role. For example, CMS could identify areas of common concern and attempt to resolve them. OIG appreciates CMS's resource constraints and urges CMS to consider low-cost solutions for involvement, such as videoconferences or teleconferences, for a more active role in dispute resolution.

We did not make any changes to the report as a result of CMS's comments. For the full text of CMS's comments, see Appendix B.

APPENDIX A

Detailed Methodology

Sample

State selection. The 31 States indicating that they could fully respond to OIG's data request were Alabama, Arkansas, Colorado, Florida, Georgia, Hawaii, Idaho, Indiana, Iowa, Kansas, Louisiana, Maine, Maryland, Massachusetts, Mississippi, Montana, Nevada, New Jersey, New Mexico, New York, Ohio, Oregon, South Dakota, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming.

The 12 States we selected for more in-depth review were California, Florida, Indiana, Illinois, Louisiana, Michigan, Missouri, New York, North Carolina, Ohio, Tennessee, and Texas.²⁹ Together, these States represented 68 percent of total Medicaid drug expenditures in FY 2011. To determine States' drug expenditures, we analyzed the data that States report to CMS on a quarterly basis.³⁰ We obtained these data from CMS's Medicaid Budget and Expenditure System for each State in FY 2011.

Manufacturer selection. We purposively selected seven manufacturers to include in our review. We selected three manufacturers that States most often reported as more cooperative and three manufacturers that States most often reported as less cooperative. We also selected one manufacturer that an equal number of States reported as more cooperative and less cooperative. After selecting the sample, we excluded two manufacturers because of ongoing OIG investigations. The final five manufacturers included two that States most often reported as more cooperative and three that States most often reported as less cooperative.

Data Collection

Data request. Specifically, we asked States to provide the amount of money in dispute for rebates invoiced in CY 2012 and to determine the percentage that this represented from all money invoiced for rebates for the same period. We asked States to include (if possible) national and supplemental rebates and to exclude uncollected money resulting from URA changes.

²⁹ The sample of 12 States included 6 States (Florida, Indiana, Louisiana, New York, Ohio, and Texas) that were in the group of 31 States and 6 States (California, Illinois, Michigan, Missouri, North Carolina, and Tennessee) that were not.

³⁰ States report these data using Form CMS-64, Quarterly Expense Report. This form tracks expenditures for which States are entitled to Federal reimbursement and the share of rebates that States must remit to the Federal government.

State survey and structured interviews. The survey focused on the types of disputes that States receive from manufacturers and how States resolve disputes. Specifically, we asked States about the types of disputes that occurred frequently, what they believed caused those disputes, the methods they use to resolve disputes, suggestions they had for changes to the rebate program that would enhance their ability to prevent and resolve disputes, and about CMS's involvement in the dispute-resolution process.

In the followup interviews, we asked States to clarify their responses to the survey and to provide additional context about their responses. Primarily, we asked each State to provide more information about the reasons for disputes in its State and for more detailed descriptions of its dispute-resolution methods.

Structured interviews with selected manufacturers. In June 2013, we also conducted structured interviews with the five selected manufacturers. We asked them about the reasons they dispute rebate invoices, the steps they take to prevent and resolve disputes, and the factors that facilitate or hinder dispute resolution.

Structured interview with CMS. In July 2013, we also conducted a structured interview with the CMS staff responsible for the drug rebate dispute-resolution program. We asked questions about the status of the program and how CMS assists States and manufacturers in resolving disputes.

Data Analysis

To determine the extent to which rebates were disputed, we analyzed the 31 States' responses to our data request. We grouped States by the percentage of money in dispute that they reported, and we counted the number of States in each group. In addition, for the States that could provide precise estimates of money in dispute, we summed the figures they provided to obtain a total amount of money in dispute.

To identify which types of disputes States reported as occurring more frequently, the challenges that States face, and States' suggestions for improvements, we analyzed the 12 States' survey responses by theme.

APPENDIX B

Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: JUL - 8 2014
TO: Daniel R. Levinson
Inspector General
FROM: ~~Marilyn Tavenner~~ ^{/S/}
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Medicaid Drug Rebate Dispute Resolution Could Be Improved" (OEI-05-11-00580)

Thank you for the opportunity to review and comment on the above-referenced OIG draft report. The Centers for Medicare & Medicaid Services (CMS) appreciates the information presented in the report and offers the following comments.

The Medicaid Drug Rebate (MDR) Dispute Resolution Program (DRP) is an alternative dispute resolution process developed and administered by CMS that provides assistance to manufacturers and states when MDR amounts are in dispute. The purpose of the report was to determine the extent to which rebates are disputed under the MDR program, the causes of frequently occurring dispute types, challenges states face in resolving disputes, and what measures states and drug manufacturers believe will help prevent or resolve disputes.

The OIG recommendations and CMS responses to the recommendations are discussed below.

OIG Recommendation

The OIG recommends that CMS work with States to improve the quality of claims data submitted by providers and pharmacies.

CMS Response

The CMS concurs with OIG's recommendation. CMS has issued guidance (State Release No. 162 and State Medicaid Directors Release No. 151) to assist with reporting physician-administered drugs. Additionally, we will consider issuing further guidance to states and manufacturers on how to accurately calculate units on claims for drugs with complicated unit of measure conversions, and the importance of submitting the correct national drug code on claims for physician-administered drugs. CMS also continues to issue sub-regulatory guidance to assist states and manufacturers regarding unit type and units per package size reporting for covered outpatient drugs.

The CMS also notes that although all states use the National Council for Prescription Drug Programs (NCPDP) standards for purposes of determining which data elements they require providers to use in submitting pharmacy claims for payment, the specific claims data elements selected vary across states. Therefore, we encourage states to work collaboratively with their respective providers and pharmacies to standardize claims level data (CLD) that would work the best for their respective systems.

OIG Recommendation

The OIG recommends that CMS help States obtain better data on ineligible drugs.

CMS Response

The CMS concurs with OIG's recommendation. CMS is working actively with the Health Resources and Services Administration regarding guidance to address drugs ineligible for rebates. Additionally, CMS has issued guidance regarding 340B billing in State Release No. 161. Notably, in one state, CMS has approved a state plan amendment to help eliminate issues concerning duplicate discounts for the state. Some states have also implemented use of the NCPDP coding system to identify 340B drugs, which includes the submission of a specific verification and cost code, to help mitigate concerns regarding duplicate discounts.

With respect to ensuring that data about terminated drugs are accurate and up-to-date, states have the ability to view current drug data in the Drug Data Reporting (DDR) for Medicaid system. In addition to the states being able to view product data in real time, we have also implemented a new field in DDR called "Date Termination Date Reported". This is a system-generated field that identifies the date on which the manufacturer reported (and certified) the termination date to CMS. CMS is considering issuing additional guidance to manufacturers regarding the need to provide accurate information to DDR regarding a drug's termination date.

Finally, CMS has issued State Release Nos. 19 and 44 and Manufacturer Release No. 7 to address concerns regarding terminated drugs. Ultimately, it is the responsibility of the manufacturers to report timely and accurate data to CMS.

OIG Recommendation

The OIG recommends that CMS facilitate States' submission of standardized claims data.

CMS Response

The CMS concurs with OIG's recommendation. CMS will offer technical assistance to those states that require assistance identifying methods to improve the quality of claims data. However, as previously mentioned, all states' systems are not uniform. States are encouraged to work collaboratively with their respective providers and pharmacies to standardize CLD that would work the best for their respective systems. Additionally, we will consider issuing guidance to states regarding best practices of claims submission data.

OIG Recommendation

The OIG recommends that CMS establish a stronger role in dispute resolution.

CMS Response

The CMS concurs in part with OIG's recommendation. The DRP program is a voluntary program. CMS staff, including the CMS Regional Office DRP Coordinators, continues to address state and manufacturer inquiries. However, due to resource limitations, CMS is not able to continue the CMS-sponsored DRP conferences. We plan to issue dispute resolution guidance to reiterate DRP best practices for both states and manufacturers.

The CMS thanks OIG for the work done on this issue and looks forward to working with OIG in the future.

ACKNOWLEDGMENTS

This report was prepared under the direction of Ann Maxwell, Regional Inspector General for Evaluation and Inspections in the Chicago regional office; Thomas F. Komaniecki, Deputy Regional Inspector General; and Laura Kordish, Deputy Regional Inspector General.

Nicole Hrycyk served as the team leader for this study, and Carolyn Pichert served as the project lead. Other Office of Evaluation and Inspections staff from the Chicago regional office who conducted the study include Poppy Coleman and Cassie Yarbrough. Central office staff who provided support include Althea Hosein, Kevin Manley, and Christine Moritz.

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