Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

CMS DID NOT ALWAYS PROVIDE ACCURATE MEDICAID UNIT REBATE OFFSET AMOUNTS TO STATE MEDICAID AGENCIES

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Office of Inspector General

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Report in Brief
Date: May 2018
Report No. A-07-17-06074

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

CMS Did Not Always Provide Accurate Medicaid Unit Rebate Offset Amounts to State Medicaid Agencies

Why OIG Did This Review

Under the Medicaid drug rebate program, drug manufacturers enter into rebate agreements with the Federal Government and pay rebates to States. The Patient Protection and Affordable Care Act of 2010 (ACA) increased the amount of rebates that drug manufacturers are required to pay to States under this program. Amounts collected by the States that are attributable to these increased rebates—Medicaid unit rebate offset amounts (UROAs)—are applied against the amounts that the Federal Government pays to the States.

Drug manufacturers provide product and pricing information to the Centers for Medicare & Medicaid Services (CMS) for Medicaid-covered outpatient drugs. Using that data, CMS calculates the Medicaid unit rebate amount (URA) and the UROA for each drug and provides the information to State Medicaid agencies (State agencies).

Our objective was to determine whether CMS provided accurate and timely UROAs to State agencies during the period January 1, 2010, through December 31, 2014, in accordance with Federal guidance.

How OIG Did This Review

Our audit covered 765,091 UROAs (comprising 55,658 National Drug Codes (NDCs)) that CMS provided to State agencies during our audit period. To determine whether CMS provided accurate and timely UROA data to State agencies, we reviewed drug pricing information and, where necessary, recalculated UROAs.

What OIG Found

CMS did not always provide accurate UROAs to the State agencies during our audit period in accordance with Federal guidance. CMS did not update the quarterly UROA information that it sent to the State agencies to include changes to the UROAs when covered drugs' best prices (as reported to CMS by the manufacturers) changed but the URAs stayed the same. We identified 6,116 NDCs associated with 15,037 inaccurate UROAs that should have been updated to reflect the accurate UROA amounts in CMS's Medicaid drug rebate (MDR) system but were not. The State agencies would have used these incorrect UROA amounts to determine the Federal share of the rebates that they then reported to CMS, which would have resulted in incorrect rebate amounts being claimed.

CMS confirmed that it had a system programming issue that led to these discrepancies. Additionally, CMS did not have adequate controls in place to ensure that the UROAs sent to the State agencies matched the amounts in the MDR system. An automated data comparison between the UROA information and the amounts in the MDR system would have identified the discrepancies.

After we notified CMS that we were undertaking this review, CMS provided the State agencies with adjusted information as of the quarter ended March 31, 2016.

What OIG Recommends and CMS Comments

We recommend that CMS conduct periodic matches that would compare the UROA information sent to State agencies to the MDR system to ensure that CMS is sending accurate rebate information.

CMS concurred with our recommendation and described actions it had taken or planned to take to implement our recommendation. Specifically, CMS said that it had implemented a process of manual checks when there are certain changes to ensure that updated UROAs are sent to State agencies. CMS added that it would update the new system to mitigate any future issues.

The full report can be found at https://oig.hhs.gov/oas/reports/region7/71706074.asp.

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INTRODUCTION

WHY WE DID THIS REVIEW

Under the Medicaid drug rebate program, States report Medicaid expenditures to the Centers for Medicare & Medicaid Services (CMS) each quarter. In turn, CMS reimburses the States for the Federal share of their Medicaid expenditures. For Federal funding to be available for covered outpatient drugs dispensed to Medicaid recipients, drug manufacturers must enter into rebate agreements with the Secretary of Health and Human Services (Secretary) and pay rebates to States (the Social Security Act (the Act) § 1927(a)). The Patient Protection and Affordable Care Act of 2010 (ACA) increased the amount of rebates that drug manufacturers are required to pay to States under the Medicaid drug rebate program.[1] Under the ACA, amounts collected by the States that are attributable to these increased rebates—Medicaid unit rebate offset amounts (UROAs)—are applied, on a dollar-for-dollar basis, against the amounts that CMS reimburses to the States.[2]

Manufacturers are required to submit to CMS a list of all Medicaid-covered outpatient drugs and to report certain product data for each drug as well as each drug's average manufacturer price and, where applicable, its best price. On the basis of this data, CMS calculates the UROA for each drug and provides that information to the State Medicaid agencies (State agencies) each quarter. Because the statutory provisions for increased rebates are relatively new, the potential for inaccuracies in the UROAs is heightened.

OBJECTIVE

The objective of our review was to determine whether CMS provided accurate and timely UROAs to State agencies during the period January 1, 2010, through December 31, 2014, in accordance with Federal guidance.

BACKGROUND

Medicaid Program

The Medicaid program provides medical assistance to low-income individuals and individuals with disabilities. The Federal and State Governments jointly fund and administer the Medicaid program. At the Federal level, CMS administers the program. Each State administers its Medicaid program in accordance with a CMS-approved State Medicaid plan. Although the State has considerable flexibility in designing and operating its Medicaid program, it must comply with applicable Federal requirements. Federal Medical Assistance Percentage (FMAP)

[1] P.L. No. 111-148 (Mar. 23, 2010), as amended by the Health Care and Education Reconciliation Act of 2010, P.L. No. 111-152 (Mar. 30, 2010), collectively referred to as "ACA."

[2] Section 2501(a)(2) of the ACA amending § 1927(b)(1)(C) of the Act.

payments are the Federal funds each State receives for its Medicaid program and are based on the State's per capita income.[3]

Medicaid Drug Rebate Program

Under the Medicaid program, States may provide coverage for outpatient drugs as an optional service (the Act § 1905(a)(12)). Currently, all 50 States and the District of Columbia offer prescription drug coverage as part of their Medicaid benefit packages. To reduce expenditures for Medicaid prescription drugs, CMS and the States have implemented certain cost-containment measures, such as the Medicaid drug rebate program. This program, created by the Omnibus Budget Reconciliation Act of 1990 that added section 1927 to the Act, requires drug manufacturers to provide rebates on covered outpatient drugs in exchange for Medicaid coverage of those same drugs.[4] CMS, the States, and drug manufacturers each have specific functions under the program.

For Federal funding to be available for covered outpatient drugs dispensed to Medicaid recipients, drug manufacturers must enter into rebate agreements with the Secretary and pay rebates to States (the Act § 1927(a)). Manufacturers are required to submit a list to CMS of all covered outpatient drugs and to report quarterly pricing data by National Drug Code (NDC) for each of their covered drugs.[5] CMS transfers these data to the Medicaid drug rebate (MDR) system.[6]

The MDR system calculates the per unit rebate amounts after the close of each quarterly reporting period; CMS sends this information to State agencies. The per unit rebate amounts include both the Medicaid unit rebate amount (URA) and the UROA.

To bill for rebates, States capture drug utilization data that identify, by NDC, the number of units of each covered outpatient drug for which the States reimbursed Medicaid providers during that quarter. States then multiply, for each NDC, the total number of units by the NDC's rebate amount to determine the total quarterly amount of the rebate due from the manufacturer for that NDC. Finally, States invoice the manufacturers for the total quarterly amount of rebates owed for the manufacturers' respective NDCs, and in turn the

[3] Under the provisions of section 1905(b) of the Act, FMAPs generally total between 50 and 83 percent of a State's Medicaid cost.

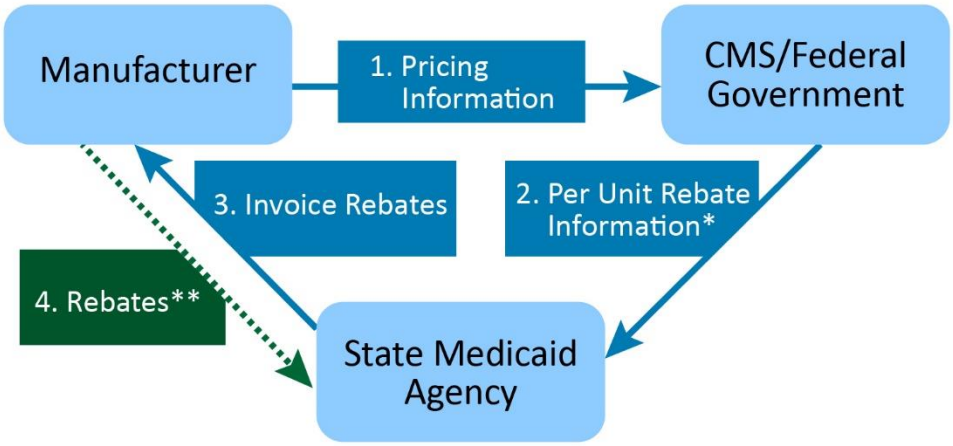
[4] The Omnibus Budget Reconciliation Act of 1990, P.L. No. 101-508, § 4401, adding § 1927 to the Act (Nov. 5, 1990).

[5] The NDC is an 11-digit identifier that represents a specific manufacturer, product, and package size.

[6] CMS, *Medicaid Drug Rebate Data Guide for States*.

manufacturers pay those rebates to the States.[7] Ultimately, the State agencies report the rebates to CMS on the Standard Form CMS-64, Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program, commonly referred to as the CMS-64 report. The figure below depicts this process.

Figure: Calculation and Collection of Medicaid Drug Rebates



Source: Modified from CMS, *Medicaid Drug Rebate Data Guide for States*, section 1927(b) of the Act.

* Per unit rebate information includes both URAs and UROAs.

** With the exception of offset rebates (which States are prohibited from keeping and which we discuss below), CMS and the States share Medicaid rebates on the basis of each State's FMAP.

Patient Protection and Affordable Care Act Revisions to the Medicaid Drug Rebate Program

Section 2501 of the ACA increased the amount of rebates that drug manufacturers are required to pay under the Medicaid drug rebate program. Under the ACA, the amounts attributable to these increased rebates—the UROAs[8]—offset the amounts that the Federal Government pays to the States (section 1927(b)(1)(C) of the Act). Therefore, States are prohibited from keeping the additional ACA-required rebate amounts.

Accordingly, CMS calculates the UROA for each covered outpatient drug by NDC and provides that information, and the drug's URA, to the States quarterly.[9]

[7] If the manufacturer disagrees with the drug utilization data reported by the State on the invoice, the manufacturer can invoke the dispute process.

[8] The term "UROA" does not appear in the ACA; rather, it is a term that CMS developed when implementing the provisions of the ACA regarding increased rebate amounts.

[9] CMS, State Medicaid Directors Letter Number 10-019 (Sept. 28, 2010).

HOW WE CONDUCTED THIS REVIEW

Our audit covered 765,091 UROAs (comprising 55,658 NDCs) that CMS provided to State agencies during calendar years 2010 through 2014. The State agencies used those UROAs to determine the Federal share of the rebates that they then reported on their CMS-64 reports. To determine whether CMS provided accurate and timely UROA information to State agencies, we reviewed drug pricing information and, where necessary, recalculated UROAs.

We limited our scope to rebate information obtained from CMS. We did not obtain or verify the utilization data from the States, nor did we contact the States to determine the overall impact of these errors. As a result, we did not quantify the dollar impact associated with inaccurate UROAs.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

Appendix A contains the details of our audit scope and methodology.

FINDING

CMS DID NOT ALWAYS PROVIDE ACCURATE UNIT REBATE OFFSET AMOUNTS TO STATE AGENCIES

CMS did not always provide accurate UROAs to the State agencies during the period January 1, 2010, through December 31, 2014, in accordance with Federal guidance. CMS did not update the quarterly UROA information that it sent to the State agencies to include changes to the UROAs when covered drugs' best prices (as reported to CMS by the manufacturers) changed but the URAs stayed the same. We identified 6,116 NDCs associated with 15,037 inaccurate UROAs that should have been updated to reflect the accurate UROA amounts in the MDR system but were not. The State agencies would have used these incorrect UROA amounts on their CMS-64 reports, which would have resulted in incorrect rebate amounts being claimed.

For example, we noted one NDC for which the UROA within the MDR system changed on November 4, 2014, from .095333 to .015810 and the URA did not change. However, the State agencies were not notified of this change in the UROA and therefore would have claimed the incorrect rebate amounts associated with this NDC on their CMS-64 reports.

INADEQUATE CONTROLS

CMS confirmed that it had a system programming issue that led to these discrepancies. In an email dated February 12, 2016, a CMS official told us that the MDR system "was only looking

for UROAs changes due to a change in URA, but was not capturing UROA changes when the URA stayed the same (i.e. but best price changed.)"[10] Additionally, CMS did not have adequate controls in place to ensure that the UROAs sent to the State agencies matched the amounts in the MDR system. An automated comparison between the UROA information and the amounts in the MDR system would have identified the discrepancies.

Because the State agencies were not always provided with updated, accurate UROAs, they would not have been able to determine the correct Federal share of the rebates reported on their CMS-64 reports. After we notified CMS that we were undertaking this review, CMS provided the State agencies with adjusted information as of the quarter ended March 31, 2016. These adjustments contained updated UROAs for the 6,116 NDCs associated with 15,037 inaccurate UROAs that CMS had updated in the MDR system but had not previously sent to the State agencies.

RECOMMENDATION

We recommend that CMS conduct periodic matches that would compare the UROA information sent to the State agencies to the MDR system to ensure that CMS is sending accurate rebate information.

CMS COMMENTS

In written comments on our draft report, CMS concurred with our recommendation and described actions it had taken or planned to take to implement our recommendation. Specifically, CMS said that it has implemented a process of manual checks when there are certain changes to ensure that updated UROAs are sent to the State agencies. CMS added that it would update the new system "to improve the process and mitigate any future issues moving forward."

CMS also provided technical comments, which we addressed as appropriate. CMS's comments, excluding the technical comments, appear as Appendix C.

[10] Because CMS subsequently addressed and resolved this programming issue, we do not make a recommendation with respect to it.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered 765,091 UROAs (comprising 55,658 NDCs) that CMS provided to State agencies during calendar years 2010 through 2014.

Our audit objective did not require an understanding or assessment of CMS's complete internal control structure. We limited our internal control review to an understanding of the controls CMS had in place for ensuring that it provided accurate UROA information to the State agencies. We limited our scope to rebate information obtained from CMS. We did not obtain or verify the utilization data from the States, nor did we contact the States to determine the overall impact of these errors. As a result, we did not quantify the dollar impact associated with inaccurate UROAs.

We performed our fieldwork from April 2015 to June 2017.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and requirements for the Medicaid drug rebate program;

- interviewed CMS personnel to obtain an understanding of CMS's use of the data in the MDR system and of the calculation of the UROAs;

- recalculated UROAs based on drug pricing information provided by CMS and compared the recalculated UROAs with those sent by CMS to the State agencies; and

- discussed the results of our review with CMS officials on June 27, 2017.

APPENDIX B: FEDERAL REQUIREMENTS AND GUIDANCE RELATED TO THE MEDICAID DRUG REBATE PROGRAM

Under the Medicaid program, States may provide coverage for outpatient drugs as an optional service (the Act § 1905(a)(12)). Section 1903(a) of the Act provides for Federal financial participation in State expenditures for these drugs. The Medicaid drug rebate program, created by the Omnibus Budget Reconciliation Act of 1990 that added section 1927 ("Payment for Covered Outpatient Drugs") to the Act, became effective on January 1, 1991 (footnote 4). For Federal funding to be available for covered outpatient drugs dispensed to Medicaid recipients, drug manufacturers must enter into rebate agreements with the Secretary and pay rebates to States (the Act § 1927(a)).

Manufacturers are required to submit a list to CMS of all covered outpatient drugs and to report certain product data for each drug as well as each drug's average manufacturer price and, where applicable, its best price (§ 1927(b) of the Act and section II of the Medicaid rebate agreement).

Section 2501 of the ACA increased the amount of rebates that drug manufacturers are required to pay under the Medicaid drug rebate program, effective January 1, 2010. Under the ACA, the amounts attributable to these increased rebates—the UROAs (footnote 8)—offset the amounts that the Federal Government pays to the States (section 1927(b)(1)(C) of the Act).

CMS State Medicaid Directors Letter Number 10-019, dated September 28, 2010, states that for the sake of efficiency, CMS would "calculate a unit rebate offset amount (UROA) that will identify the offset amount per unit of a drug at the 9-digit national drug code (NDC) level on a quarterly basis for States . . . ."

As stated in CMS's *Medicaid Drug Rebate Data Guide for States*, the drug manufacturers submit product and quarterly pricing data to CMS; in turn, CMS transfers these data to the MDR system. The MDR system calculates the URAs and UROAs after the close of each quarterly reporting period; CMS sends the drug rebate information to the State agencies.

APPENDIX C: CMS COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

200 Independence Avenue SW
Washington, DC 20201

DATE: MAR 19 2018

TO: Daniel R. Levinson
Inspector General

FROM: Seema Verma
Administrator

SUBJECT: CMS Did Not Always Provide Accurate Medicaid Unit Rebate Offset Amounts to State Agencies (A-07-17-06074)

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 Unit Rebate Offset Amounts (UROAs) in the Medicaid Drug Rebate program. CMS takes seriously its responsibility to administer the Medicaid Drug Rebate program.

Section 2501 of the Patient Protection and Affordable Care Act of 2010 (as amended by section 1206 of the Health Care and Education Reconciliation Act of 2010 (PPACA)), retroactively increased the amount of rebates that drug manufacturers are required to pay states under the Medicaid Drug Rebate program effective January 1, 2010. The PPACA also required that amounts attributable to these increased rebates be remitted to the Federal government.

To determine the amount of manufacturer rebates to states that will be remitted to the Federal government, CMS calculates the UROAs. States use the UROAs to determine the total Quarterly Rebate Offset Amount (QROA). States report the QROA to CMS on the Medicaid Quarterly Expenditure report, which is used to reconcile Medicaid expenditures between states and the Federal government. UROAs do not impact the rebates states receive from drug manufacturers.

While the UROAs were calculated correctly during this audit's study period, some UROAs were not sent to states on the quarterly UROA files in a timely fashion. Once CMS identified that the UROAs were omitted from the quarterly UROA files, CMS implemented a fix to prevent future omissions. CMS expeditiously notified the states of the omission and sent the omitted UROAs to them in the first quarter of 2016.

OIG's recommendation and CMS's response is below.

OIG Recommendation

We recommend that CMS conduct periodic matches that would compare the quarterly drug rebate files to the MDR system to ensure that CMS is sending accurate rebate information to the State agencies.

CMS Response

CMS concurs with this recommendation. Since the time period for this audit, CMS has implemented new processes to remediate this finding. For example, CMS performs manual checks when there are certain changes to ensure that updated UROAs are included on the quarterly UROA file to states. Additionally, CMS will update the new system to improve the process and mitigate any future issues moving forward.

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