

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**STATES' COLLECTION OF
REBATES FOR DRUGS PAID
THROUGH MEDICAID
MANAGED CARE
ORGANIZATIONS**



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**September 2012
OEI-03-11-00480**

EXECUTIVE SUMMARY: STATES' COLLECTION OF REBATES FOR DRUGS PAID THROUGH MEDICAID MANAGED CARE ORGANIZATIONS OEI-03-11-00480

WHY WE DID THIS STUDY

In general, drug manufacturers must pay rebates for covered outpatient drugs reimbursed under Medicaid for States to receive Federal matching funds. Drugs dispensed by Medicaid Managed Care Organizations (MCO) were excluded from this requirement until March 23, 2010, when section 2501(c) of the Patient Protection and Affordable Care Act (ACA) expanded the rebate requirement to include these drugs. To realize the full savings under this expansion, it is important that States collect accurate drug utilization data from MCOs and that States invoice and collect rebate payments from manufacturers.

HOW WE DID THIS STUDY

In October 2011, we sent surveys about rebate collections involving MCOs to all 50 States and the District of Columbia (hereinafter referred to as States) and received responses from all but 1 State. States that paid for drugs through their MCOs (the carve-in approach) were asked about the drug utilization data collected from MCOs, their processes for invoicing and collecting rebates from manufacturers using these data, and the amounts of rebates collected between the second quarter of 2010 and the second quarter of 2011. We asked States that did not pay for drugs through their MCOs (the carve-out approach) or did not contract with MCOs about potential changes to their drug programs' structures as a result of the rebate expansion.

WHAT WE FOUND

Between April 1, 2010, and June 30, 2011, 18 of the 22 States using a carve-in approach collected all the data needed to invoice manufacturers for rebates from their MCOs, 3 collected data from a portion of their MCOs, and 1 never collected any drug utilization data. All but one State that used a carve-in approach performed some type of data verification check. Twelve of the twenty-two States using a carve-in approach invoiced manufacturers and collected \$1.6 billion in rebates for utilization in the second quarter of 2010 through the second quarter of 2011. However, 10 of the 22 States did not invoice manufacturers and collect rebates because, for example, they had to complete programming changes to the systems that process MCO claims. Additionally, the rebate expansion has prompted five States that used the carve-out approach to change to a carve-in approach.

WHAT WE RECOMMEND

We recommend that the Centers for Medicare & Medicaid Services (CMS) follow up with the 10 States that had not collected rebates for drugs dispensed to Medicaid MCO beneficiaries and take action to enforce rebate collection if necessary. CMS concurred.

TABLE OF CONTENTS

Objectives	1
Background	1
Methodology	6
Findings.....	11
Eighteen of the twenty-two States using the carve-in approach obtained the Medicaid MCO utilization data needed to collect rebates in all of the quarters under review	11
In the five quarters after the rebate expansion, 12 of the 22 States using the carve-in approach invoiced manufacturers and collected \$1.6 billion in rebates for Medicaid MCO drug utilization	14
As of October 1, 2011, 10 of the 22 States using a carve-in approach had not invoiced manufacturers and collected rebates for Medicaid MCO drug utilization	16
Five States that did not pay for drugs through Medicaid MCOs changed the structures of their drug programs as a result of the rebate expansion	17
Conclusion and Recommendation	18
Agency Comments and Office of Inspector General Response.....	20
Appendixes	21
A: Percentage of Medicaid Managed Care Organizations That Provided Drug Utilization Data to States for the Second Quarter of 2011	21
B: Total Amount of Medicaid Managed Care Organization Rebates That 12 States Using a Carve-In Approach Collected From Second Quarter 2010 to Second Quarter 2011	22
C: Ten States Using a Carve-In Approach That Had Not Invoiced or Collected Medicaid Managed Care Organization Rebates as of October 1, 2011	23
D: Agency Comments	24
Acknowledgments.....	26

OBJECTIVES

1. To determine whether State Medicaid agencies (States) have collected drug utilization data from Medicaid Managed Care Organizations (MCO), as required by the Patient Protection and Affordable Care Act (ACA).
2. To examine the processes States used to invoice and collect rebates from manufacturers for drugs dispensed to beneficiaries enrolled in MCOs.
3. To determine how many States invoiced manufacturers for rebates for drugs dispensed to MCO beneficiaries.
4. To calculate the amount States collected in rebates from manufacturers for drugs dispensed to MCO beneficiaries, as well as how much went uncollected.
5. To determine whether States that do not currently pay for drugs through MCOs will change the structures of their drug programs as a result of the new rebate requirements.

BACKGROUND

In general, drug manufacturers must pay rebates for covered outpatient drugs reimbursed under Medicaid for a State to receive Federal matching funds.¹ However, until the March 23, 2010, enactment of the ACA, P.L. 111-148, drugs dispensed by Medicaid MCOs were excluded from the rebate requirements.² Section 2501(c) of the ACA expanded the rebate requirements to include drugs dispensed to beneficiaries who receive care from MCOs if the organizations are responsible for coverage of such drugs, effective March 23, 2010. To facilitate rebate collection, States must include the utilization data collected from MCOs in their rebate invoices to manufacturers.³ The Congressional Budget Office (CBO) estimated that this provision will result in savings of \$3.7 billion between 2010 and 2014.⁴

To realize these potential savings under the ACA, it is important that States collect accurate and timely drug utilization data from MCOs, implement procedures to invoice manufacturers, and collect these rebates. If States do not invoice promptly following the rebate expansion, they still

¹ Social Security Act (the Act), § 1903(i)(10)(A), 42 U.S.C. § 1396b(i)(10)(A).

² The Act, § 1927(j), 42 U.S.C. § 1396r-8(j) (2009 GPO FDsys).

³ Section 2501(c) of the ACA.

⁴ CBO, *Budget Options Volume 1 Health Care*, December 2008, pp. 141–142. Accessed at <http://www.cbo.gov> on April 19, 2011.

have the opportunity to retroactively invoice manufacturers and collect rebates for utilization dating back to March 23, 2010. However, prior Office of Inspector General (OIG) reports have found that States have not collected all non-MCO rebates owed by manufacturers because of various procedural issues and manufacturer disputes.⁵

Medicaid Prescription Drug Coverage

Medicaid provides health coverage for certain low-income and medically needy people, jointly funded by Federal and State governments. Individual States establish eligibility requirements, benefit packages, and payment rates for their Medicaid programs under broad Federal standards. Currently, all 50 States and the District of Columbia (referred to as States) offer prescription drug coverage as part of their Medicaid benefit packages. Medicaid expenditures for prescription drugs totaled approximately \$29 billion in 2010.⁶

Medicaid Drug Rebate Program

To reduce State and Federal expenditures for prescription drugs, Congress created the Medicaid drug rebate program in 1990.⁷ Between 2006 and 2010, the rebate program has saved Medicaid an average of about \$9 billion annually.

Drug manufacturers are required to enter into rebate agreements with the Secretary of Health and Human Services (the Secretary) and pay quarterly rebates to States for Federal payment to be available for covered outpatient drugs provided under Medicaid.^{8,9} As of December 2011, the States and approximately 600 pharmaceutical companies participated in the rebate program.¹⁰

Under these rebate agreements and pursuant to section 1927(b)(3) of the Act, manufacturers must provide CMS with the average manufacturer price (AMP) by national drug code (NDC) for each of their covered

⁵ OIG, *States' Collection of Medicaid Rebates for Physician-Administered Drugs* (OEI-03-09-00410), June 2011; *Medicaid Rebates for Physician-Administered Drugs* (OEI-03-02-00660), April 2004; and *Multistate Review of Medicaid Drug Rebate Programs* (A-06-03-00048), July 2005.

⁶ Medicaid expenditures were calculated using data from the Centers for Medicare & Medicaid Services' (CMS) Medicaid Budget and Expenditures System. This total does not reflect rebates collected through the Medicaid drug rebate program.

⁷ The Omnibus Budget Reconciliation Act of 1990, P.L. 101-508, § 4401; the Act, § 1927; 42 U.S.C. § 1396r-8.

⁸ The Act, §§ 1927(a)(1) and (b)(1).

⁹ Federal payment refers to the matching funds provided to States by the Federal Government for certain social services, including Medicaid.

¹⁰ CMS, *Medicaid & CHIP Program Information*. Accessed at <http://www.medicaid.gov/> on February 15, 2012.

drugs.^{11, 12} 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.¹³ Manufacturers must report the AMPs no later than 30 days after the end of each quarter.¹⁴

Medicaid Drug Rebate Process

CMS uses the AMP and best price data to calculate the unit rebate amount (URA) for each NDC included in the Medicaid drug rebate program. The URA varies depending on whether the drug is brand-name or generic. CMS calculates a URA for each NDC and transmits this information to the States. States then calculate the total quarterly rebates that participating manufacturers owe by multiplying the URA for a specific drug by the number of units of that drug for which the State reimbursed providers in that quarter. Within 60 days of the end of the quarter, States must invoice the manufacturers for the units reimbursed and indicate the total rebate due for each NDC. The manufacturers process the invoices and pay the rebates to the States within 30 days of receipt of the invoices.^{15, 16}

Effective January 1, 2010, section 2501 of the ACA revised the rebate calculation and increased the minimum rebate percentage manufacturers are required to pay for brand-name and generic drugs. The basic URA for brand-name drugs was increased to the greater of 23.1 percent of the AMP or the difference between the AMP and the best price.^{17, 18} In addition to the basic URA, manufacturers are required to pay an additional rebate if

¹¹ Section 1927(b)(3) of the Act requires manufacturers provide CMS, in addition to the AMP, with the best price available for each of their brand-name drugs. “Best price” is defined in § 1927(c)(1)(C)(i) of the Act as the lowest price available from the manufacturer during the rebate period to any purchaser in the United States, with certain exceptions.

¹² An NDC is an 11-digit identifier that represents a specific manufacturer, product, and package size for a drug.

¹³ Section 1927(k)(1) of the Act as amended by § 2503(a)(2) of the ACA.

¹⁴ Section 1927(b)(3) of the Act. Manufacturers also report AMPs on a monthly basis; however, only the quarterly AMPs are used for rebate purposes.

¹⁵ Section 1927(b)(1)(A) of the Act.

¹⁶ If the manufacturer does not pay the invoice within 30 days, interest will accrue beginning with the 38th day from the invoice’s postmark date. CMS, *Medicaid & CHIP Program Information*. Accessed at <http://www.medicaid.gov/> on February 15, 2012.

¹⁷ Section 1927(c)(1) of the Act as amended by § 2501(a) of the ACA.

¹⁸ From 1996 to 2009, the basic URA for a brand-name drug was either 15.1 percent of the AMP or the difference between the AMP and best price (whichever was greater).

the AMP for a brand-name drug has risen at a rate greater than inflation.¹⁹ The URA for generic drugs was increased to 13 percent of the AMP.^{20, 21} The ACA also requires that the additional amounts attributed to these increased rebate percentages (e.g., the amount between 15.1 and 23.1 percent of AMP for brand-name drugs) be remitted to the Federal Government. Therefore, States are prohibited from keeping the additional money that results from the ACA changes to the rebate calculation.

Because of changes to the definition of AMP, rebate percentages, and Federal share rules under the ACA, CMS was not able to modify its systems to calculate URAs during 2010. As a result, the States' invoices to manufacturers included the number of units reimbursed for the drugs but did not contain URAs.²² Instead, CMS reminded manufacturers to calculate the URAs and make the appropriate 2010 quarterly rebate payments directly to States in accordance with the rebate changes for that year.²³ In May 2011, CMS calculated URAs for each quarter of 2010 and provided those data to States as a prior period adjustment.

Medicaid MCOs and Drug Rebates—Carve-In and Carve-Out Approaches

Managed care plans aim to maximize efficiency by negotiating rates, coordinating care, and managing the use of services. MCOs differ from the traditional fee-for-service (FFS) system in that States prospectively pay MCOs a fixed monthly amount (i.e., capitation payment) for each Medicaid enrollee, regardless of whether that beneficiary seeks care during the month. A State may provide its Medicaid beneficiaries with the option to voluntarily enroll in MCOs or may mandate that all or certain categories of its Medicaid beneficiaries enroll in MCOs.²⁴

States may pay for drugs dispensed through MCOs using either the carve-in or the carve-out approach. To use the carve-in approach, States include payment for the drugs dispensed to beneficiaries in the MCOs'

¹⁹ Section 1927(c)(2) of the Act. To determine whether manufacturers owe an additional rebate for a drug, its "base date" AMP is updated for the current quarter using the consumer price index. If the resulting figure is greater than or equal to the reported AMP in the quarter, no additional rebate is owed. If the resulting figure is less than the reported AMP in the quarter, then the additional URA is equal to the difference between the reported AMP and the inflation-adjusted base date AMP.

²⁰ Section 1927(c)(3) of the Act as amended by § 2501(b) of the ACA.

²¹ From 1996 to 2009, the basic URA for a generic drug was 11 percent of the AMP.

²² CMS instructed States to report each URA as \$0 on the rebate invoice.

²³ CMS, *Medicaid Drug Rebate Program Release No. 155*, August 11, 2010.

²⁴ Section 1903(m)(1)(A) of the Act defines a "Medicaid MCO" as a health maintenance organization that contracts with a State Medicaid agency to provide or arrange for health services to eligible individuals.

fixed monthly payment amounts. In the carve-out approach, States exclude payment for the drugs dispensed to beneficiaries from the MCOs' fixed monthly payment amounts and instead pay for these drugs using the traditional FFS system.

MCO Rebate Collections Prior to March 23, 2010. Before the enactment of the ACA, manufacturers were not required to pay rebates for drugs dispensed to beneficiaries by Medicaid MCOs. For that reason, a number of States carved out some or all prescription drugs from the Medicaid MCOs' fixed payments. In other words, beneficiaries would receive most of their care through MCOs, but the State instead paid for drugs dispensed through MCOs on an FFS basis. Carving out prescription drugs from the MCOs' fixed payment amounts enabled these States to invoice manufacturers for rebates for these drugs before the ACA was enacted.

MCO Rebate Collections on or After March 23, 2010. As of March 23, 2010, section 2501(c) of the ACA expanded the rebate requirements to include prescription drugs provided to Medicaid beneficiaries enrolled in MCOs.²⁵ To facilitate the States' collection of these rebates from manufacturers, MCOs are required to report utilization data to each State by NDC for each covered outpatient drug dispensed to Medicaid enrollees. In April and September 2010, CMS sent letters to States that provided guidance about the changes to the rebate program under the ACA, including the new MCO provisions.²⁶

States are to include MCO utilization data in their quarterly rebate invoices to manufacturers. As previously mentioned, because CMS did not calculate URAs in 2010, States were unable to invoice manufacturers using the established process in that year. Instead, States provided manufacturers with the utilization data collected from MCOs and instructed manufacturers to calculate the rebate amounts and remit the amounts owed each quarter.

The rebate expansion does not directly affect States that do not include prescription drugs in their MCOs' payment rates (i.e., the carve-out approach) or that do not contract with MCOs. However, industry reports indicate that the ACA expansion may prompt these States to contract with

²⁵ Section 340B of the Public Health Service Act established the 340B Drug Pricing Program, which requires pharmaceutical manufacturers to charge at or below the statutorily defined prices for sales to certain qualified entities (e.g., community health centers). Drug purchases by MCOs that qualify for discounted 340B rates are not subject to the Medicaid rebate because this would result in duplicate discounts from manufacturers.

²⁶ CMS, Letter to State Medicaid Directors, *SMDL #10-006* and *SMDL #10-019*. Accessed at <http://www.cms.gov/> on August 8, 2011.

MCOs using a carve-in approach. According to industry reports, this is because the prior rebate advantage to carving out no longer exists and because industry research has found that MCOs manage the pharmacy benefit more efficiently than would otherwise occur in an FFS setting.²⁷

METHODOLOGY

Data Collection

In October 2011, we sent online surveys to the 51 State pharmacy directors. We followed up with nonresponding States in November and December 2011. As of January 2012, we had received responses from 50 States.²⁸

First, we asked States whether they contracted with Medicaid MCOs to provide medical care to beneficiaries as of October 1, 2011. If they answered yes, we asked them to provide the number of Medicaid beneficiaries in the State, the number enrolled in MCOs, and the number of MCOs that had contracts with the State from the second quarter of 2010 until the second quarter of 2011 (i.e., from April 1, 2010, to June 30, 2011). Next, we asked whether the States maintained a carve-out approach, a carve-in approach, or a combination of the both approaches or had changed their payment approach since March 23, 2010 (i.e., switched from a carve-out to a carve-in approach or vice versa).

Among responding States, half carved in prescription drugs and half either carved out prescription drugs or did not have MCO contracts. See Table 1 for the number of States with different approaches to MCO drug coverage. The survey then asked States different questions based on whether they had MCO contracts and used a carve-in approach, had MCO contracts and used a carve-out approach, or did not have MCO contracts.

²⁷ For example, see the Lewin Group, *Projected Impacts of Adopting a Pharmacy Carve-In Approach Within Medicaid Capitation Programs*. Accessed at <http://www.mhpa.org> on February 17, 2012.

²⁸ We made multiple attempts to obtain a response from Rhode Island; however, the State did not respond.

Table 1: States' Approaches to Drug Coverage Through Medicaid MCOs From March 23, 2010, to October 1, 2011

Approach	Number of States
Total States That Paid for Drugs Through MCOs (Carve-In Approach)	25
Maintained only a carve-in approach	16
Changed from a carve-out to a carve-in approach	3
Used a combination of carve-out and carve-in approaches ²⁹	6
Total States With MCOs That Maintained Only a Carve-Out Approach	10
Total States That Did Not Have MCO Contracts	15

Source: OIG analysis of State survey responses, 2012.

Questions for Medicaid MCO States Using a Carve-In Approach. We asked these 25 States to describe the quality and timeliness of the utilization data provided by Medicaid MCOs and any followup action the States took in relation to flaws in these data. We asked States whether they verified (1) the completeness of the utilization data (e.g., that they included utilization for all covered drugs), (2) that the data did not include utilization for drugs paid through the 340B program, and (3) the data's accuracy.

We also asked whether, as of October 1, 2011, States invoiced manufacturers or collected rebates from manufacturers for drugs dispensed through Medicaid MCOs. We asked States that had invoiced manufacturers to describe the invoicing method used (e.g., sent manufacturers one invoice for Medicaid MCO utilization and a separate invoice for FFS utilization), whether they tracked the collection of the amounts invoiced, and whether manufacturers disputed the amounts invoiced.

We asked that States provide the dollar amounts invoiced (both retroactively and nonretroactively) and collected from the second quarter of 2010 to the second quarter of 2011. We asked States that had not invoiced manufacturers during this time whether they intended to retroactively invoice. We also asked for the reasons for the delay, an estimated start date, and the method they anticipated using (e.g., send manufacturers one invoice for Medicaid MCO utilization and a separate invoice for FFS utilization).

²⁹ Six States used a combination of carve-out and carve-in approaches. In general, the drugs that these States carved out include those used to treat HIV/AIDS and depression and other mental health disorders.

Questions for Medicaid MCO States Using a Carve-Out Approach. We asked these 10 States whether they intended to continue this approach now that rebates are available for drugs provided to beneficiaries enrolled in MCOs. If a State intended to no longer carve out, we asked that it describe any plans related to changing its rebate collection process.

Questions for States Without Medicaid MCO Contracts. We asked these 15 States whether they had plans to change the current structures of their drug programs because of the ACA. We asked these States whether section 2501(c) of the ACA had prompted them to consider such contracts in the future and, if so, to describe their course of action and provide possible implementation dates.³⁰

Data Analysis

Medicaid MCO Drug Utilization Data. We reviewed the States' survey responses to determine whether and when Medicaid MCOs provided drug utilization data in the five quarters after March 23, 2010 (i.e., second quarter 2010 through second quarter 2011). For this portion of the review, we included 22 of the 25 States that had carved in all or a portion of their prescription drugs since the rebate expansion became effective on March 23, 2010; we excluded the 3 States that had switched from a carve-out to a carve-in approach.³¹ We calculated the number of States that:

- collected data for all five quarters from every MCO for which they had contracts (collected either within 60 days after the quarter or more than 60 days after the quarter),
- collected data from a portion of their MCOs in at least one of the five quarters, and
- did not collect data from any of their MCOs in all five quarters.

States' Verification of Medicaid MCO Data. We calculated the number of States that verify that the Medicaid MCOs' drug utilization data: (1) include utilization for all covered outpatient drugs, (2) exclude utilization for drugs paid through the 340B program, and (3) include data that are accurate and correct. We summarized how States perform these verification checks and the reasons why other States decided not to perform them. For this portion of the review, we included the three States

³⁰ Section 2501(c) of the ACA extended the Medicaid rebate requirements to include drugs dispensed by MCOs.

³¹ These three States did not switch to a carve-in method until mid- to late 2011 (one State switched in the third quarter and two switched on October 1, 2011). When these States received our survey, there had not been enough time to fully evaluate the timeliness of MCOs' data submissions.

that switched from a carve-out to a carve-in approach. Therefore, this portion of the analysis includes 25 States.

Invoice and Collection of Rebates for Medicaid MCO Utilization. Of the 22 States that have carved in all or a portion of their prescription drugs since the rebate expansion, we identified States that did and did not invoice manufacturers for these rebates as of October 1, 2011.

For the States that invoiced manufacturers, we calculated the total rebate amounts collected for each quarter between the second quarter of 2010 and the second quarter of 2011. We also calculated the total amount of rebates that were uncollected because of unresolved disputes with manufacturers and determined whether States had methods to track unpaid rebates. Next, we summarized the methods used to invoice manufacturers, calculated the number of States that retroactively invoiced, and calculated the total amount retroactively invoiced. Lastly, we calculated the total amount that States invoiced manufacturers in the first and second quarters of 2011. Because CMS had not provided States with URAs in 2010, States were unable to invoice manufacturers for specific rebate amounts in that year and therefore could not provide invoice totals for 2010.³²

For the States that did not invoice, we summarized why they had not invoiced, when they intended to start, and the method they planned to use. We also calculated the total number of beneficiaries enrolled in MCOs for these States.

States That Carve Out or Do Not Have Medicaid MCO Contracts. We reviewed survey responses for the 25 States that carve out prescription drugs from their Medicaid MCO payments or that did not have MCO contracts. We determined whether the MCO rebate expansion had influenced these States to change their payment policies for prescription drugs.

Limitations

The findings are based on survey responses provided by State Medicaid agencies. We did not independently verify their accuracy. We also did not attempt to verify the accuracy of the rebate amounts manufacturers paid to the States. The rebate amounts that States invoiced and collected from manufacturers were current at the time we received their responses. If a State invoiced and collected rebates after we received its response, then these rebate amounts would not be reflected in our totals.

³² For drugs without URAs, CMS instructs States to provide utilization data to manufacturers, which are then responsible for determining the correct URAs to be used in calculating total rebates owed (enabling States to collect these rebates without actually invoicing for specific rebate amounts).

In addition, we reviewed only the rebate collections and rebate processes related to Medicaid MCOs and did not focus on the effect these may have had on the capitation rates States pay to MCOs. We also did not review the effect the rebate expansion may have had on beneficiary services or provider payments.

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

Eighteen of the twenty-two States using the carve-in approach obtained the Medicaid MCO utilization data needed to collect rebates in all of the quarters under review

Among the 22 States that paid for prescription drugs through Medicaid MCOs (i.e., carved in), 18 obtained all the drug utilization data necessary for rebate collection between the second quarter of 2010 and the second quarter of 2011.³³ In addition to these 22 States, 3 States (Illinois, New York, and Ohio) switched from a carve-out to a carve-in approach in mid- to late 2011. Because they switched after the second quarter of 2011, we did not include them in this portion of our analysis.

Of the remaining four States, one (Nevada) did not collect data in the quarter after the rebate expansion but did so for all its MCOs in all four subsequent quarters. Two additional States (California and West Virginia)³⁴ collected the data from only a portion of their MCOs in each of the five quarters. California estimated that the majority of its MCOs would report the data by December 2011, and West Virginia reported that it would not take action to collect the data until data validation procedures were in place. The District of Columbia was the only State that never collected any of the utilization data needed from its MCOs to invoice manufacturers in all of the five quarters. It did not project a date when it would collect the data.³⁵

States must include data about each drug's utilization on the rebate invoices they send to manufacturers within 60 days after a quarter ends, meaning that the timely collection of MCOs' data is imperative for the completeness of these invoices. As shown in Table 2, the majority of States that collected utilization data generally received it from MCOs within 60 days after the quarter's end. None of the States (including those that never collected utilization data) took action to encourage timelier

³³ One of the 18 States, Mississippi, did not contract with MCOs in 2010 and therefore did not need to collect utilization data in that year. However, Mississippi collected utilization data from all its MCOs in 2011.

³⁴ California and West Virginia use a combination of carve-in and carve-out approaches.

³⁵ However, the District of Columbia estimated that it would begin invoicing for these rebates in the first quarter of 2012. To do so, it would first need to collect utilization data from its MCOs.

submission from MCOs.³⁶ See Appendix A for a State-by-State depiction of when MCOs provided utilization data in the second quarter of 2011.

Table 2: Collection of Drug Utilization Data: Characteristics of States Using the Carve-In Approach

Data Collected	Second Quarter 2010	Third Quarter 2010	Fourth Quarter 2010	First Quarter 2011	Second Quarter 2011
Collected All Data From MCOs	17*	18*	18*	19	19
All data collected within 60 days	11	13	14	15	16
All data collected more than 60 days after the quarter	3	2	2	1	1
Some data collected within and some data more than 60 days after the quarter	3	3	2	3	2
Collected Data From Portion of MCOs	2	2	2	2	2
Did Not Collect Data From Any MCOs	2	1	1	1	1
Total Number of States	21	21	21	22	22

Source: OIG analysis of State survey responses, 2012.

* Mississippi did not contract with MCOs in 2010. Therefore, the total number of States in the 2010 quarters is 21.

All but one State using a carve-in approach performed at least some type of verification check on the Medicaid MCOs' utilization data

Among the 25 States that used a carve-in approach by the end of 2011, the District of Columbia had not implemented any checks to verify Medicaid MCOs' utilization data because it had not yet collected any data. The 21 States that had collected data and the 3 States that recently switched from a carve-out to a carve-in approach reported having methods to ensure that the utilization data (1) were complete, (2) did not include 340B utilization, or (3) were accurate. In addition, States that followed up with MCOs about the data thought that MCOs were readily available and helpful with answering their questions.

Eighteen of Twenty-Five States Verified That the MCO Data Are Complete.

These 18 States reported that they verified that the data included utilization for all covered drugs by performing checks, such as requiring the MCO to certify the data, comparing the data to other sources (e.g., financial statements), or validating the data through a series of edits. For example, one of the verification checks Pennsylvania performed

³⁶ We did not ask about specific actions taken. Instead, States were generally asked to describe any action taken if the MCO did not provide the utilization data in a timely manner.

included running queries that target missing or questionable data from MCOs. These queries have helped the State identify a lower-than-expected submission of claims for certain drug groups, which the State then addressed with the MCOs.

Among the seven States that did not verify the completeness of the data, four are in the process of implementing these checks and the other three did not mention having data-verification plans (although one mentioned that the MCO's agreement with the State requires it to provide complete data).³⁷ All of these States, except the District of Columbia, performed at least one of the other two data verification checks we specifically asked about in our survey (i.e., that the data exclude 340B utilization and that the data are correct).

Twenty-One of Twenty-Five States Verified That the MCO Data Exclude 340B Utilization. To verify that the MCO drug utilization data excluded 340B utilization, these States either requested that the MCOs include a 340B-entity indicator on the claims or matched the utilization data to a database identifying 340B entities and then removed the 340B entities' utilization from the MCO data.^{38, 39}

Twenty-Three of Twenty-Five States Verified That the MCO Data Are Accurate. The primary tools these States used to verify that the data are accurate are claim edits and audit reports.^{40, 41} For example, New York completes a series of control and validation edits when a claim is first processed and then produces reports to verify the accuracy of the data submission once the claim is paid. The State uses these reports to follow up with the MCOs when necessary. New Jersey created an encounter-monitoring unit whose responsibility is to perform quality control checks of the data submitted by MCOs.

³⁷ The seven States are California, the District of Columbia, Florida, Kansas, Massachusetts, New Jersey, and South Carolina.

³⁸ States are prohibited from collecting rebates on drugs purchased under the 340B program. Section 340B of the Public Health Service Act requires States to establish a mechanism to exclude 340B-purchased drugs from Medicaid rebate requests to prevent subjecting manufacturers to duplicate discounts. 42 U.S.C. § 256b(a)(5).

³⁹ The four States that did not have a 340B check are the District of Columbia, New Jersey, Ohio, and West Virginia.

⁴⁰ In addition to the District of Columbia, Ohio reported that it does not verify the accuracy of the MCO data. However, Ohio reported that it employs several methods to monitor data quality.

⁴¹ Although New Mexico reported that it verified that data were accurate, it was unsure of how it verified this information.

In the five quarters after the rebate expansion, 12 of the 22 States using the carve-in approach invoiced manufacturers and collected \$1.6 billion in rebates for Medicaid MCO drug utilization

At the time of our survey, 12 of the 22 States using the carve-in approach invoiced manufacturers and collected \$1.6 billion in rebates for Medicaid MCO utilization for the second quarter of 2010 through the second quarter of 2011.^{42, 43} This amount will likely grow because three of these States reported that they were waiting for additional rebate payments from prior quarters at the time of our request. These 12 States had a total of 8.8 million beneficiaries enrolled in MCOs at the time of our survey.⁴⁴ See Table 3 for the amount of rebates collected in each quarter and Appendix B for a list of the 12 States that invoiced manufacturers and the total amount of rebates collected by each State.

Table 3: Amounts That 12 States Invoiced and Collected Between Second Quarter 2010 and Second Quarter 2011 for Medicaid MCO Rebates

Rebate Quarter	Amount Invoiced	Amount Retroactively Invoiced	Amount Collected
Second quarter 2010	State did not have URAs; manufacturer calculated invoice amounts	\$116 million	\$273 million
Third quarter 2010	State did not have URAs; manufacturer calculated invoice amounts	\$101 million	\$317 million
Fourth quarter 2010	State did not have URAs; manufacturer calculated invoice amounts	\$110 million	\$278 million
First quarter 2011	\$390 million*	\$40 million	\$413 million
Second quarter 2011	\$396 million*	\$39 million	\$337 million
Total	Cannot determine total	\$406 million	\$1.6 billion**

Source: OIG analysis of State survey responses, 2012.

* Massachusetts was unable to determine the amounts invoiced for MCO rebates; therefore, these amounts are not included in first and second quarter 2011 invoice totals.

** Three States reported that they expect to collect additional rebate payments.

⁴² Although the rebate expansion was effective on March 23, 2010, we asked States to provide rebate data for the first full quarter (i.e., second-quarter 2010) after that date.

⁴³ Illinois, New York, and Ohio were excluded from this count because they had switched from a carve-out to a carve-in approach (Illinois on July 1 and New York and Ohio on October 1, 2011). Typically, States invoice manufacturers for rebates 60 days after the close of a quarter, meaning that not enough time had passed to enable these States to invoice the manufacturers when they completed our survey.

⁴⁴ Enrollment figures were approximations provided by each State in late 2011.

As previously mentioned, States could not provide the URAs or exact dollar amounts on the rebate invoices sent to manufacturers in 2010.⁴⁵ Instead, States provided manufacturers with the drugs' utilization data and relied on them to calculate and pay the amounts of rebates owed for each quarter in 2010. In the first and second quarters of 2011, the 12 States had invoiced manufacturers for \$390 million and \$396 million, respectively. In addition, 10 of the 12 States retroactively invoiced manufacturers \$406 million in rebates for the second quarter of 2010 through the second quarter of 2011. Retroactive invoices for utilization in 2010 averaged \$109 million per quarter, but dropped in the first half of 2011 to an average of \$40 million per quarter (when CMS resumed providing URAs). The majority of the 12 States invoiced manufacturers by sending 1 invoice for the MCO data and a separate invoice for the FFS data (10 States). Of the remaining two States, one sent manufacturers individual invoices for each of its four MCOs and a separate invoice for FFS data (a total of five separate invoices) and the other sent one invoice that combined all MCO and FFS data.

Additionally, all 12 States reported that they have processes to ensure that manufacturers pay the rebate amounts owed for MCO drug utilization. The process States used to collect unpaid invoiced amounts that were not disputed ranged from sending out prior period adjustments with the subsequent quarter's invoice to taking a multistep approach to collecting the payments. For example, Massachusetts sends collection notices, produces a report identifying manufacturers with amounts past due, and provides details of past due amounts on the quarterly invoices.

Eleven of the twelve States had \$33 million in rebates that were uncollected at the time of our survey because of unresolved disputes with manufacturers

The 11 States reported that the disputes with manufacturers involved potentially incorrect claim information provided by the Medicaid MCOs (e.g., invalid drug codes, incorrect units of measure, incorrect quantities listed on the claim), provider reimbursement issues, and manufacturer requests for more details about information on the invoices. Pennsylvania⁴⁶ and Georgia accounted for the majority (70 percent) of the

⁴⁵ Two of the 12 States reported amounts invoiced in 2010 that were not retroactive.

⁴⁶ Pennsylvania included unpaid invoices in its total amount of dollars not collected because of unresolved disputes.

\$33 million in rebates that were uncollected because of unresolved disputes with manufacturers.^{47, 48}

As of October 1, 2011, 10 of the 22 States using a carve-in approach had not invoiced manufacturers and collected rebates for Medicaid MCO drug utilization

Ten of the twenty-two States⁴⁹ that carved in prescription drugs did not invoice and collect rebates for Medicaid MCO utilization as of October 1, 2011. Combined, these 10 States have 8.3 million Medicaid beneficiaries enrolled in MCOs, which is comparable to the enrollment of the 12 States that have invoiced and collected rebates for MCO drug utilization.⁵⁰ See Appendix C for a list of the 10 States that did not invoice manufacturers and collect rebates.

Nine of the ten States reported that they intended to begin invoicing manufacturers in the fourth quarter of 2011 or the first quarter of 2012, with just one State planning to do so by the end of 2012 (approximately 2 years after the MCO rebate expansion was enacted).⁵¹ However, all of the 10 States that had not sent rebate invoices to manufacturers planned to make invoice amounts retroactive, in most cases back to March 23, 2010, when the related ACA provision became effective.

Seven of the ten noninvoicing States had collected all the drug utilization data needed to invoice manufacturers from all their Medicaid MCOs

Seven of the ten noninvoicing States had collected all the drug utilization data necessary to invoice manufacturers for rebates. According to these seven States, they had not invoiced because they had to complete programming changes to the systems that process MCO claims and

⁴⁷ CMS had developed and implemented the Medicaid Drug Rebate Dispute Resolution program to address the problem of unpaid and disputed drug rebates.

⁴⁸ Massachusetts reported that manufacturers did not owe money for unresolved disputes.

⁴⁹ Illinois, New York, and Ohio were excluded from this count because they had switched from a carve-out to a carve-in approach (Illinois on July 1 and New York and Ohio on October 1, 2011). Typically, States invoice manufacturers for rebates 60 days after the close of a quarter, meaning that not enough time had passed to enable these States to invoice the manufacturers when they completed our survey.

⁵⁰ Enrollment figures were approximations provided by each State in late 2011.

⁵¹ When these 10 States invoice manufacturers, 7 plan to send one invoice for MCO data and another for FFS data, 2 plan to send individual invoices for each MCO's data and another for FFS data, and 1 plans to send a single invoice that combines data for all 5 of its MCOs with the FFS data.

invoice manufacturers for these claims, were still receiving claims data, or had to finalize contractual changes with the States' rebate contractors.

Two States (California and West Virginia) that had not collected all utilization data from their MCOs⁵² were waiting to invoice manufacturers for rebates after programming changes to accommodate the new invoicing process were complete. The District of Columbia could not invoice manufacturers because it had not collected any utilization data from its MCOs.

Five States that did not pay for drugs through Medicaid MCOs changed the structures of their drug programs as a result of the rebate expansion

The ACA rebate expansion does not directly affect States that carve out prescription drugs or that do not contract with Medicaid MCOs. However, this rebate expansion prompted three States to switch from a carve-out approach to a carve-in approach in mid- to late 2011. According to these States, switching to a carve-in approach creates efficiencies by allowing them to consolidate care within an MCO and to take advantage of the new rebate inclusion. In addition, 2 of the 10 States that carved out prescription drugs at the time of our survey (Texas and Utah) reported that they have filed legislative changes to carve in at least a portion of their MCO utilization as a result of the rebate expansion. The expected implementation date for Texas was March 2012 and for Utah was July 2012.⁵³

As of October 1, 2011, 15 States did not contract with MCOs to provide medical care to beneficiaries. The inclusion of MCOs in the rebate agreement has not prompted any of these States to consider contracting with MCOs.

⁵² Four States (California, the District of Columbia, Nevada, and West Virginia) did not collect all the quarterly drug utilization data from their MCOs. Of these States, only Nevada invoiced manufacturers using the drug utilization data it had collected from its MCOs.

⁵³ According to its survey response, Utah filed a waiver to carve in some prescription drugs and was waiting for its approval at the time of our survey.

CONCLUSION AND RECOMMENDATION

Effective March 23, 2010, section 2501(c) of the ACA expanded the Medicaid rebate requirements to include drugs dispensed to beneficiaries by a Medicaid MCO. As a result, States contracting with MCOs that carve prescription drugs into the MCOs' fixed payments are now required to collect rebates. The rebate expansion has the potential to provide these States with a significant source of additional funds. This is evident in the fact that the 12 States that collected these rebates received \$1.6 billion collectively for just over 1 year's utilization. However, not all eligible States had invoiced manufacturers for these rebates—money that these States are clearly entitled to collect.

In addition, the Federal Government is potentially losing a significant source of funds as a result of States' not collecting MCO rebates. Section 2501 of the ACA increased the rebate amounts manufacturers pay and required manufacturers to remit the entire portion of this increase to the Federal Government. However, the Federal Government is unable to obtain these dollars if the States do not collect rebates.

Therefore, we recommend that CMS:

Follow Up With the 10 States That Had Not Collected Rebates for Drugs Dispensed to Medicaid MCO Beneficiaries and Take Action To Enforce Rebate Collection If Necessary

Even though nearly 2 years had passed since the March 23, 2010, rebate expansion went into effect, 10 States were not meeting the ACA's requirement to invoice and collect rebates from manufacturers for drugs dispensed to MCO beneficiaries. At a time when many States are facing financial difficulties, this new requirement enables them to pursue the collection of these additional rebates and further reduce Medicaid spending on prescription drugs. Furthermore, all but one State had obtained at least a portion of the MCO utilization data necessary for invoicing. Therefore, the factors that hinder rebate invoicing are mostly within the States' control.

Responses from these 10 States indicated that they intended to invoice manufacturers for drugs dispensed to MCO beneficiaries, generally starting in early 2012. CMS should follow up with these 10 States to verify that they have begun to invoice manufacturers and collect these rebates. CMS should also verify that States are invoicing manufacturers retroactively to the effective date of this provision (i.e., March 23, 2010). During its followup, if CMS finds that any of these 10 States have not sent invoices for the entire period since the rebate expansion, it should enforce the rebate collection requirements. CMS could consider denying Federal

matching funds to these States until they comply with the ACA rebate requirements.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with our recommendation. CMS noted that it has continuously undertaken such actions for all States. In regard to the 10 States we had identified as not collecting rebates for drugs dispensed to Medicaid MCO beneficiaries, CMS conducted further followup and found that 2 had taken steps that indicate they are now collecting these rebates. CMS believes the remaining eight States will come into compliance, thereby negating the need for enforcement actions.

We did not make any changes to the report based on CMS's comments. For the full text of CMS's comments, see Appendix D.

APPENDIX A

Percentage of Medicaid Managed Care Organizations That Provided Drug Utilization Data to States for the Second Quarter of 2011

State	Number of Medicaid MCOs* in Second Quarter 2011	Percentage That Provided Data Within 60 Days	Percentage That Provided Data More Than 60 Days After the Quarter	Percentage That Did Not Provide Data
Arizona	21	100%	-	-
California	29	17%	-	83% ¹
District of Columbia	3	-	-	100%
Florida	25	100%	-	-
Georgia	3	100%	-	-
Hawaii	5	-	100%	-
Kansas	2	100%	-	-
Kentucky	1	100%	-	-
Maryland	7	100%	-	-
Massachusetts	5	100%	-	-
Michigan	14	100%	-	-
Minnesota	8	88%	13% ²	-
Mississippi	2	100%	-	-
Nevada	2	100%	-	-
New Jersey	4	100%	-	-
New Mexico	7	100%	-	-
Oregon	15	100%	-	-
Pennsylvania	7	100%	-	-
South Carolina	4	100%	-	-
Virginia	5	100%	-	-
Washington	7	86%	14%	-
West Virginia	3	-	33%	67% ³

Source: Office of Inspector General analysis of State survey responses, 2012.

* Managed care organizations.

¹ California estimated that 53 percent of the Medicaid population was covered by the MCOs that did not provide the utilization data.

² Totals do not add to 100 percent because of rounding.

³ West Virginia estimated that 50 percent of the Medicaid population was covered by the MCOs that did not provide the utilization data.

APPENDIX B

Total Amount of Medicaid Managed Care Organization Rebates That 12 States Using a Carve-In Approach Collected From Second Quarter 2010 to Second Quarter 2011

State	Approach to Prescription Drug Payment in Medicaid MCOs*	Population Enrolled in MCOs	Total MCO Rebates Collected Between Second Quarter 2010 and Second Quarter 2011
Arizona	Carve-in	1,255,500	\$304,922,162
Georgia	Carve-in	1,118,978	\$126,146,641
Kentucky	Carve-in	115,000	\$56,500,258
Maryland	Combination of carve-out and carve-in	747,000	\$116,987,931
Massachusetts	Carve-in	487,180	\$87,195,855
Michigan	Combination of carve-out and carve-in	1,300,000	\$160,529,095
Minnesota	Carve-in	400,000	\$0 ¹
Nevada	Carve-in	260,000 ²	\$12,203,599
New Jersey	Combination of carve-out and carve-in	1,004,000	\$62,796,646
Oregon	Combination of carve-out and carve-in	503,000	\$35,227,390
Pennsylvania	Carve-in	1,200,000	\$590,541,831
South Carolina	Carve-in	442,000	\$64,252,200
Total		8,832,658	\$1,617,303,608

Source: Office of Inspector General analysis of State survey responses, 2012.

Note: Rebate collection figures were current at the time the States responded to our survey (i.e., late 2011 until January 2012).

* Managed care organizations.

¹ At the time of our survey, Minnesota had collected \$1.1 million in rebates for the week following March 23, 2010, but had not collected rebates for second quarter 2010 and subsequent quarters. However, when we followed up with the States for clarification in January 2012, Minnesota had collected an additional \$800,000 for the week following March 23, 2010, and \$18 million for the second quarter of 2010.

² Nevada did not provide its population enrolled in MCOs. We obtained the 2009 population figure (the most recent available) from <http://www.Medicaid.gov> on February 10, 2012.

APPENDIX C

Ten States Using a Carve-In Approach That Had Not Invoiced or Collected Medicaid Managed Care Organization Rebates as of October 1, 2011

State	Approach to Prescription Drug Payment	Population Enrolled
California	Combination of carve-out and carve-in	4,008,547
District of Columbia	Carve-in	145,000
Florida	Carve-in	1,800,000
Hawaii	Carve-in	283,000
Kansas	Carve-in	231,506
Mississippi	Carve-in	51,500
New Mexico	Carve-in	370,000
Virginia	Carve-in	530,000
Washington	Carve-in	685,000
West Virginia	Combination of carve-out and carve-in	166,373
Total		8,270,926

Source: Office of Inspector General analysis of State survey responses, 2012.

APPENDIX D

Agency Comments



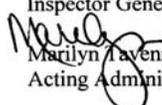
DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: JUL 16 2012

TO: Daniel R. Levinson
Inspector General

FROM: 
Marilyn Favenner
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "States' Collection of Medicaid Rebates for Drugs Paid Through Medicaid Managed Care Organizations" (OEI-03-11-00480)

Thank you for the opportunity to review and comment on the OIG Draft Report entitled "*States' Collection of Medicaid Rebates for Drugs Paid through Medicaid Managed Care Organizations*" (OEI-03-11-00480). The purpose of this report was to survey states regarding their processes for collecting information on drugs paid by Medicaid managed care organizations (MCOs), and invoicing manufacturers for rebates associated with these drugs.

The Affordable Care Act expanded the Medicaid drug rebate requirements to include those drugs covered by Medicaid MCOs, effective March 23, 2010. The new requirement placed responsibility on states to collect accurate drug utilization data from Medicaid MCOs and invoice manufacturers for these rebates.

OIG Findings

Between April 1, 2010, and June 30, 2011, 18 of the 22 "carve-in" states (states with their pharmacy benefit included in the Medicaid MCO benefit package) collected all the data needed to invoice manufacturers for rebates from their Medicaid MCOs. Three states did not collect data from a portion of their Medicaid MCOs, and one did not collect any drug utilization data. Except for the state that did not collect any data, all states performed some type of data verification check. Twelve of the 22 carve-in states invoiced manufacturers and collected \$1.6 billion in rebates for utilization for this time period. However, ten of the 22 states did not invoice manufacturers and collect Medicaid MCO rebates because they had to complete programming changes to the system that processes Medicaid MCO claims.

Additionally, OIG noted that the MCO rebate expansion has prompted five states that carved-out (states that provided their pharmacy benefit outside of the Medicaid MCO benefit package) prescription drugs to change to a carve-in approach.

OIG Recommendation

OIG recommends that the Centers for Medicare & Medicaid Services (CMS) follow up with the ten states that had not collected rebates for drugs dispensed to Medicaid MCO beneficiaries and take action to enforce rebate collection if necessary.

CMS Response

CMS concurs with OIG's recommendation and notes that we have continuously undertaken such actions for all states. CMS' Regional Offices and Central Office staff are in close contact with the states as part of the rebate offset process to determine the status of reporting rebates and offsets on the CMS-64. In further follow-up with the ten states cited by OIG, we have found that Virginia is now reporting MCO units separately from fee-for-services (FFS) units for all quarters back to the first calendar quarter of 2010, and West Virginia has now reported MCO units separately from FFS units for all quarters back to the fourth calendar quarter of 2010. Virginia has also begun reporting MCO rebates on the CMS-64 beginning with the fourth calendar quarter of 2011. At this time, CMS believes that through our ongoing efforts, the remaining eight states will come into compliance, avoiding enforcement actions.

CMS would like to thank OIG for their continued support in reviewing the states' compliance with the requirements of the Medicaid drug rebate program.

ACKNOWLEDGMENTS

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

Stephanie Yeager served as the team leader for this study. Other Office of Evaluation and Inspections staff from the Philadelphia regional office who conducted the study include Eric Merron. Central office staff who provided support include Tasha Trusty, Kevin Manley, and Debra Roush.

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