Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

STATES' COLLECTION OF OFFSET AND SUPPLEMENTAL MEDICAID REBATES

Daniel R. Levinson
Inspector General

December 2014
OEI-03-12-00520

EXECUTIVE SUMMARY: STATES' COLLECTION OF OFFSET AND SUPPLEMENTAL MEDICAID REBATES
OEI-03-12-00520

WHY WE DID THIS STUDY

To reduce Medicaid expenditures for prescription drugs, the Centers for Medicare & Medicaid Services (CMS) and the State Medicaid agencies (States) have implemented the Medicaid drug rebate program. In addition, many States have negotiated supplemental rebate agreements (SRAs) with drug manufacturers to generate additional rebates and further reduce expenditures. The Affordable Care Act (ACA) increased Federal Medicaid rebates—by an amount referred to as the "offset rebate"—in a way that may affect States' collection of supplemental Medicaid rebates.

HOW WE DID THIS STUDY

In February 2013, we emailed surveys to 51 States. In the survey, we asked each State to report the total amount of offset rebates for 2011 and 2012. We then asked each State whether it had an SRA and, if so, to provide the total amount of supplemental rebates collected for drugs dispensed between 2010 and 2012. We also asked each State with an SRA in effect to describe its policies and procedures as they relate to calculating supplemental rebates and to describe how recent changes related to the ACA have affected the State's collection of supplemental rebates. We received responses from all 51 States.

WHAT WE FOUND

Forty-eight States reported $2 billion in ACA offset rebates for 2011 and 2012, and 44 States reported collecting $1.7 billion in supplemental Medicaid rebates during the same time period. We also found that the method most States used to calculate supplemental rebates may reduce rebate amounts. Finally, we found that six States reported making changes to their SRAs as a result of changes related to the ACA.

WHAT WE RECOMMEND

We recommend that CMS ensure that all States appropriately report offset rebate amounts. We also recommend that CMS consider further whether all States should be encouraged to establish supplemental rebate programs and to encourage States to explore alternate methods for calculating supplemental rebates. CMS concurred with all three recommendations.

TABLE OF CONTENTS

OBJECTIVES

1. To determine the amount of offset rebates that State Medicaid agencies (States) reported in 2011 and 2012.
2. To determine the amount of supplemental drug rebates that States collected in 2011 and 2012.
3. To determine how States calculate supplemental rebate amounts.
4. To determine the impact of changes related to the Affordable Care Act (ACA) on the collection of supplemental rebates, as reported by States.

BACKGROUND

Medicaid

The Medicaid program, established under Title XIX of the Social Security Act (the Act), provides medical assistance for certain low-income and medically needy individuals. Medicaid is administered by States and financed using State and Federal funds. Federal Medical Assistance Percentage (FMAP) payments are the Federal funds each State receives for its Medicaid program and are based on the State's per capita income.[1]

Medicaid Reimbursement for Prescription Drugs

Currently, all 50 States and the District of Columbia offer prescription drug coverage as part of their Medicaid benefit packages. The Office of Inspector General (OIG) estimates that gross Medicaid expenditures for prescription drugs totaled approximately $36 billion in 2012.[2]

Medicaid beneficiaries typically receive covered drugs through pharmacies, which are then reimbursed by States. Federal regulations require, with certain exceptions, that each State Medicaid agency's reimbursement for a covered outpatient drug not exceed (in the aggregate) the lower of (1) the estimated acquisition cost (EAC) plus a reasonable dispensing fee or (2) the provider's usual and customary charge to the public for the drug.[3] CMS gives States flexibility to define EAC; most States base their calculations on average wholesale price (AWP) or

---

[1] Pursuant to § 1905(b) of the Act, FMAPs generally total between 50 and 83 percent of a State's Medicaid cost.

[2] This estimate was calculated from two sources: CMS's Medicaid Budget and Expenditure System (MBES) and Medicaid State utilization data. To calculate this estimate, we combined the fee-for-service (FFS) Medicaid expenditures from MBES and the expenditures from Managed Care Organization (MCO) records in the Medicaid State utilization data. This total does not include rebates and excludes problematic MCO utilization data from one State.

[3] 42 CFR § 447.512.

wholesale acquisition cost (WAC), although some States have begun to use average acquisition costs as the basis for reimbursement.[4, 5, 6]

Medicaid Drug Rebate Program

To reduce expenditures for Medicaid prescription drugs, CMS and the States have implemented certain cost-containment measures, such as the Medicaid drug rebate program.[7] Between 2010 and 2012, the rebate program saved Medicaid an average of about $15 billion annually. CMS and the States share these rebates on the basis of each State's FMAP amount. For Federal payment to be available for covered outpatient drugs provided under Medicaid, drug manufacturers are generally required to enter into rebate agreements with the Secretary of Health and Human Services and pay quarterly rebates to States.[8] As of July 2013, all States and approximately 600 pharmaceutical companies participated in the Medicaid drug rebate program.[9]

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 their covered outpatient drugs. An NDC is an 11-digit identifier that represents a specific manufacturer, product, and package size. AMP is 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

---

[4] Historically, the majority of States obtained AWPs from the publisher First Databank. However, First Databank stopped publishing AWPs in September 2011. This has caused many States to reevaluate their reimbursement methodologies. Unlike WAC, which is prescribed by Federal law (in § 1847A(c)(6)(B) of the Act), AWP is not defined in statute or regulation. Further, previous OIG work consistently found that AWPs often greatly exceeded prices available in the marketplace.

[5] Section 1847A(c)(6)(B) of the Act defines WAC as the manufacturer's list price for the drug to wholesalers or direct purchasers in the United States, not including certain kinds of discounts or rebates, as reported in wholesale price guides or other publications of drug pricing data.

[6] CMS, *Medicaid Covered Outpatient Prescription Drug Reimbursement Information by State—Quarter Ending September 2013*. Accessed at http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/State-Prescription-Drug-Resources.html on November 12, 2013.

[7] Congress established the Medicaid drug rebate program in § 1927 of the Act as added by the Omnibus Budget Reconciliation Act of 1990, P.L. No. 101-508. Other examples of cost-containment measures include the Federal upper limit program and State maximum allowable cost programs.

[8] Sections 1927(a)(1) and (b)(1) of the Act.

[9] CMS, *Medicaid Drug Rebate Program.* Accessed at http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Rebate-Program.html on July 18, 2013.

pharmacies that purchase drugs directly from the manufacturer, with certain exclusions.[10]

Section 2501(c) of the ACA expanded the Medicaid drug rebate program to include covered outpatient drugs dispensed to beneficiaries who receive care from Medicaid MCOs if the MCO is responsible for coverage of such drugs.[11] Managed care plans aim to maximize efficiency by negotiating rates, coordinating care, and managing the use of services. MCOs differ from the traditional FFS system in that States prospectively pay MCOs a fixed monthly amount (called a capitation payment) for each Medicaid enrollee, regardless of whether that beneficiary seeks care during the month.[12]

States may pay for drugs dispensed through MCOs using either a "carve-in" or a "carve-out" approach. In the carve-in approach, States *include* in the MCOs' fixed monthly payment amounts the payment for the drugs dispensed to beneficiaries. In the carve-out approach, States *exclude* from the MCOs' fixed monthly payment amounts the payment for drugs dispensed to beneficiaries and instead pay for these drugs using the traditional FFS system.[13]

Medicaid Drug Rebate Process

For some drugs covered under the Medicaid drug rebate program, CMS uses the AMP and best price to calculate the unit rebate amount (URA); for other drugs, a rebate percentage is used.[14] 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. States invoice manufacturers for the units reimbursed and manufacturers then pay the rebates to the States.

---

[10] Section 1927(k)(1) of the Act as amended by § 2503(a)(2) of the ACA, P.L. No. 111-148.

[11] Section 1927(b)(1)(A) of the Act as amended by § 2501(c) of the ACA.

[12] 42 CFR § 438.2. CMS, *Managed Care*. Accessed at http://www.medicaid.gov/medicaid-chip-program-information/by-topics/delivery-systems/managed-care/managed-care-site.html on December 1, 2014.

[13] The Lewin Group. "Projected Impacts of Adopting a Pharmacy Carve-In Approach Within Medicaid Capitation Programs," February 2011.

[14] Section 1927(c) of the Act. "Best price" is defined in § 1927(c)(1)(C)(i) of the Act as essentially the lowest price available from the manufacturer during the rebate period to any purchaser in the United States, with certain exceptions.

URAs Pre-ACA. Prior to the ACA, the basic URA for brand-name drugs was equal to either 15.1 percent of AMP or the difference between AMP and best price, whichever was greater. If the AMP for a brand-name drug had risen at a rate greater than inflation, then the drug's manufacturer was required to pay an additional rebate amount that was added to the basic rebate amount.[15] The URA for generic drugs was 11 percent of AMP.

URAs Post-ACA. Effective January 1, 2010, sections 2501(a) and (b) of the ACA increased URAs for brand-name and generic drugs. The basic URA for brand-name drugs is now equal to either 23.1 percent of AMP or the difference between AMP and best price, whichever is greater.[16] Manufacturers are still required to pay an additional rebate if the AMP for a brand-name drug has risen at a rate greater than inflation. The URA for generic drugs is now equal to 13 percent of the AMP.[17]

The ACA also requires the amounts attributed to these increased rebates—amounts known as the "offset rebate"—to be applied against the amounts that the Federal Government pays to the States.[18] Therefore, States are prohibited from keeping the additional ACA-required rebate amounts.

In a September 2010 letter to State Medicaid Directors, CMS outlined its plans to calculate the offset rebate amount for each drug (i.e., the amount attributed to the rebate increase required by the ACA that must be remitted to CMS). After consulting with the States, CMS decided to calculate a unit rebate offset amount (UROA), which will identify the offset amount per unit of a drug. States multiply the UROA by the number of units of each drug for which they receive payment from the manufacturer to determine the quarterly rebate offset amount (hereinafter referred to as

---

[15] Section 1927(c)(2) of the Act.

[16] Section 1927(c)(1) of the Act as amended by § 2501(a) of the ACA. The URA for certain brand-name drugs (e.g., a clotting factor for which a separate furnishing payment is made or a drug approved exclusively for pediatric indications) was increased to 17.1 percent of AMP.

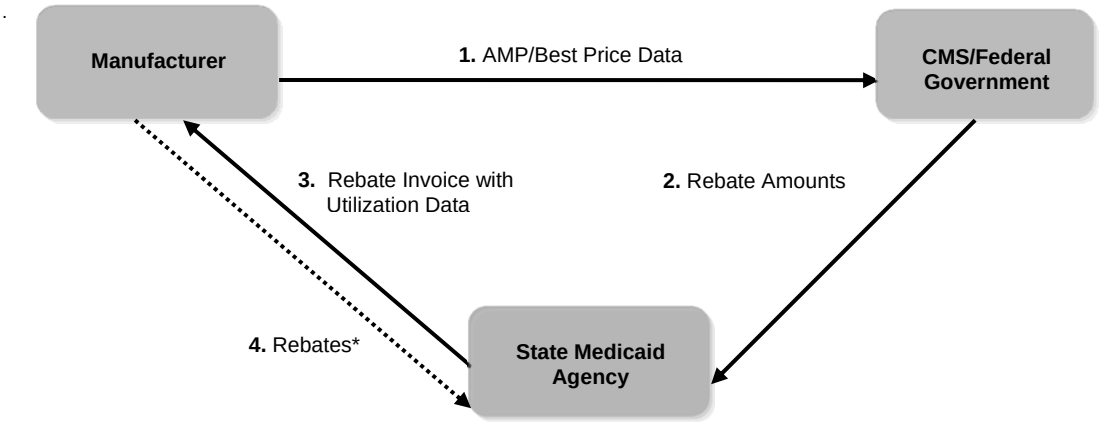
[17] Section 1927(c)(3) of the Act as amended by § 2501(b) of the ACA.

[18] Section 1927(b)(1)(C) of the Act.

offset rebates). This offset amount will be included on the Quarterly Expenditure reports.[19]

Because of changes to Medicaid rebates under the ACA, CMS was not able to modify its systems to calculate URAs during 2010. As a result, States' invoices to manufacturers included the number of units reimbursed for the drugs but did not contain URAs.[20] CMS reminded manufacturers to calculate the URAs and make the appropriate rebate payments to States in accordance with the rebate changes for that year.[21] In May 2011, CMS provided 2010 URAs to States as a prior-period adjustment. See Figure 1 for an illustration of rebate collection.

Figure 1. Calculation and Collection of Medicaid Drug Rebates, Post-ACA



Source: CMS, *Medicaid Drug Rebate Data Guide for States,* section 1927(b) of the Act.
* With the exception of offset rebates (which States are prohibited from keeping), CMS and the States share Medicaid rebates on the basis of each State's FMAP.

Supplemental State Medicaid Rebates

Supplemental Rebates. The Medicaid drug rebate program consists of rebates collected under the national rebate agreement and the ACA-required offset rebates. States may also negotiate supplemental rebate agreements (SRAs) with drug manufacturers to generate additional

---

[19] According to CMS, if the difference between AMP and best price is less than or equal to 15.1 percent of AMP, the UROA equals 8 percent of AMP (i.e., the difference between 23.1 and 15.1 percent of AMP). If the difference between AMP and best price is greater than 15.1 percent of AMP, but less than 23.1 percent of AMP, the UROA equals the difference between 23.1 percent of AMP and AMP minus best price. If the difference between AMP and best price is greater than or equal to 23.1 percent of AMP, the UROA equals $0. The UROA for generic drugs equals 2 percent of AMP. See CMS, *SMDL#10-019* [State Medicaid Director Letter #10-019]—*Medicaid Prescription Drugs,* September 28, 2010. Accessed at http://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SMD10019.pdf on June 28, 2012.

[20] CMS instructed States to report each URA as $0 on the rebate invoice.

[21] CMS, Medicaid Drug Rebate Program Release No. 155, August 11, 2010.

rebates and further reduce expenditures. As they do with rebates collected through the Medicaid drug rebate program, States share supplemental rebates with the Federal Government on the basis of their FMAP amounts.

Most States have received CMS approval on their State Plan Amendments to enter into supplemental drug rebate agreements that generate additional rebates. States may enter into SRAs alone or in conjunction with other States. The terms of the SRA describe the rebate amounts and drugs covered by the agreement.

Preferred Drug List and Prior Authorization. In conjunction with their SRAs, States may establish preferred drug lists (PDLs) or require prior authorization for certain covered outpatient drugs. Manufacturers pay States supplemental rebates for including their drugs on the PDLs. The drugs included on a State's PDL may result in lower beneficiary costs; the drugs *not* included on a State's PDL may require prior authorization.

METHODOLOGY

Data Collection

CMS Data. We obtained CMS's policies and procedures for collecting, calculating, and reporting of Medicaid rebate data. We also obtained data from CMS (through MBES) on Medicaid drug expenditures and Federal rebates from 2008 through 2012.

Electronic Survey of State Medicaid Agencies. In February 2013, we emailed surveys to the 51 State Medicaid agencies. We received responses from all 51 States.

State Rebate Data. We first asked States to report the total amount of offset rebates for 2011 and 2012. We then asked States whether they had SRAs in effect as of January 1, 2013, to collect supplemental Medicaid rebates. If they answered yes, we asked them to provide the total amount of supplemental rebates collected for drugs dispensed from 2010 through 2012. If they answered no, we asked them to explain why they did not collect supplemental Medicaid rebates and whether they had plans to start collecting these rebates by the end of 2013.

We also asked the States that collected supplemental Medicaid rebates whether they contracted with Medicaid MCOs to provide medical care—specifically, drug coverage—to Medicaid beneficiaries. We asked the States to describe how they provided drug coverage to beneficiaries enrolled in Medicaid MCOs and whether they extended their supplemental rebate programs to include drugs covered through Medicaid MCOs. If States did extend their supplemental rebate programs to include drugs

covered through MCOs, we asked them to provide the amount of supplemental rebates requested and collected for these drugs.

State Medicaid Agency Policies and Procedures. We asked each State that had an SRA in effect as of January 1, 2013, to describe the methodology it used to calculate supplemental rebates and the type of SRA in effect as of January 1, 2013 (i.e., single-State SRA or multi-State SRA). Finally, we asked States to report on how the recent changes under the ACA affected their collection of supplemental rebates. We asked States whether they changed or renegotiated their SRAs and whether the amount of supplemental rebates collected decreased as a result of the collection of offset rebates.

Data Analysis

Using States' responses to the survey, we first determined the number of States that reported offset rebates in 2011 and 2012 and the number of States collecting supplemental Medicaid rebates as of January 1, 2013. We then calculated the total offset rebates reported in 2011 and 2012 as well as the total supplemental rebates collected from 2010 through 2012. For States that did not collect supplemental rebates, we determined, on the basis of States' responses, the reasons for not collecting and whether the States intended to begin collecting these rebates. Using Federal rebate data from CMS, we estimated the portion of supplemental rebates retained by the States.

We reviewed survey responses to determine the method each State used to calculate supplemental rebates and to determine the number of States that extended their supplemental rebate programs to include the utilization of drugs covered through MCOs. Finally, we determined which States reported changes to their supplemental rebate programs as a result of the changes related to the ACA.

Limitations

The responses provided by the States are self-reported. We did not verify the accuracy or completeness of States' responses or rebate data; we also did not verify the accuracy of CMS's data. In addition, several States indicated that the reported offset and supplemental rebate amounts for 2012 were not complete at the time we collected the information, and one State provided offset rebate totals for 2012 only.

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

Forty-eight States reported a total of $2 billion in ACA offset rebates for 2011 and 2012

Offset rebates for 48 States totaled approximately $1.2 billion in 2011 and $819 million in 2012.[22, 23] Offset rebates for individual States ranged from less than $1 million to over $100 million in both 2011 and 2012. Of the remaining three States, one reported a combined total for 2010 through 2012, but did not report rebate amounts separated by year; one did not provide a separate amount for offset rebates; and one State responded that computer and technology problems prevented it from reporting the offset rebate information.

Forty-four States reported collecting a total of $1.7 billion in supplemental Medicaid rebates in 2011 and 2012

As of January 2013, 44 States reported having SRAs in effect, allowing them to collect supplemental Medicaid rebates. These States reported collecting approximately $1.7 billion in rebates in 2011 and 2012 combined.[24] We estimate that the State share of supplemental rebates totaled $656 million in 2011 and 2012.[25] See Appendix A for a list of States that collected supplemental Medicaid rebates as of January 2013.

Of the 44 States that collect supplemental Medicaid rebates, 17 States have single-State SRAs, 25 States have multi-State SRAs, and 2 States have both single-State and multi-State SRAs.[26] See Table 1 for a description of State SRAs.

[22] At least five States reported 2012 offset rebates that were not for the full year. Therefore, the 2012 total might not represent the complete amount for the year.

[23] One State was able to report offset rebates for 2012 only.

[24] At least nine States indicated that the supplemental rebates collected for 2012 were not for the full year. Therefore, the 2012 total might not represent the complete amount for the year.

[25] This estimate is based on FMAPs calculated using MBES expenditure data.

[26] Four States noted in their responses that they have their own individual SRAs, but are part of a group. We classified these States as having multi-State SRAs.

Table 1: State SRAs

Type of SRA	Number of States
No SRA	7
Single-State SRA only	17
Multi-State SRA only	25
Single- and Multi-State SRAs	2
Total	**51**

Source: OIG analysis of State Medicaid agency responses, May 2013.

Seven States did not have SRAs as of January 2013; one of these States intended to establish an SRA

The seven States that did not have SRAs as of January 2013 provided several reasons for not collecting these rebates. Two of these States previously collected supplemental rebates, and one of the two intended to begin collecting supplemental rebates again. Two other States noted that a substantial portion of their Medicaid populations were enrolled in MCOs that carved in the drug benefit. Among the remaining three States, one State did not provide a specific reason; another State noted that it has a relatively low volume of the market share; and the remaining State said that its legislature had passed a law prohibiting supplemental rebates.

The method that most States used to calculate supplemental rebates may reduce rebate amounts

Under most States' rebate agreements, supplemental rebates are inverse to Federal rebate amounts (which include offset rebates): if the Federal rebate increases, the supplemental rebate decreases by an equal amount. Specifically, 41 of the 44 States that collect supplemental Medicaid rebates negotiate a guaranteed, fixed price that is the basis for the supplemental rebate amount.[27] The remaining three States usually calculate supplemental rebates as a percentage of WAC, although two of these States noted that in limited circumstances, they base their methodology on a guaranteed price.

[27] Ten of these forty-one States also calculate supplemental rebates on the basis of a percentage of WAC. One additional State also calculates supplemental rebates on the basis of a percentage of AMP; another State also calculates supplemental rebates on the basis of a set amount.

The guaranteed price is a fixed final net price for a drug that the manufacturer assures to provide the State. In other words, the State negotiates the rebate amount in relation to the final amount it will pay for the drugs. The supplemental rebate for these States is calculated by subtracting the CMS (i.e., Federal) rebate and the bid price or guaranteed price from a benchmark price such as AWP, AMP, or WAC. Under this model, States could negotiate the same discounts pre- and post-ACA, but would retain fewer rebates because they do not share in the offset rebates. See Figure B-1 in Appendix B for an illustration of the effect of offset rebates.

Although States reported that supplemental rebates increased in the aggregate, most States reported that supplemental rebate amounts decreased

Although States reported that supplemental rebates slightly increased in the aggregate from 2010 to 2011, individual States reported that supplemental rebates for individual drugs were lower than they would have been under the pre-ACA rebate amounts.[28, 29] Thirty-nine States reported a decrease in supplemental Medicaid rebate amounts because of changes to Medicaid rebates in the ACA; the remaining five States reported no decrease. Twenty of these States estimated a total of approximately $22 million in lost supplemental rebates.[30]

Six States reported making changes to their SRAs as a result of changes related to the ACA

Several provisions of the ACA changed the Medicaid drug rebate program, including increases to the URAs for certain drugs and the requirement to

---

[28] States attributed the increase in rebates to several reasons, including the increase in the number and cost of drugs covered by the supplemental rebate program and/or the lack of URA data from CMS. Because of changes to (1) the definition of AMP, (2) rebate percentages, and (3) Federal share rules, CMS was not able to calculate URAs during 2010. In May 2011, CMS calculated URAs for each quarter of 2010 and provided those data to States. Several States noted that 2011 data would include prior-quarter adjustments resulting from the lack of URA data for 2010 and that this inclusion may lead to inflated totals for 2011.

[29] Additionally, some States reported that there was an increase in the number of drugs for which the supplemental unit rebate amount decreased and/or was $0 because of Federal rebate increases (i.e., the supplemental rebate amount was reduced to $0 because of the offset rebate).

[30] Twenty States provided estimates of lost supplemental rebates. The estimates for 17 of these States were for the third quarter of 2012; the remaining 3 States did not specify the time period for the lost rebates. One additional State provided a percentage estimate of its decrease in supplemental rebates only; another State provided a percentage estimate of supplemental rebates only.

collect rebates for drugs covered through Medicaid MCOs. Thirty-eight States did not report making any changes to their SRAs as a result of changes under the ACA. Of the six States that made changes, three reported changes related to "line extension" drugs[31] and the other three reported that they began collecting supplemental rebates on drugs utilized by beneficiaries who receive drug coverage through MCOs.[32]

A small number of States collected supplemental rebates on drugs covered through Medicaid MCOs

Thirty-two of the forty-four States that collect supplemental rebates also had contracts with MCOs. Six of these States reported that they are or intend to begin collecting supplemental rebates on drugs covered through a Medicaid MCO.[33] Two of these six States were able to provide the amount of supplemental rebates for drugs covered through MCOs; of the remaining four States, one did not have the data available,[34] another had just started requesting these rebates and did not have the amounts available, and the remaining two had not started collecting rebates at the time of our survey.

Of the remaining 26 States, 20 carved in at least some portion of their prescription drug benefits.[35] Sixteen of these States cited the fact that MCOs have their own PDLs, that there is no common PDL, that MCOs want to negotiate their own rebates, or that SRAs apply to only FFS beneficiaries as the reasons they were unable to collect supplemental rebates on drugs covered through MCOs. For the remaining four States, one State prohibited supplemental rebates for MCO utilization, one State maintained a majority carve-out approach and said it was not practical at that time to expand its supplemental rebate program, one State responded that manufacturers would not pay supplemental rebates for MCO

---

[31] In a proposed rule, CMS defines a line extension drug as a single-source or innovator multiple-source drug that is an oral solid dosage form that has been approved by the Food and Drug Administration as a change to the initial brand-name listed drug in that it represents a new version of the previously approved listed drug. See 77 Fed. Reg. 5318, 5323 (Feb. 2, 2012).

[32] Three additional States also reported changing or renegotiating their SRAs as a result of changes to Medicaid rebates under the ACA.

[33] One additional State noted that it was exploring changes to its SRA that would provide opportunities to acquire supplemental rebates for its MCO population under certain conditions.

[34] One State reported that it collects supplemental rebates on drugs covered through a Medicaid MCO, but did not report changes to its SRA as a result of the ACA.

[35] The other six States carve out their drug benefit and provide drug coverage through FFS, not through the MCO.

utilization, and the remaining State did not provide a reason. See Appendix C for information on supplemental rebates and MCOs.

CONCLUSION AND RECOMMENDATIONS

Our results show that nearly all States reported offset rebates and that supplemental rebates were one method that States used to reduce Medicaid expenditures on prescription drugs. For 2011 and 2012, States reported a total of approximately $2 billion in offset rebates and approximately $1.7 billion in supplemental Medicaid rebates.

The ACA changes to the Federal Medicaid rebate program increased total rebates to the Federal Government, but may affect States' collection of supplemental rebates because the method that most States used to calculate supplemental rebates may result in lower rebate amounts. Nearly all States that collect supplemental rebates base them on a guaranteed price. The guaranteed price limits the total rebates available for the drugs; because the Federal Government retains all offset rebates, the guaranteed-price methodology may result in reduced supplemental rebate amounts for States. Given our findings that (1) not all States reported offset rebates, (2) not all States collected supplemental rebates, and (3) States' methods for calculating supplemental rebates may result in lower supplemental rebate amounts, we recommend that CMS:

Ensure that all States appropriately report offset rebate amounts

Section 1927(b)(1)(C) of the Act requires CMS to reduce payments to the States by an amount attributable to the rebate increase (i.e., by the amount of the ACA offset rebates). To ensure that CMS receives the benefit of all eligible rebates, States must be able to report the ACA offset rebates. CMS could work with States to ensure they are able to perform this function.

Consider further whether to encourage all States to establish supplemental rebate programs

Given that 44 States have reduced Medicaid drug expenditures by implementing SRAs, CMS should consider further whether States that do not currently collect supplemental rebates should be encouraged to implement supplemental rebate programs.

Encourage States to explore alternate methods for calculating supplemental rebates

For all but 3 of the 44 States that collect supplemental Medicaid rebates, the method for calculating these rebates (i.e., basing the rebate amount on a guaranteed price) is directly affected by the Federal rebate increase. Some States currently base supplemental rebates on benchmark prices (e.g., AWP, WAC) minus a set percentage, a method that may not be directly affected by changes to the Federal rebate amount.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with our recommendation to ensure that all States appropriately report offset rebate amounts and noted that it has been monitoring and enforcing the ACA requirements. CMS stated that it is monitoring whether States are reporting offset rebate amounts appropriately and, to the extent it finds a State has not reported offset rebate amounts or is having problems reporting them, it has been providing technical assistance to States to ensure they are able to report offset rebates and will continue to do so.

CMS concurred with our recommendation to consider encouraging States to establish supplemental rebate programs as a cost-containment measure, but noted that States have flexibility as to whether to do so. CMS issued guidance to States in 2002 and 2004 that provided clarification regarding establishing and implementing SRAs and stated that it will continue to provide technical support to States. CMS further noted that multiple States are submitting State plan amendments to include in their supplemental rebate collections the drug utilization of beneficiaries enrolled in Medicaid MCOs.

Finally, CMS concurred with the recommendation to encourage States to explore alternate methods for calculating supplemental rebates. CMS noted that fluctuation in drug pricing caused most States to use the guaranteed price methodology because this price is not affected by price changes. In addition, CMS noted that the three States that base supplemental rebates on a benchmark price minus a set percentage may not be significantly affected by a change to the offset rebate amount, but may be impacted by various drug pricing changes.

We did not make any changes to the report on the basis of CMS's comments. However, after we received CMS's comments, one State revised its submission for offset rebates reported in 2011 and 2012; we incorporated the State's revised rebate totals into the report. For the full text of CMS's comments, see Appendix D.

APPENDIX A

Table A-1. States Collecting Supplemental Medicaid Rebates as of January 1, 2013

State	State Has an SRA
Alabama	Yes
Alaska	Yes
Arizona	No
Arkansas	Yes
California	Yes
Colorado	Yes
Connecticut	Yes
Delaware	Yes
District of Columbia	Yes
Florida	Yes
Georgia	Yes
Hawaii	No
Idaho	Yes
Illinois	Yes
Indiana	Yes
Iowa	Yes
Kansas	Yes
Kentucky	Yes
Louisiana	Yes
Maine	Yes
Maryland	Yes
Massachusetts	No
Michigan	Yes
Minnesota	Yes
Mississippi	Yes
Missouri	Yes
Montana	Yes
Nebraska	Yes
Nevada	Yes
New Hampshire	Yes
New Jersey	No
New Mexico	No
New York	Yes
North Carolina	Yes
North Dakota	No
Ohio	Yes
Oklahoma	Yes
Oregon	Yes
Pennsylvania	Yes
Rhode Island	Yes
South Carolina	Yes
South Dakota	No
Tennessee	Yes
Texas	Yes
Utah	Yes
Vermont	Yes

continued on next page

States Collecting Supplemental Medicaid Rebates as of January 1, 2013 (continued)

State	State Has an SRA
Virginia	Yes
Washington	Yes
West Virginia	Yes
Wisconsin	Yes
Wyoming	Yes

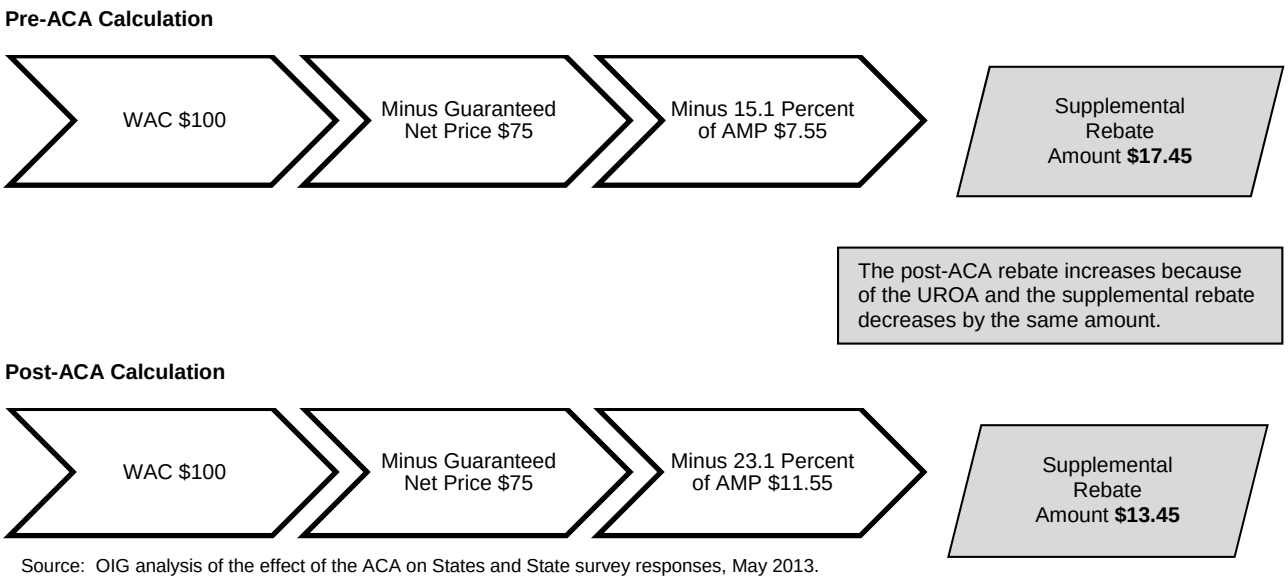
Source: OIG analysis of State Medicaid agency survey responses, May 2013.

APPENDIX B

The Potential Effect of Offset Rebates on Supplemental Medicaid Rebates

As Figure B-1 illustrates, the hypothetical rebate increase under the ACA is shifted from the supplemental rebate (which the State shares with the Federal Government) to the offset rebate (which the Federal Government does not share with States). In both the pre-ACA and post-ACA calculations, the State negotiates a $25 discount from the manufacturer. However, because States do not share in the offset rebate, they receive less of the discount.

Figure B-1. An Example of the Potential Effect of Increased Federal Rebates on State Supplemental Rebates[36]



Source: OIG analysis of the effect of the ACA on States and State survey responses, May 2013.

[36] This example assumes a WAC of $100, a guaranteed price of $75, an AMP of $50, and the Federal rebate percentage for brand-name drugs (15.1 percent of AMP pre-ACA and 23.1 percent of AMP post-ACA). This example would not produce the same result for States that use alternative methods—such as a percentage of WAC—for calculating supplemental rebates.

APPENDIX C

Table C-1. Supplemental Rebates on Drugs Covered through MCOs

State Description	Number of States
Among States that utilize MCOs and have SRAs	
Collect or intend to collect supplemental rebates on drugs covered through MCOs	6
Carve in at least some portion of the drug benefit but do not collect supplemental rebates on drugs covered through MCOs[37]	20
Carve out drug benefit; drugs covered through FFS	6
Among States that do not utilize MCOs or do not have SRAs	
Have SRAs, but do not utilize MCOs	12
Do not have SRAs	7
Total Number of States	**51**

Source: OIG analysis of State Medicaid agency survey responses, May 2013.

[37] Eight of these States reported using a mixture of carve-in and carve-out approaches (although one of these States noted that it maintains a majority carve-out approach). For example, three of these States carve out specific classes of drugs, such as HIV drugs and antipsychotics.

APPENDIX D

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: APR 10 2014

TO: Daniel R. Levinson
Inspector General

/S/

FROM: Marilyn Tavenner
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "States' Collection of Offset and Supplemental Medicaid Rebates" (OEI-03-12-00520)

Thank you for the opportunity to review and comment on the above subject OIG draft report. The Centers for Medicare & Medicaid Services (CMS) appreciates the information presented in the report and offers the following comments. The purpose of this report was to survey states' methods and amounts for Medicaid supplemental rebate calculations, collections, and reporting as well as to determine the impact of the changes under ACA that increased the federal Medicaid rebate portion identified as the offset rebate amount. OIG found that 48 states reported approximately $1.2 billion in 2011 and $900 million in 2012 for ACA offset rebates with the offset rebates for individual states ranging from less than $1 million to over $100 million in both 2011 and 2012. OIG also found that 44 states reported collecting approximately $1.7 billion in supplemental rebates in 2011 and 2012 combined. OIG also learned that the guaranteed net unit price (GNUP) method which most states use to calculate supplemental rebates may result in lower rebate amounts. OIG reported that 41 of the 44 states collecting supplemental Medicaid rebates negotiate a GNUP which is a fixed final net price for a drug that the manufacturer assures to provide to the state. Post-ACA, only those states that base the supplemental rebates on the GNUP would retain lesser rebate amounts. Although the states reported that the supplemental rebates increased in the aggregate due to the increase in the number and cost of the drugs covered by the supplemental rebate program, 20 states estimated approximately $22 million lost in supplemental rebates due to the increased federal offset. OIG found that 38 states did not report making any changes to their Medicaid supplemental rebate agreements (SRAs) with drug manufacturers to increase the federal Medicaid rebate percentage to include the offset.

In accordance with 1927(a) of the Social Security Act, Medicaid drug rebates including supplemental rebates are collected from drug manufacturers that participate in the Medicaid drug rebate program to reduce Medicaid expenditures for prescription drugs. The Affordable Care Act (ACA) made significant changes to the Medicaid Drug Rebate Program by increasing the federal Medicaid rebate collection from manufacturers which is referred to as the offset and by expanding the drug manufacturers' obligation to pay rebates for drugs dispensed to beneficiaries enrolled under a Medicaid managed care organization (MCO).

Agency Comments (continued)

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

OIG Recommendation

The OIG recommends that CMS ensure that all states appropriately report offset rebate amounts.

CMS Response

The CMS concurs and has been monitoring and enforcing the ACA requirements. As part of the certification review at the closing of each reporting period, CMS is monitoring whether states are reporting their offset rebate amounts appropriately. To the extent we find that a state has not reported or is having problem reporting their offset rebate amounts appropriately, we have been providing technical assistance to states to ensure they are able to report the ACA offset rebates and will continue to do so.

OIG Recommendation

The OIG recommends that CMS consider further whether to encourage all states to establish supplemental rebate programs.

CMS Response

The CMS concurs with OIG's recommendation to encourage states to consider establishing a supplemental rebate program as a cost containment measure by reducing net expenditures for Medicaid prescription drugs; however, states have the flexibility whether or not to establish a SRA. CMS issued guidance in 2002 and 2004 to states that provided clarification regarding establishing and implementing supplemental rebate arrangements. We will continue to provide technical support to states as they amend their state plans to include supplemental rebate arrangements.

Also, CMS notes that states are submitting state plan amendments (SPAs) to CMS which propose to revise the SRA to include the MCO provisions under ACA. As of March 2014, three states have approved SPAs to include MCO utilization in their supplemental rebate collections. In addition, 13 states have approved SPAs and 2 states have pending approval SPAs which propose to include the MCO supplemental rebate provision in the SRA template.

OIG Recommendation

The OIG recommends that CMS encourage states to explore alternate methods for calculating supplemental rebates.

Agency Comments (continued)

CMS Response

The CMS concurs with the recommendation to encourage states to explore alternate methods for calculating supplemental rebates. Further CMS will review SPAs that propose new methodologies for supplemental rebates.

As noted in OIG's report findings, 41 of the 44 states that collect Medicaid supplemental rebates calculate rebates using a method based on the GNUP, which is a fixed, final net price for a drug that manufacturers assure to provide to the states. Due to the fluctuation of drug prices, the majority of states made the decision to use the GNUP methodology, since this price is guaranteed by the manufacturer and is not impacted by the various drug pricing changes. Our understanding is that the states rely on the stability of a guaranteed price. We also note that some states have explored other options; 3 of the 44 states currently base supplemental rebates on a percentage off benchmark price, such as average wholesale price and wholesale acquisition cost, which may not be significantly affected by change to the federal offset, but is impacted by the various drug pricing changes.

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 Robert A. Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office.

Edward K. Burley served as the team leader for this study. Central office staff who provided support include Kevin Farber, Kevin Manley, and Christine Moritz.

Office of Inspector General

http://oig.hhs.gov

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.