Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICAID COULD SAVE HUNDREDS OF MILLIONS BY EXCLUDING AUTHORIZED GENERIC DRUG TRANSACTIONS TO SECONDARY MANUFACTURERS FROM BRAND NAME DRUGS' AVERAGE MANUFACTURER PRICE CALCULATIONS

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Inspector General

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Office of Inspector General

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

Medicaid Could Save Hundreds of Millions by Excluding Authorized Generic Drug Transactions to Secondary Manufacturers from Brand Name Drugs' Average Manufacturer Price Calculations

Why OIG Did This Review

The 2017 U.S. Department of Health and Human Services (HHS) Budget in Brief states that excluding authorized generics from average manufacturer price (AMP) calculations could save the Federal Government $20 million per year. A prior Office of Inspector General (OIG) report indicated that this is a low estimate.

Our objective was to determine the impact on Medicaid drug rebates from including authorized generic drug transactions in the brand name drugs' AMP calculations.

How OIG Did This Review

Our review covered nine brand name drugs that included authorized generic drugs to secondary manufacturers in their AMP calculations. The nine brand name drugs included 40 nine-digit national drug codes that made up approximately 45 percent of the total Medicaid dollars reimbursed for drugs with authorized generics for 2017.

After the manufacturers provided the AMP data for each drug, we verified the data, removed the authorized generic transactions, and recalculated the AMP. Next, we recalculated rebate amounts based on the recalculated AMP. We compared the recalculated rebates to the original rebates to determine the impact on Medicaid rebate amounts for the nine drugs.

What OIG Found

By including authorized generic drug transactions to secondary manufacturers in the brand name drug's AMP calculations, Medicaid received 46 percent less in rebates than it otherwise would have for the nine brand name drugs we reviewed, amounting to $595 million for calendar year 2017.

What OIG Recommends and CMS Comments

We recommend that the Centers for Medicare & Medicaid Services (CMS) seek legislative change to exclude authorized generic drug transactions to secondary manufacturers from the AMP calculation of the brand name drug, which may increase manufacturer Medicaid rebate obligations by hundreds of millions each year.

CMS concurred with our recommendation. CMS stated that it informs HHS of OIG recommendations for legislative change through the development of the President's Budget. CMS noted the President's Fiscal Year 2020 Budget includes a legislative proposal to exclude the authorized generic sales from the primary manufacturer's average price.

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INTRODUCTION

WHY WE DID THIS REVIEW

The 2017 U.S. Department of Health and Human Services (HHS) Budget in Brief includes a series of targeted policies to both lower drug costs and improve drug coverage in Medicaid. One such proposal "excludes authorized generic drugs from calculations used to determine brand name rebates." The Federal share of cost savings included in the budget is $20 million per year through increased drug rebate amounts. A prior Office of Inspector General (OIG) report indicated that a savings of $20 million per year is a low estimate.

OBJECTIVE

The objective of our review was to determine the impact on Medicaid drug rebates from including authorized generic drug transactions in the brand name drugs' average manufacturer price calculations.

BACKGROUND

The Medicaid Drug Rebate Program

Section 1927 of the Social Security Act (the Act) outlines the requirements of the Medicaid drug rebate program (the rebate program), which became effective January 1, 1991. In general, for a manufacturer's covered outpatient drug to be eligible for Federal reimbursement under the Medicaid program, the manufacturer must enter into a rebate agreement administered by Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. These rebates are shared between the States and the Federal Government to offset the overall cost of prescription drugs under the Medicaid program.

Unit Rebate Amount Calculation

Under the rebate program, manufacturers are required to report to CMS on a monthly and quarterly basis the average manufacturer price (AMP)[1] and, if applicable, the best price for each covered outpatient drug offered by the manufacturer (the Act, § 1927(b)(3)(A)(i)). CMS uses the AMP and, in some cases, the best price to calculate a unit rebate amount (URA) for each drug. The unit rebate amount for single-source and innovator multiple-source drugs[2] is equivalent to the greater of either 23.1 percent of the AMP per unit or the difference between the AMP and the best price per unit. If a particular drug's AMP increases more than the

[1] Manufacturers perform the AMP calculation and only submit the AMP value to CMS.

[2] We will use the term "brand" to mean single-source and innovator multiple-source drugs.

increase in the Consumer Price Index for All Urban Consumers (CPI-U) over a certain period of time, an additional rebate amount is added to the drug. The total unit rebate amount for each innovator drug is capped at 100 percent of the AMP.

Authorized Generics

An authorized generic drug is any drug product that is sold, licensed, or marketed under the brand manufacturer's New Drug Application,[3] but that is marketed, sold, or distributed under a different National Drug Code (NDC) from the brand name product.[4] That is, an authorized generic drug is a brand name drug that a brand manufacturer either sells or permits another manufacturer (referred to as the secondary manufacturer) to sell as a generic drug.

The Deficit Reduction Act

Congress made significant changes to the rebate program when it enacted the Deficit Reduction Act of 2005 (DRA). As part of those changes, a manufacturer must take into consideration any drugs that it permits to be sold under an approved New Drug Application of the manufacturer, such as authorized generics, when calculating AMP and best price. Before the DRA, there were no statutory requirements specifically addressing authorized generics under the rebate program. In July 2007, CMS issued regulations implementing provisions of the DRA.[5] In the final regulation, CMS interpreted the statutory language to require that brand manufacturers include sales of authorized generic drugs in calculating the AMP only when the drugs are sold "directly to a wholesaler."[6]

The Affordable Care Act

In 2010, Congress passed the Patient Protection and Affordable Care Act (ACA),[7] which made major changes in the methodology manufacturers used to determine the AMP. Among other things, the ACA contained the first statutory definition of "wholesaler," which specifically included manufacturers among the entities that could be considered wholesalers. In 2016, CMS issued a final rule implementing provisions of the ACA that pertain to the rebate

[3] In general, the Food and Drug Administration (FDA) approves new drugs through the New Drug Application process and approves generic drugs through the Abbreviated New Drug Application Process.

[4] 42 CFR § 447.502 (2016).

[5] 72 Fed. Reg. 39142 (July 17, 2007).

[6] 42 CFR § 447.506(b) (2007).

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

program.[8] In its final rule, CMS directed that primary manufacturers include in their AMP calculations the sales of authorized generic drugs to secondary manufacturers if the secondary manufacturer is "acting as a wholesaler for drugs distributed to retail community pharmacies."[9] If a manufacturer sells a drug to another manufacturer (a second manufacturer) that is not engaged in wholesale distribution of prescription drugs to retail community pharmacies, then the second manufacturer will not be treated as a wholesaler, and the sales price of a covered outpatient drug from the first manufacturer to the second manufacturer should not be included in the primary manufacturer's AMP.[10]

Authorized Generic Drug Arrangements

Brand manufacturers may have various arrangements for the marketing and distribution of their authorized generic drugs and may not always include them in the AMP of the brand name drug. For instance, some secondary manufacturers may not be "acting as a wholesaler" (for example, if they sold the product to wholesalers). In this instance, the regulations state that the brand manufacturer should not include the authorized generic drug transactions in the calculation of the brand name drug's AMP.

Previous Office of Inspector General Report on Average Manufacturer Price Methodologies

A previous OIG review[11] obtained information on manufacturers' AMP methodologies after the effective date of the ACA. Many of the manufacturers surveyed during the review addressed the treatment of authorized generics. Most of these manufacturers indicated that they began including authorized generic transactions because of the statutory change in the definition of "wholesaler" in the ACA.

HOW WE CONDUCTED THIS REVIEW

Our review covered brand name drugs that had an authorized generic version during 2017. We reviewed a sample of nine brand name drugs[12] for which the manufacturer transferred the authorized generic to a secondary manufacturer and included the transfer price of the

[8] 81 Fed. Reg. 5170 (February 1, 2016).

[9] 42 CFR § 447.506(b) (2016).

[10] 81 Fed. Reg. 5207 (February 1, 2016).

[11] HHS-OIG *Average Manufacturer Price Determinations by Selected Drug Manufacturers Generally Were Consistent With Federal Requirements* (A-06-13-00014), June 2, 2014. Available at http://oig.hhs.gov/oas/reports/region6/61300014.asp.

[12] All versions (forms and strengths) were included for each selected brand name drug.

authorized generic in the AMP calculation of the brand name drug.[13] The drugs in our review accounted for approximately 45 percent of the total Medicaid dollars for brand name drugs with authorized generic drugs during 2017.[14] We obtained or recalculated the AMP excluding the authorized generic transactions.[15] The recalculated AMP was then used to recalculate the URA. We applied the updated URA to the number of units sold for the brand name drug for the period to determine the impact to Medicaid rebates. See Appendix B for an explanation and example of the AMP and URA calculation. Our objective did not require that we verify whether the AMPs were calculated in accordance with Federal regulations.

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

Appendix A describes our audit scope and methodology.

RESULTS OF REVIEW

Medicaid drug rebate amounts were significantly impacted by including authorized generic drug transactions to secondary manufacturers in the calculation of AMP. The transfer price of the authorized generic drug was usually significantly less than the sales price of the brand name drug. By including the authorized generic drug in the AMP calculation of the brand name drug, the AMP was reduced, which lowered the URAs and therefore the rebate amounts. See Table 1 on the following page for the differences in the average price per unit for the brand name drug and the authorized generic drug for one quarter.

[13] If a manufacturer informed us that the authorized generic transactions were not included in the brand name drug's AMP calculation, we selected an alternate drug for our review. As a result, three of our original selections were replaced.

[14] The total Medicaid dollars included all authorized generic arrangements.

[15] This included the transfer price and royalties associated with the authorized generic drug.

Table 1: Price Difference Between the Brand Name Drug and the Authorized Generic Drug for One Quarter[*]

DRUG	AVERAGE BRAND NAME PRICE PER UNIT	AVERAGE AUTHORIZED GENERIC PRICE PER UNIT	DIFFERENCE
DRUG A	$ 7.12	$ .26	$ 6.86
DRUG B	445.49	220.00	225.49
DRUG C	7.18	.49	6.69

[*] The authorized generic price per unit represents the transfer price and royalties between the primary and secondary manufacturer.

Because authorized generic drug transactions to secondary manufacturers were included in the brand name drug's AMP calculations, Medicaid received 46 percent less in rebates than it otherwise would have for the nine brand name drugs we reviewed, amounting to $595 million for calendar year (CY) 2017. This represents the total amount that would have been shared between the States and the Federal Government. We did not estimate the total Federal share of this amount because percentages would vary.[16] See Table 2 below for a summary of the rebate differences that resulted from excluding authorized generic sales transactions in the drugs we reviewed for 2017.

Table 2: Summary of Select Medicaid Drug Rebate Differences for 2017

BRAND NAME DRUG[**]	REBATES WITH RECALCULATED AMP	REBATES WITH REPORTED AMP	DIFFERENCE IN REBATE AMOUNTS	PERCENTAGE DIFFERENCE
DRUG A	$ 385,923,901	$ 154,053,684	$ 231,870,217	60%
DRUG B	37,938,795	19,471,031	18,467,764	49%
DRUG C	1,706,989	248,167	1,458,822	85%
DRUG D	902,794	205,330	697,464	77%
DRUG E	300,188,370	175,096,921	125,091,449	42%
DRUG F	51,727,310	28,735,286	22,992,024	44%
DRUG G	169,888,938	71,984,345	97,904,593	58%
DRUG H	313,196,502	226,580,493	86,616,009	28%
DRUG I	25,204,344	15,139,423	10,064,921	40%
TOTALS	**$ 1,286,677,943**	**$ 691,514,680**	**$ 595,163,263**	**46%**

[**] This is the sum of all the NDCs with authorized generic drugs for the selected brand name drug. Drugs A, B, and C correlate to Drugs A, B, and C in Table 1.

[16] The Federal Medical Assistance Percentages (FMAPs) are used in determining the amount of Federal matching funds for State expenditures. There are also different percentages depending on where the drugs are reported on the CMS 64, such as the regular FMAP (varies by State), Indian Health Service Facility FMAP (100%), Family Planning FMAP (90%), and the Increased ACA Offset FMAP (varies by State but may be up to 100%).

CONCLUSION AND RECOMMENDATION

Federal regulations require the inclusion of authorized generic drug transactions in the calculation of AMP for brand name drugs when certain conditions are met. However, sales of an authorized generic drug to a secondary manufacturer were explicitly allowed in AMP calculation only after the implementation of the statutory definition of "wholesaler" that was included in the ACA. This has had a significant impact on Medicaid drug rebate amounts. We recommend that CMS seek legislative change to exclude authorized generic drug transactions to secondary manufacturers from the AMP calculation of the brand name drug. This change may increase manufacturer Medicaid rebate obligations by hundreds of millions each year.

CMS COMMENTS

In written comments on our draft report, CMS concurred with our recommendation. CMS stated that it informs HHS of OIG recommendations for legislative change through the development of the President's Budget. CMS noted the President's Fiscal Year 2020 Budget includes a legislative proposal to exclude the authorized generic sales from the primary manufacturer's average price. CMS also provided technical comments on our draft report, which we addressed as appropriate. CMS's comments, excluding the technical comments, are included as Appendix C.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our review covered nine brand name drugs that had an authorized generic drug sold to a secondary manufacturer for which the brand manufacturer included the authorized generic drug transactions in its AMP calculations during CY 2017.[17] We obtained the AMP data from the drug manufacturers included in our review. Our review included 40 NDCs[18] for brand name drugs with authorized generics sold to secondary manufacturers. The total number of NDCs of brand name drugs with authorized generics available during 2017 was 1,133. The drugs in our review accounted for approximately 45 percent of the total Medicaid dollars for brand name drugs with authorized generic drugs during 2017.[19]

This review did not require an assessment of internal controls.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- obtained information from CMS to determine a list of authorized generic drugs;
- obtained information from CMS and FDA to determine the brand name drugs associated with the identified authorized generic drugs;
- obtained information from CMS to determine the number of units and dollars paid for the authorized generics and their associated brand name drugs for CY 2017;
- selected nine brand name drugs to review;
- contacted the manufacturers of the selected drugs to verify that they included the sales of the authorized generic drug to a secondary manufacturer in the brand name drug's AMP calculation and replaced drugs for which the authorized generic transactions were not included in the AMP calculation of the brand name drug;

[17] We determined which drugs to review on the basis of whether the brand name drug had high Medicaid expenditures.

[18] The nine brand name drugs included in our review had a total of 40 product-level (9-digit) NDCs.

[19] The total Medicaid dollars included all authorized generic arrangements.

- obtained data from the manufacturers and gained an understanding of the AMP calculations and sales transactions provided;

- obtained the manufacturer reported AMPs from CMS for each drug and compared it to the AMP information provided directly to us by the manufacturer to verify the data;

- obtained or recalculated the AMP after removing the authorized generic drug transactions;

- calculated the URAs using the reported AMP and compared it to the URAs from CMS to verify that our methodology for calculating the URA was correct;

- recalculated the URA using the recalculated AMP;

- obtained from CMS the number of units reimbursed by Medicaid for each drug included in our review;

- multiplied the number of units by the reported URA and the recalculated URA to get the total rebate amounts and calculated the difference; and

- discussed the results of our review with CMS.

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

APPENDIX B: AVERAGE MANUFACTURER PRICE AND UNIT REBATE AMOUNT CALCULATION EXAMPLE

The AMP for a covered outpatient drug represents the average price paid by wholesalers and retail community pharmacies to manufacturers for drugs distributed to retail community pharmacies.[20] Although the calculation is complicated and may vary in how a manufacturer gets to the final numbers, fundamentally AMP reflects the number of sales dollars divided by the number of units sold.

For example, if Manufacturer X reports $100 million in net AMP eligible sales dollars and 2 million in net AMP eligible sales units for the first quarter of 2017, the reported quarterly AMP for this manufacturer is $50 ($100 million/2 million units). In this example, if Manufacturer X had $40 million in sales for the authorized generic drug for 1,350,000 units, the recalculated AMP for this manufacturer would be $92 ($60 million/650,000 units), after taking out authorized generic transactions.

The AMP is then used to determine a unit rebate amount, which is another multi-step formula that takes into account multiple factors. The basic formula is the greater of either the quarterly AMP multiplied by 23.1 percent, or the quarterly AMP minus the quarterly best price (for single-source or innovator drugs). An additional rebate obligation may be owed if the AMP has increased more than general inflation as measured by CPI-U. If the total rebate amount is greater than the quarterly AMP, the rebate amount is reduced to equal the AMP.

In our example, if Manufacturer X's original total URA was $12 ($50 x 23.1%) and the recalculated URA (using the recalculated AMP after taking out authorized generic transactions) was $21 ($92 x 23.1%), this amounts to a difference of $9 per unit.

The URA is multiplied by the total number of units sold for the quarter for the brand name drug to arrive at the total rebate obligation. In our example, if Manufacturer X sold 650,000 units of the brand name drug during the same quarter, the manufacturer's original rebate obligation would be $7.8 million (650,000 units x $12) and the recalculated rebate obligation for the quarter would be $13.7 million (650,000 units x $21), a difference of $5.9 million for the quarter.

[20] Section 1927(k)(1) of the Act.

APPENDIX C: CMS COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: APR - 4 2019

TO: Daniel R. Levinson
Inspector General

FROM: Seema Verma
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Medicaid Could Save Hundreds of Millions by Excluding Authorized Generic Drug Transactions to Secondary Manufacturers from Brand Name Drugs' Average Manufacturer Price Calculations" (A-06-18-04002)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report. CMS appreciates the opportunity to examine the current structure of the Medicaid Drug Rebate Program.

The Medicaid Drug Rebate Program is a partnership between CMS, State Medicaid Agencies, and participating drug manufacturers that helps to offset the federal and state costs of most outpatient prescription drugs dispensed to individuals covered by Medicaid. The program requires a drug manufacturer to enter into, and have in effect, a Medicaid National Drug Rebate Agreement with the Secretary of the Department of Health and Human Services (HHS) in exchange for state Medicaid coverage of most of the manufacturer's drugs. Manufacturers are required to report all of their covered outpatient drugs to the Medicaid Drug Rebate Program. Manufacturers are then responsible for paying a rebate on those drugs for which payment was made under the state plan. These rebates are paid by drug manufacturers on a quarterly basis to states and are shared between the states and the Federal government. Approximately 600 drug manufacturers currently participate in this program.

As OIG noted in its draft report, current law allows for the inclusion of authorized generics in the brand name drug Medicaid Drug Rebate Program calculations. The President's Fiscal Year 2020 Budget includes a legislative proposal to clarify authorized generic drugs sales under this program.

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

OIG Recommendation

CMS seek legislative change to exclude authorized generic drug transactions from the AMP calculation of the brand name drug which may increase manufacturer Medicaid rebate obligations by millions each year.

CMS Response

CMS concurs with this recommendation. CMS informs HHS of OIG recommendations for legislative change through the development of the President's Budget. As noted above, the President's Fiscal Year 2020 Budget includes a legislative proposal to clarify authorized generic drugs sales under the Medicaid Drug Rebate Program, specifically, that the primary manufacturer's average price must exclude these authorized generic sales.