Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

AVERAGE MANUFACTURER PRICES INCREASED FASTER THAN INFLATION FOR MANY GENERIC DRUGS

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EXECUTIVE SUMMARY

The Medicaid program would have received an additional $1.4 billion in Medicaid rebates on the top 200 generic drugs for 2005 through 2014 if the rebate calculation for generic drugs contained an inflationary factor similar to the rebate calculation for brand-name drugs.

WHY WE DID THIS REVIEW

The Office of Inspector General (OIG) received a congressional request to examine recent increases in the prices charged for generic drugs and the effect these prices have had on generic drug spending in the Medicare and Medicaid programs. In response to that request, OIG has updated a previous review of generic drug price increases under the Medicaid drug rebate program.

The objective of this review was to determine the extent to which generic drug price increases have exceeded the statutory inflation factor used in the rebate calculation for brand-name drugs.

BACKGROUND

The Medicaid drug rebate program became effective in 1991 (the Social Security Act (the Act) § 1927). For a covered outpatient drug to be eligible for Federal Medicaid funding, the drug's manufacturer must enter into a rebate agreement that is administered by the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. CMS, the States, and drug manufacturers each have specific functions under the program. Among other things, section 1927(b)(3) of the Act requires a participating manufacturer to report quarterly to CMS the average manufacturer price (AMP) and, if applicable, the best price for each covered outpatient drug.

The Act requires the payment of additional rebates for single-source and innovator multiple-source drugs (collectively, "brand-name drugs") under certain situations. Section 1927(c)(2) requires manufacturers to pay an additional rebate when the AMP for a brand-name drug increases by more than a specified inflation factor. Generally, the amount of the additional rebate is based on the amount that the drug's reported AMP exceeds its inflation-adjusted baseline AMP, and manufacturers pay the additional rebate for each unit of the drug reimbursed by Medicaid. The Act does not include a similar inflation-based rebate provision for generic drugs.

A previous OIG report found that generic drug price increases exceeded the specified statutory inflation factor applicable to brand-name drugs for 35 percent of the quarterly AMPs reviewed. If the provision for brand-name drugs had been extended to generic drugs, the Medicaid program would have received additional rebates. We calculated that Medicaid would have received a total of $966 million in additional rebates for the top 200 generic drugs, ranked by Medicaid reimbursement, from 1991 through 2004. We recommended that CMS consider seeking

legislative authority to extend the additional rebate provisions to generic drugs. CMS agreed to consider our recommendation when it considered future legislative proposals.

HOW WE CONDUCTED THIS REVIEW

We limited our review to the top 200 generic drugs, as ranked by Medicaid reimbursement, for each year from 2005 through 2014. A total of 869 drugs were in the top 200 generic drugs at least once during the 10 years. We assigned each drug a baseline AMP based on the second quarter that pricing data was reported on CMS's Medicaid Drug Rebate System for the drug and compared each quarterly AMP to the inflation-adjusted baseline AMP. We then applied the method in the Act for calculating additional rebates on brand-name drugs to the top 200 generic drugs for each quarter that the quarterly AMP exceeded the inflation-adjusted baseline AMP.

WHAT WE FOUND

Generic drug price increases exceeded the specified statutory inflation factor applicable to brand-name drugs for 22 percent of the quarterly AMPs we reviewed. If the provision for brand-name drugs were extended to generic drugs, the Medicaid program would receive additional rebates. We calculated that Medicaid would have received a total of $1.4 billion in additional rebates for the top 200 generic drugs, ranked by Medicaid reimbursement, from 2005 through 2014. The additional rebates for the top 200 generic drugs increased most years, from more than $39 million in 2005 to more than $464 million in 2014.

CONCLUSION

Our findings are consistent with our previous work and support our prior recommendation that CMS consider seeking legislative authority to extend the additional rebate provisions to generic drugs. On November 2, 2015, the Bipartisan Budget Act of 2015 (P.L. No. 114-74) was enacted and included provisions extending the additional rebate to generic drugs. The additional rebate for generic drugs will apply to rebate periods beginning with the first quarter of 2017. Therefore, we are not making any additional recommendations.

TABLE OF CONTENTS

INTRODUCTION 1

Why We Did This Review 1

Objective 1

Background 1
Medicaid Drug Rebate Program 1
Previous Office of Inspector General Report on Generic Drug Prices 2

How We Conducted This Review 2

FINDINGS 3

Generic Drug Price Increases Exceeded Inflation 3

Additional Rebates 4

CONCLUSION 5

APPENDIX

AUDIT SCOPE AND METHODOLOGY 6

INTRODUCTION

WHY WE DID THIS REVIEW

The Office of Inspector General (OIG) received a congressional request to examine recent increases in the prices charged for generic drugs and the effect these prices have had on generic drug spending in the Medicare and Medicaid programs. In response to that request, OIG has updated a previous review of generic drug price increases under the Medicaid drug rebate program.

OBJECTIVE

Our objective was to determine the extent to which generic drug price increases have exceeded the statutory inflation factor used in the rebate calculation for brand-name drugs.

BACKGROUND

Medicaid Drug Rebate Program

The Medicaid drug rebate program became effective in 1991 (the Social Security Act (the Act) § 1927). For a covered outpatient drug to be eligible for Federal Medicaid funding, the drug's manufacturer must enter into a rebate agreement that is administered by the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. CMS, the States, and drug manufacturers each have specific functions under the program.

Under the program, manufacturers are required to report monthly and quarterly to CMS the Average Manufacturer Price (AMP) and, if applicable, the best price for each covered outpatient drug.[1] CMS uses the AMP and, in some cases, the best price to calculate a unit rebate amount (URA) for each drug. A basic rebate amount for single-source and innovator multiple-source drugs (collectively, "brand-name drugs") is defined as the greater of the difference between the AMP and the best price or a specified percentage of the AMP, which was 15.1 percent for periods beginning after December 31, 1995, and before January 1, 2010. Generally, the specified percentage has been 23.1 percent for periods beginning after December 31, 2009.[2,3] The Act defined the URA for generic drugs as 11 percent of the AMP for periods beginning after December 31, 1993, and before January 1, 2010. The URA for generic drugs rose to 13 percent of AMP after December 31, 2009.[4]

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[1] The Act § 1927(b)(3)(A)(i), 42 CFR § 447.510(a)(1), and 42 CFR § 447.510(d), as set forth in the July 17, 2007, Federal regulation at 72 Fed. Reg. 39142.

[2] The Act § 1927(c)(1).

[3] Certain types of drugs, namely clotting factors and drugs approved exclusively for pediatric indications, use a specified percentage of 17.1 percent for periods beginning after December 31, 2009. *Id*.

[4] The Act § 1927(c)(3).

Manufacturers are required to pay an additional rebate when the AMP for a brand-name drug increases more than a specified inflation factor.[5] Generally, the amount of the additional rebate is based on the amount that the drug's reported AMP exceeds its inflation-adjusted baseline AMP, and manufacturers pay the additional rebate based on utilization (i.e., units of the drug reimbursed by Medicaid).

The baseline AMP for a brand-name drug that was on the market when the Act was passed was the AMP for the quarter ended September 30, 1990. The baseline AMP for a drug that entered the market after 1990 was generally the AMP in effect for the quarter after it entered the market. The baseline AMP for each drug was indexed to the consumer price index for urban consumers for the appropriate quarter. The Act does not include a similar inflation-based rebate provision for generic drugs.

Previous Office of Inspector General Report on Generic Drug Prices

A previous OIG report[6] found that generic drug price increases exceeded the specified statutory inflation factor applicable to brand-name drugs for 35 percent of the quarterly AMPs reviewed. If the provision for brand-name drugs had been extended to generic drugs, the Medicaid program would have received additional rebates. We calculated that Medicaid would have received a total of $966 million in additional rebates for the top 200 generic drugs, ranked by Medicaid reimbursement, from 1991 through 2004. We recommended that CMS consider seeking legislative authority to extend the additional rebate provisions to generic drugs. CMS agreed to consider our recommendation when it considered future legislative proposals.

HOW WE CONDUCTED THIS REVIEW

We limited our review to the top 200 generic drugs, as ranked by Medicaid reimbursement, for each year from 2005 through 2014. A total of 869 drugs were in the top 200 generic drugs at least once during the 10 years. We assigned each drug a baseline AMP based on the second quarter that pricing data was reported on CMS's Medicaid Drug Rebate System for the drug and compared each quarterly AMP with the inflation-adjusted baseline AMP. We then applied the method in the Act for calculating additional rebates on brand-name drugs to the top 200 generic drugs for each quarter that the quarterly AMP exceeded the inflation-adjusted baseline AMP. Our objective did not require that we identify and review any internal controls.

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.

[5] The Act § 1927(c)(2).

[6] *Review of Generic Drug Prices* (A-06-07-00042). Available online at http://oig.hhs.gov/oas/reports/region6/60700042.htm. Accessed on May 28, 2015.

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

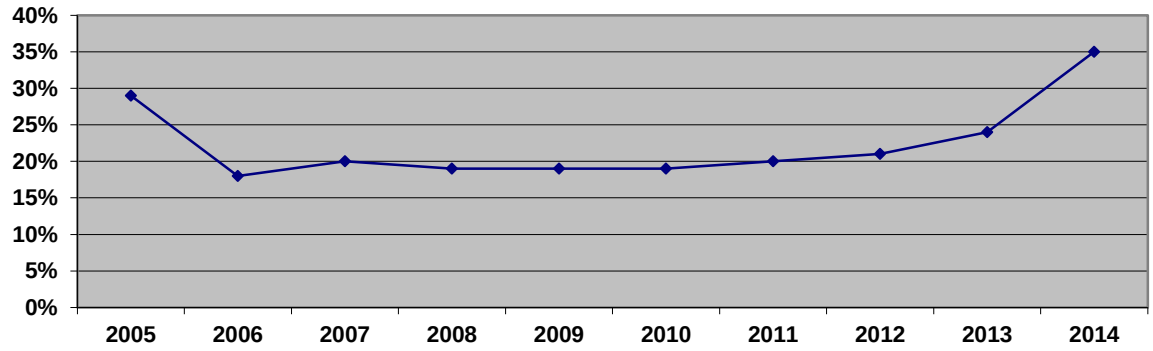
FINDINGS

Generic drug price increases exceeded the specified statutory inflation factor applicable to brand-name drugs for 22 percent of the quarterly AMPs we reviewed. If the provision for brand-name drugs were extended to generic drugs, the Medicaid program would receive additional rebates. We calculated that Medicaid would have received a total of $1.4 billion in additional rebates for the top 200 generic drugs, ranked by Medicaid reimbursement, from 2005 through 2014. The additional rebates for the top 200 generic drugs increased most years, from more than $39 million in 2005 to more than $464 million in 2014.

GENERIC DRUG PRICE INCREASES EXCEEDED INFLATION

For the top 200 generic drugs, 22 percent of the quarterly AMPs exceeded their inflation-adjusted baseline AMPs.[7] For 356 of the 869 drugs we reviewed, there was at least one quarter in which the drugs' quarterly AMPs exceeded the inflation-adjusted baseline AMPs. We also noted that 139 drugs had quarterly AMPs exceeding their inflation-adjusted baseline AMPs for every quarter that the drugs were included in the review. The graph below shows the percentage of quarterly AMPs that exceeded their inflation-adjusted baseline AMPs each year from 2005 to 2014.

Percentage of Quarterly Average Manufacturer Prices Greater Than Inflation-Adjusted Average Manufacturer Prices



The AMP increases exceeding the specified statutory inflation factor were frequent and significant for some drugs. For example, one drug had quarterly AMPs that exceeded the inflation-adjusted AMPs by an average of 200 percent for all 32 of the quarters that the drug was

[7] CMS determines Medicaid URAs quarterly. We reviewed information on the top 200 generic drugs for all 4 quarters of each year; however, not all 200 had utilization or Medicaid drug rebate information for all 4 quarters of each year.

in the top 200 generic drugs.[8] In another example, the quarterly AMPs exceeded the inflation-adjusted AMPs by an average of 2,363 percent for the 12 quarters that the drug was in the top 200.

Overall, the AMP increases exceeding the specified statutory inflation factor were less than they were in the previous review. In the previous review, 35 percent of the quarterly AMPs exceeded their inflation-adjusted baseline AMPs, and the annual percentage of AMPs exceeding their inflation-adjusted baseline AMPS ranged from 28 percent to 41 percent.

ADDITIONAL REBATES

Using the method specified in the Act for calculating the additional rebate on brand-name drugs, we calculated additional rebates for the yearly top 200 generic drugs in our review. The additional rebates totaled $1.4 billion from 2005 through 2014. The additional rebates for the top 200 generic drugs increased most years, from more than $39 million in 2005 to more than $464 million in 2014. The table below shows the annual amount of additional rebates, actual rebates, and percentage difference from actual to calculated rebates for the top 200 generic drugs.

Calculated Additional Rebates and Actual Rebates for the Top 200 Generic Drugs, 2005–2014

Year	Calculated Additional Rebates	Actual Rebates	Difference From Actual to Calculated Additional Rebates
2005	$39,593,030	$37,302,333	106%
2006	16,279,817	18,317,452	89%
2007	36,729,684	36,618,506	100%
2008	66,212,657	64,241,376	103%
2009	66,084,517	59,407,036	111%
2010	84,474,332	109,575,929	77%
2011	122,255,473	136,326,917	90%
2012	187,995,320	145,280,656	129%
2013	305,712,634	167,499,451	183%
2014	464,528,664	245,801,884	189%
Total	**$1,389,866,128**	**$1,020,371,540**	**136%**

[8] We determined baseline information based on the second quarter that pricing data was reported on CMS's Medicaid Drug Rebate System for the drug. We looked at a total of 40 quarters from the first quarter of 2005 through the fourth quarter of 2014.

CONCLUSION

Our findings are consistent with our previous work and support our prior recommendation that CMS consider seeking legislative authority to extend the additional rebate provisions to generic drugs. On November 2, 2015, the Bipartisan Budget Act of 2015 (P.L. No. 114-74) was enacted and included provisions extending the additional rebate to generic drugs. The additional rebate for generic drugs will apply to rebate periods beginning with the first quarter of 2017. Therefore, we are not making any additional recommendations.

APPENDIX: AUDIT SCOPE AND METHODOLOGY

SCOPE

We limited our review to the top 200 generic drugs, as ranked by Medicaid reimbursement, for each year from 2005 through 2014.[9] We assigned each drug a baseline AMP and compared each quarterly AMP with the inflation-adjusted baseline AMP. Our objective did not require that we identify and review any internal control systems.

We conducted our audit work from February through July 2015.

METHODOLOGY

To accomplish our objective, we:

- reviewed section 1927 of the Act;
- reviewed CMS guidance on the URA calculation;
- obtained Medicaid utilization from CMS;
- obtained drug classification information from CMS;
- determined the top 200 generic drugs, in terms of Medicaid reimbursements, for each year from 2005 through 2014;
- obtained AMP, best price, URA, consumer price index for urban consumers values, and utilization from CMS for the top generic drugs for all years;
- assigned a baseline AMP to each generic drug in our review based on the second quarter that pricing data was reported on CMS's Medicaid Drug Rebate System for the drug;[10]
- compared each quarterly AMP with the inflation-adjusted baseline AMP;
- calculated an additional rebate amount for the top generic drugs, using steps similar to the additional rebate calculation for brand-name drugs, for each quarter that the quarterly AMPs exceeded the inflation-factored baseline AMPs;[11]

[9] A total of 869 drugs were in the top 200 generic drugs at least once during the 10 years.

[10] We used the second quarter of reported pricing data as the baseline AMP to be similar to the current method used for brand-name drugs, which uses the AMP of the second quarter on the market as the baseline AMP.

[11] The Affordable Care Act (§ 2501(e)) limited the URA on brand-name drugs to 100 percent of the AMP of the drug. We applied this cap to the entire period of this review. The cap was not applied on the prior OIG review of generic drug price increases.

- applied the additional rebate amount for each of the top generic drugs to the utilization of the drug to determine a total dollar amount of additional rebates for generic drugs; 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.