DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

OCT 24 2007

TO: Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services

FROM: Daniel R. Levinson
Inspector General

SUBJECT: Review of Generic Drug Price Increases (A-06-07-00042)

Attached is our final report on generic drug price increases. Our objective was to determine the extent to which generic drug price increases have exceeded the specified statutory inflation factor used to calculate the inflation-based rebate for brand-name drugs.

Section 1927 of the Social Security Act (the Act) requires manufacturers to pay additional rebates for brand-name drugs when the average manufacturer prices (AMP) for those drugs increase more than a specified inflation factor. The Act does not include a similar inflation-based rebate provision for generic drugs.

Generic drug price increases exceeded the specified statutory inflation factor applicable to brand-name drugs for 35 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. By applying the method in the Act for calculating additional rebates on brand-name drugs to generic drugs, we calculated that the Medicaid program 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 recommend that the Centers for Medicare & Medicaid Services (CMS) consider seeking legislative authority to extend the additional rebate provisions to generic drugs.

In its comments on our draft report, CMS said that the report provides evidence that additional rebates would be payable if the inflation-based rebate provision were applied to generic drugs. However, CMS said that it cannot commit to pursuing the legislative change we recommended at this time because it has not yet had sufficient time to assess the impact of recent changes to the Medicaid prescription drug program required by the Deficit Reduction Act of 2005. CMS agreed to consider our recommendation when it considers future legislative proposals.

If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact George M. Reeb, Assistant Inspector General for the Centers for Medicare & Medicaid Audits, at (410) 786-7104 or through e-mail at George.Reeb@oig.hhs.gov. Please refer to report number A-06-07-00042 in all correspondence.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF GENERIC DRUG PRICE INCREASES

Daniel R. Levinson
Inspector General

October 2007
A-06-07-00042

Office of Inspector General

http://oig.hhs.gov

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The designation of financial or management practices as questionable or a recommendation for the disallowance of costs incurred or claimed, as well as other conclusions and recommendations in this report, represent the findings and opinions of the HHS/OIG/OAS. Authorized officials of the HHS divisions will make final determination on these matters.

EXECUTIVE SUMMARY

BACKGROUND

Medicaid Drug Rebate Program

The Medicaid drug rebate program became effective on January 1, 1991, pursuant to section 1927 of the Social Security Act (the Act). For a covered outpatient drug to be eligible for Federal Medicaid funding, the 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. During the period covered by our review, section 1927(b)(3) of the Act required 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 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 noninnovator (generic) drugs.

Objective

Our objective was to determine the extent to which generic drug price increases have exceeded the specified statutory inflation factor.

FINDINGS AND RECOMMENDATION

Generic drug price increases exceeded the specified statutory inflation factor applicable to brand-name drugs for 35 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. By applying the method in the Act for calculating additional rebates on brand-name drugs to generic drugs, we calculated that the Medicaid program 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 recommend that CMS consider seeking legislative authority to extend the additional rebate provisions to generic drugs.

CENTERS FOR MEDICARE & MEDICAID SERVICES'S COMMENTS

In its comments on our draft report, CMS agreed to consider our recommendation as it considers future legislative proposals. The full text of CMS's comments is included as the Appendix.

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INTRODUCTION

BACKGROUND

Medicaid Drug Rebate Program

The Medicaid drug rebate program became effective on January 1, 1991, pursuant to section 1927 of the Social Security Act (the Act). For a covered outpatient drug to be eligible for Federal Medicaid funding, the 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. During the period covered by our review, section 1927(b)(3) of the Act required a participating manufacturer to report quarterly to CMS the average manufacturer price (AMP) and, if applicable, the best price for each covered outpatient drug.

CMS uses the AMP and, in some cases, the best price to calculate a unit rebate amount (URA) for each drug. Section 1927(c)(1) defines a basic rebate amount for single source and innovator multiple source drugs (collectively, "brand-name drugs") as the greater of the difference between the AMP and the best price or a specified percentage of the AMP, which has been 15.1 percent since January 1, 1996. Section 1927(c)(3) defines the URA for noninnovator (generic) drugs as 11 percent of the AMP.

Section 1927(c)(2) requires manufacturers to pay an additional rebate when the AMP for a brand-name drug increases 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 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 ending 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.

President's Budgetary Proposal for Fiscal Year 2001

The President's budget request for fiscal year 2001 contained a proposal that would have extended the additional rebate provision to generic drugs. The Congressional Budget Office estimated that the proposal would have saved $800 million over 10 years. The proposal was not implemented.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine the extent to which generic drug price increases have exceeded the specified statutory inflation factor.

Scope

We obtained and reviewed a list of the top 200 generic drugs (top 200 generics), ranked by Medicaid reimbursement, for each year from 1991 through 2004.[1] Our objective did not require that we identify and review any internal control systems.

Methodology

To accomplish our objective, we:

- reviewed section 1927 of the Act;
- reviewed CMS guidance on the URA calculation;
- obtained from CMS a list of the top 200 generics, in terms of Medicaid reimbursements, for each year from 1991 through 2004;
- obtained market date, AMP, best price, URA, consumer price index for urban consumers values, and utilization from CMS for the top 200 generics for each year;
- assigned a baseline AMP to each generic drug in our review based on the AMP for the second quarter the drug was on the market;
- compared each quarterly AMP to the inflation-adjusted baseline AMP;
- calculated an additional rebate amount for the top 200 generics, 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; and
- applied the additional rebate amount for each of the top 200 generics to the utilization of the drug to determine a total dollar amount of additional rebates for generic drugs.

We performed our review in accordance with generally accepted government auditing standards.

[1]We obtained this list from CMS. A total of 772 drugs were in the top 200 generics at least once during the 14 years.

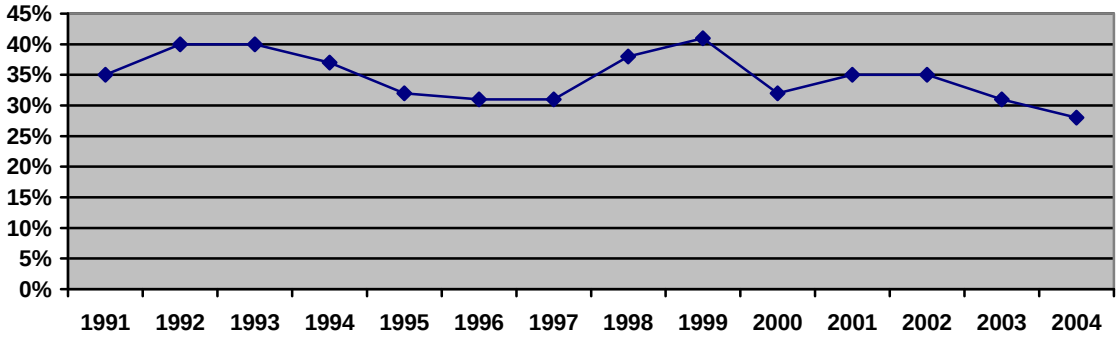
FINDINGS AND RECOMMENDATION

Generic drug price increases exceeded the specified statutory inflation factor applicable to brand-name drugs for 35 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. By applying the method in the Act for calculating additional rebates on brand-name drugs to generic drugs, we calculated that the Medicaid program would have received a total of $966 million in additional rebates for the top 200 generics, ranked by Medicaid reimbursement, from 1991 through 2004.

GENERIC PRICE INCREASES

For the top 200 generics, 35 percent of the quarterly AMPs exceeded their inflation-adjusted baseline AMPs.[2] For 523 of the 772 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 100 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 percent of quarterly AMPs that exceeded their inflation-adjusted baseline AMPs each year from 1991 to 2004.

Percent 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 40 percent for all 54 of the quarters in our review.[3] In another example, one drug had quarterly AMPs that exceeded the inflation-adjusted AMPs by an average of 53 percent for all 22 of the quarters that the drug was in the top 200 generics.

[2]CMS determines Medicaid drug rebates quarterly. We reviewed information on the top 200 generics for all four quarters of each year; however, not all 200 had utilization or Medicaid drug rebate information for all four quarters of each year.

[3]We determined baseline information based on the second quarter a drug was on the market. For drugs on the market when the rebate program began, we began our review for the second quarter of 1991 and looked at a total of 54 quarters from the third quarter of 1991 through the fourth quarter of 2004.

ADDITIONAL REBATES

Using the method in the Act for calculating the additional rebate on brand-name drugs, we calculated additional rebates for the yearly top 200 generics in our review. The additional rebates totaled $966 million from 1991 through 2004. The additional rebates for the top 200 generics increased most years, from more than $4 million in 1991 to more than $151 million in 2004. The table below shows the annual amount of additional rebates, actual rebates, and percentage increases in rebates for the top 200 generics.

Calculated Additional Rebates and Actual Rebates for the Top 200 Generic Drugs 1991–2004

Year	Calculated Additional Rebates	Actual Rebates	Percentage Increase in Rebates
1991	$4,121,324	$21,766,915	19%
1992	16,589,099	27,813,999	60%
1993	29,470,249	34,476,275	85%
1994	40,643,737	39,279,335	103%
1995	47,805,812	44,482,024	107%
1996	62,452,669	44,029,230	142%
1997	65,504,220	47,121,700	139%
1998	93,019,527	48,885,496	190%
1999	85,501,693	48,007,739	178%
2000	65,424,060	49,847,262	131%
2001	95,784,852	71,888,361	133%
2002	106,853,451	83,665,873	128%
2003	101,571,893	85,383,928	119%
2004	151,077,044	100,891,678	150%
Total	**$965,819,630**	**$747,539,815**	**129%**

RECOMMENDATION

We recommend that CMS consider seeking legislative authority to extend the additional rebate provisions to generic drugs.

CENTERS FOR MEDICARE & MEDICAID SERVICES'S COMMENTS

In its comments on our draft report, CMS said that the report provides evidence that additional rebates would be payable if the inflation-based rebate provision were applied to generic drugs. However, CMS said that it cannot commit to pursuing the legislative change we recommended at this time because it has not yet had sufficient time to assess the impact of recent changes to the Medicaid prescription drug program required by the Deficit Reduction Act of 2005. CMS agreed to consider our recommendation when it considers future legislative proposals.

The full text of CMS's comments is included as the Appendix.

APPENDIX

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Office of the Administrator
Washington, DC 20201

DATE: SEP 1 0 2007

TO: Daniel R. Levinson
Inspector General

FROM: Kerry Weems
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Review of Generic Drug Price Increases" (A-06-07-00042)

Thank you for the opportunity to review and comment on the Office of Inspector General's (OIG) draft report entitled "Review of Generic Drug Price Increases." This report provides evidence that additional rebates would be payable if the inflation-based rebate provision is applied to generic drugs. Legislation would be needed to extend the inflation-based rebate provisions to generic drugs.

In light of recent changes implemented by the Deficit Reduction Act of 2005 (DRA), the Centers for Medicare & Medicaid Services (CMS) cannot commit to pursuing the legislative change recommended by OIG at this time. CMS will consider OIG's recommendation as we consider legislative proposals in the future.

The OIG findings and recommendations and the CMS responses are as follows:

OIG Findings

Overall, prices for generic drugs exceeded increases in the CPI-U for 35 percent of the generic drugs reviewed by the OIG. If the additional rebate had been applied to generic drugs, the Medicaid program would have received additional rebates of $966 million for the top 200 generic drugs, ranked by Medicaid reimbursement, from 1991 through 2004.

For 532 of the 772 drugs reviewed, the quarterly AMPs exceeded the inflation-adjusted baseline AMP in at least one quarter. One hundred drugs had quarterly AMPs exceeding their inflation–adjusted baseline AMPs for every quarter of the review. 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 AMP by an average of 40 percent for every quarter of the 14 years reviewed. In another example, one drug had quarterly AMPs that exceeded the inflation-adjusted AMPs by an average of 53 percent for all 22 of the quarters that the drug was in the top 200 generic drugs, ranked by Medicaid reimbursement.

Using the method for calculating the additional rebates for brand name drugs, the OIG calculated that the additional rebates that would have been due for the top 200 generics increased most years, from more than $4 million in 1991 to more than $151 million in 2004.

OIG Recommendation

CMS should consider seeking legislation to extend the additional rebate provision to generic drugs.

CMS Response

The CMS will consider OIG's recommendation as we consider legislative proposals in the future. The DRA included major changes to the Medicaid prescription drug program. The final rule implementing these changes was published in the **Federal Register** on July 17, 2007. We have not yet had sufficient time to assess the impact of these changes and need to do so before seeking additional changes to the program.

Again we thank you for the opportunity to review and comment on the subject draft report.