March 11, 2010

TO: Charlene Frizzera
Acting Administrator
Centers for Medicare & Medicaid Services

FROM: /Daniel R. Levinson/
Inspector General

SUBJECT: Review of Additional Rebates for Brand-Name Drugs With Multiple Versions (A-06-09-00033)

The attached final report provides the results of our review of additional rebates of brand-name drugs with multiple versions.

The Medicaid drug rebate program became effective on January 1, 1991, pursuant to section 1927 of the Social Security Act (the Act). For a manufacturer's 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. The Act requires manufacturers to pay an additional rebate when the average manufacturer price (AMP) for a brand-name drug increases more than inflation.

Rebates, including additional rebates, are calculated separately for each different strength and dosage form (version) of a drug. Accordingly, manufacturers could circumvent paying additional rebates by developing new versions of existing brand-name drugs for which price increases have exceeded inflation. The manufacturers could bring the new versions to market at higher prices but would not have to pay additional rebates on the new versions unless subsequent price increases exceeded inflation.

Our objectives were to determine the number of the top 150 brand-name drugs, ranked by Medicaid reimbursement, having multiple versions and their potential impact on the additional rebate component of the Medicaid drug rebate program.

Of the top 150 brand-name drugs for calendar year 2007 ranked by Medicaid reimbursement, 114 had more than one version. For 65 of the 114, the prices of the earliest versions of the drugs exceeded their inflation-adjusted prices when the new versions entered the market. We calculated that for calendar years 1993 through 2007, States could have collected approximately $2.5 billion in additional rebates for the 65 brand-name drugs if the baseline AMPs of the new

versions had been adjusted (i.e., reduced) to reflect price increases in excess of inflation for the earliest versions.

We did not evaluate the drug manufacturers' bases for developing the new versions of existing drugs identified in our review. Drug manufacturers may have had valid reasons to seek approval from the Food and Drug Administration for these new versions. However, because the Medicaid drug rebate program calculates rebates separately for each version of a drug, manufacturers could develop new versions of existing brand-name drugs solely to avoid paying additional rebates when they substantially increase prices. Without some modification to the rebate law, the risk of manufacturers taking advantage of this potential loophole may increase over time. We recommend that CMS continue to seek legislative authority to modify the present rebate formula calculation to ensure that manufacturers cannot circumvent paying additional rebates by bringing new versions of existing brand-name drugs to market. In comments on our draft report, CMS concurred with our findings and recommendation.

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that the Office of Inspector General (OIG) post its publicly available reports on the OIG Web site. Accordingly, this report will be posted at http://oig.hhs.gov.

Please send us your final management decision, including any action plan, as appropriate, within 60 days. 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 email at George.Reeb@oig.hhs.gov. Please refer to report number A-06-09-00033 in all correspondence.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF ADDITIONAL REBATES FOR BRAND-NAME DRUGS WITH MULTIPLE VERSIONS

Daniel R. Levinson
Inspector General

March 2010
A-06-09-00033

Office of Inspector General

http://oig.hhs.gov

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

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

EXECUTIVE SUMMARY

BACKGROUND

The Medicaid drug rebate program became effective on January 1, 1991, pursuant to section 1927 of the Social Security Act (the Act). For a manufacturer's 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. Section 1927(b)(3) of the Act requires a participating manufacturer to report to CMS the average manufacturer price (AMP) and, if applicable, the best price for each covered outpatient drug.

Section 1927(c)(1) defines a basic rebate amount for each unit of their 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)(2) requires manufacturers to pay an additional rebate when the AMP for a brand-name drug increases more than inflation. 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 Food and Drug Administration (FDA) regulates and controls new drugs through the new drug application (NDA) process. New drugs include new molecular entities, which contain active ingredients previously not approved for marketing in any form in the United States, and new dosage forms or strengths ("versions" in this report) of an active ingredient previously approved for marketing in the United States. To market a new molecular entity, a drug manufacturer must submit a new NDA. However, new versions of currently marketed drugs may be approved through a supplemental application to a previous NDA.

Rebates, including additional rebates, are calculated separately for each different version of a drug. Accordingly, manufacturers could circumvent paying additional rebates by developing new versions of existing brand-name drugs for which price increases have exceeded inflation. The manufacturers could bring the new versions to market at higher prices but would not have to pay additional rebates on the new versions unless subsequent price increases exceeded inflation.

OBJECTIVES

Our objectives were to determine the number of the top 150 brand-name drugs, ranked by Medicaid reimbursement, having multiple versions and their potential impact on the additional rebate component of the Medicaid drug rebate program.

SUMMARY OF RESULTS

Of the top 150 brand-name drugs for calendar year 2007 ranked by Medicaid reimbursement, 114 had more than one version. For 65 of the 114, the prices of the earliest versions of the drugs exceeded their inflation-adjusted prices when the new versions entered the market. We

calculated that from calendar years 1993 through 2007, States could have collected approximately $2.5 billion in additional rebates for the 65 brand-name drugs if the baseline AMPs of the new versions had been adjusted (i.e., reduced) to reflect price increases in excess of inflation for the earliest versions.

CONCLUSION

We did not evaluate the drug manufacturers' basis for developing the new versions of existing drugs identified in our review. Drug manufacturers may have many valid reasons to seek approval from FDA for these new versions. However, because the Medicaid drug rebate program calculates rebates separately for each version of a drug, manufacturers could develop new versions of existing brand-name drugs solely to avoid paying additional rebates when they substantially increase prices. Without some modification to the rebate law, the risk of manufacturers taking advantage of this potential loophole may increase over time.

RECOMMENDATION

We recommend that CMS continue to seek legislative authority to modify the present rebate formula calculation to ensure that manufacturers cannot circumvent paying additional rebates by bringing new versions of existing brand-name drugs to market.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In comments on our draft report, CMS concurred with our findings and recommendation. CMS said that it will continue to work with Congress to seek a legislative change. CMS's comments are included in their entirety as Appendix D.

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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 manufacturer's 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. Section 1927(b)(3) of the Act requires a participating manufacturer to report 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 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 unit rebate amount 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 inflation. 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.

Pursuant to section 1927(c)(2), the baseline AMP for a brand-name drug that was on the market when the Act was passed is the AMP for the quarter ending September 30, 1990. The baseline AMP for a drug that entered the market after October 1, 1990, is generally the AMP in effect for the quarter after it entered the market. The baseline AMP for each drug is indexed to the consumer price index for urban consumers (CPI-U) for the appropriate quarter. The baseline AMP is adjusted each quarter by the percentage change in the consumer price index.

Food and Drug Administration's Role

The Food and Drug Administration (FDA) regulates and controls new drugs through the new drug application (NDA) process. According to the Food, Drug, and Cosmetic Act, section 201(p) [21 U.S.C. § 321(p)], the term "new drug" means:

> (1) any drug . . . the composition of which is such that such drug is not generally recognized, . . . as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . . ; or . . . (2) [a]ny drug . . . the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent for a material time under such conditions.

This definition includes new molecular entities, which contain active ingredients previously not approved for marketing in any form in the United States, and new forms or strengths ("versions" in this report) of an active ingredient previously approved for marketing in the United States. To market a new molecular entity, a drug manufacturer must submit a new NDA. However, new versions of currently marketed drugs may be approved through a new NDA or a supplemental application to a previous NDA. In fiscal year (FY) 2008, only 31 of 128 NDAs that FDA received were for new molecular entities.

The FDA officials indicated that manufacturers could have various reasons for seeking approval to market new versions of previously approved drugs, including drug improvements, marketing purposes, product line extensions, and exclusive marketing rights extensions.

Potential Rebate Loophole and Budgetary and Legislative Proposals

Rebates, including additional rebates, are calculated separately for each different version of a drug. Manufacturers could circumvent paying additional rebates by developing new versions of existing brand-name drugs for which price increases have exceeded inflation. Manufacturers could bring the new versions to market with higher prices but would not have to pay additional rebates on the new drug versions unless subsequent price increases exceeded inflation.

The President's budget request for FY 2010, the Congressional Budget Office's (CBO) *Budget Options, Volume I—Health Care* (December 2008), and legislation pending in the House of Representatives (H.R. 3200) and Senate (Chairman's Mark, America's Healthy Future Act of 2009), as of September 16, 2009, acknowledge this loophole:

- The President's budget addresses "the current loophole that enables drug manufacturers to circumvent the additional rebate by creating new formulations of drugs and charging higher initial prices for these drugs" and recommends applying the Medicaid additional rebate to new formulations of existing drugs. For FY 2010, CMS estimated the cost savings of this proposal to be $150 million. Cumulative savings by FY 2014 could be approximately $1.3 billion, and by FY 2019, the cumulative cost savings could be approximately $3.0 billion.

- CBO published a budget option regarding new extended-release versions of existing drugs. The additional rebate obligation for a new drug would be the greater of the AMP percentage that is owed for the new drug or the AMP percentage that is owed for the original drug. CBO estimated potential savings of $130 million for FY 2010, approximately $1.3 billion in cumulative cost savings for FYs 2010 through 2014, and approximately $3.0 billion for FYs 2010 through 2019.

- H.R. 3200 is sponsored by Representative John D. Dingell and cosponsored by eight representatives. H.R. 3200 would amend the current rebate law to allow additional rebates on new extended-release versions of existing drugs.

- A Senate bill, America's Healthy Future Act, has been proposed by Senator Max Baucus. The bill proposes that the additional rebate obligation for a new version of an existing drug be calculated using the baseline AMP of the original drug.

OBJECTIVES, SCOPE, AND METHODOLOGY

Objectives

Our objectives were to determine the number of the top 150 brand-name drugs, ranked by Medicaid reimbursement, having multiple versions and their potential impact on the additional rebate component of the Medicaid drug rebate program.

Scope

We reviewed the top 150 brand-name drugs for calendar year (CY) 2007 ranked by Medicaid reimbursement. We identified brand-name drugs using the brand name and innovator fields in the National Drug Data File Plus.[1] We focused our review on brand-name drugs with multiple versions and the potential additional rebates of those brand-name drugs that States could have collected from the inception of the Medicaid drug rebate program through CY 2007.

We did not evaluate the drug manufacturers' reasons for developing new versions of existing drugs.

Our objective did not require that we identify or review any internal controls.

Methodology

To accomplish our objectives, we:

- reviewed laws and CMS guidance regarding the Medicaid drug rebate program;
- interviewed FDA representatives;
- reviewed FDA guidance on the NDAs;
- identified the unique drug names in the National Drug Data File Plus that were classified as brand-name drugs;[2]
- identified the top 150 brand-name drugs for CY 2007 based on CMS's State Medicaid Utilization Data;

[1]The National Drug Data File Plus, maintained by First DataBank, Inc., includes a brand name and an innovator indicator for every drug approved by FDA. The brand name is the name that appears on the package label provided by the manufacturer. The innovator indicator identifies whether the drug is a generic or a brand-name drug.

[2]We considered drugs with variations of the same brand name (e.g., drug ABC and ABC XR, for which the "XR" represented extended release) to be the same drug if they had the same active chemical ingredients.

- obtained from CMS pricing, rebate, and utilization information for the top 150 brand-name drugs;

- identified top brand-name drugs with more than one version;

- eliminated from consideration new versions entering the market within 1 year of the earliest versions;

- determined whether additional rebates were applicable by identifying the new drug versions that entered the market when the earliest versions' quarterly AMPs were greater than the inflation-adjusted baseline AMPs;

- calculated a modified baseline quarterly AMP for each of the new versions identified above;

- calculated the additional rebate amounts based on the modified baseline quarterly AMPs for each quarter that the new versions were on the market; and

- calculated the monetary effect of the modified baseline quarterly AMPs on the additional rebates for each quarter affected from CYs 1993 to 2007.

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.

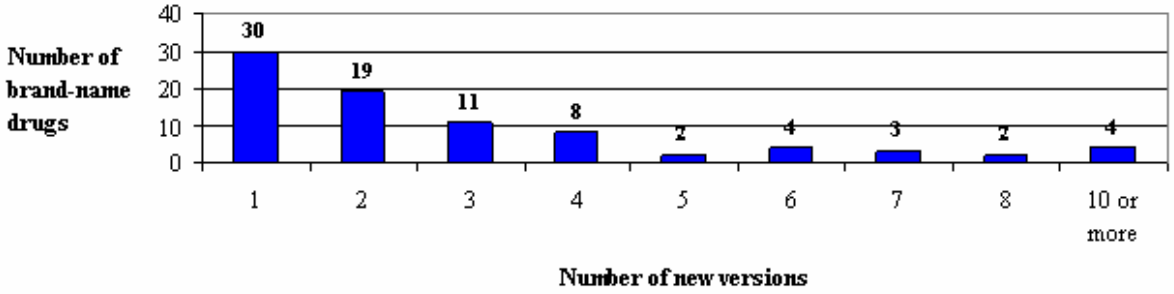
RESULTS OF REVIEW

Of the top 150 brand-name drugs for CY 2007 ranked by Medicaid reimbursement, 114 had more than one version. For 65 of the 114, the prices of the earliest versions of the drugs exceeded their inflation-adjusted prices when the new versions entered the market. We calculated that for CYs 1993 through 2007, States could have collected approximately $2.5 billion in additional rebates for the 65 brand-name drugs if the baseline AMPs of the new versions had been adjusted (i.e., reduced) to reflect price increases in excess of inflation for the earliest versions.

BRAND-NAME DRUGS WITH MORE THAN ONE VERSION

Of the top 150 brand-name drugs for CY 2007 ranked by Medicaid reimbursement, 114 had more than one version. Eighty-three of the brand-name drugs had at least one new version with a market entry date more than a year after the earliest versions were marketed. While 49 of the 83 brand-name drugs had only 1 or 2 new versions, 15 drugs had 5 or more new versions. Table 1 provides a breakdown of the number of new versions associated with the 83 brand-name drugs.

Table 1: Brand-Name Drugs With New Versions



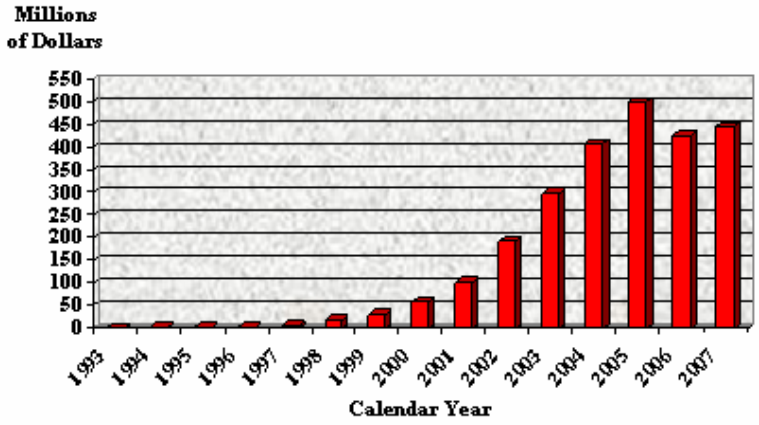
The time between the market entry dates of the earliest versions and the new versions for the 83 brand-name drugs ranged from approximately 1 year to 15½ years. The average length of time between market entry dates was more than 5½ years. The manufacturers of 10 of the 83 brand-name drugs brought new versions to the market more than 10 years after the earliest versions had been marketed. Appendix A shows the time between manufacturers' placement of the earliest versions of the 83 brand-name drugs on the market and their placement of the new versions on the market.

POTENTIAL IMPACT OF NEW DRUG VERSIONS ON ADDITIONAL REBATES

The prices of the earliest versions of 65 of the top 150 drugs exceeded their inflation-adjusted prices when new versions of the drugs entered the market. The prices of the earliest versions averaged 18.8 percent more than their inflation-adjusted prices. The average price in excess of the inflation-adjusted price was significantly higher when the new versions were marketed more than 10 years after the earliest versions. For 9 of the 65 brand-name drugs with new versions marketed more than 10 years later, the prices of the earliest versions exceeded their inflation-adjusted prices by an average of nearly 42 percent.

We calculated that, for CYs 1993 through 2007, States would have collected approximately $2.5 billion in additional rebates for the 65 brand-name drugs if the baseline AMPs of the new versions had been lowered by the percentage that the earliest versions exceeded their inflation-adjusted prices. With actual rebates over the period approaching $6 billion, the additional $2.5 billion represented what would have been a nearly 42-percent increase in rebates for the new versions. Table 2 shows the potential annual impact on the rebate program. (Appendix B provides the potential rebate amounts for each of the 65 brand-name drugs for CYs 1993 through 2007.)

Table 2: Potential Impact by Year



Appendix C provides a hypothetical example to illustrate our calculation of the modified baseline AMP for a new version of a previously approved drug. We developed that example based on the following assumptions:

A. Baseline AMP of the earliest version at the inception of the drug rebate program = $1.00
B. AMP of the earliest version when the new drug version was introduced = $2.00
C. Baseline AMP of new drug version, first marketed December 1996 = $3.00
D. CPI-U for baseline quarter of the earliest version = 132.7
E. CPI-U for first quarter of CY 2007 = 158.6

From these assumptions, we could calculate the following:

F. Inflation-adjusted baseline AMP for earliest version = (A / D) × E or ($1.00 / 132.7) × 158.6 = $1.20
G. Modified baseline AMP for new version = C – ([(B – F) / B] × C) or $3.00 – ([($2.00 – $1.20) / $2.00] × $3.00) = $1.80
H. Additional rebate for new version = C – G = $3.00 – $1.80 = $1.20

The additional rebate using the modified baseline AMP would have been $1.20. Under current law, no additional rebate is due on the new version of a drug when it is put on the market.

CONCLUSION

We did not evaluate the drug manufacturers' bases for developing the new versions of existing drugs identified in our review. Drug manufacturers may have had valid reasons to seek approval from FDA for these new versions. However, because the Medicaid drug rebate program calculates rebates separately for each version of a drug, manufacturers could develop new versions of existing drugs solely to avoid paying additional rebates when they substantially increase prices. Without some modification to the rebate law, the risk of manufacturers taking advantage of this potential loophole may increase over time.

RECOMMENDATION

We recommend that CMS continue to seek legislative authority to modify the present rebate formula calculation to ensure that manufacturers cannot circumvent paying additional rebates by bringing new versions of existing brand-name drugs to market.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In comments on our draft report, CMS concurred with our findings and recommendation. CMS said that it will continue to work with Congress to seek a legislative change. CMS's comments are included in their entirety as Appendix D.

APPENDIXES

APPENDIX A: TIME BETWEEN EARLIEST DRUG VERSIONS AND NEW VERSIONS

Drug Number[1]	Number of Earliest Versions	Base Calendar Year/ Quarter	Number of New Versions	Less Than 2 Years	2 Years Through Less Than 5 Years	5 Years Through Less Than 10 Years	10 or More Years
1	4	1994/2	12	0	1	8	3
2	3	1998/1	3	0	1	2	0
3	4	2003/1	6	0	6	0	0
4	2	1998/2	2	0	1	1	0
5	3	1996/4	7	0	4	3	0
6	2	1995/3	5	0	0	5	0
7	4	1990/4	2	0	0	0	2
8	2	1996/2	16	4	6	6	0
9	3	2001/3	3	0	0	3	0
10	2	2000/4	1	1	0	0	0
11	1	1998/4	3	1	0	2	0
12	4	1995/2	2	0	2	0	0
13	3	1997/2	3	2	0	1	0
14	4	2001/2	2	0	0	2	0
15	2	1997/2	1	0	1	0	0
16	2	2002/4	1	1	0	0	0
17	5	2003/1	2	0	2	0	0
18	4	2001/2	1	1	0	0	0
19	5	1994/2	3	0	3	0	0
20	1	1998/2	4	0	2	2	0
21	2	2000/3	3	0	1	2	0
22	3	2000/2	1	1	0	0	0
23	3	2002/2	4	0	4	0	0
24	3	2005/2	1	0	1	0	0
25	2	1999/3	2	0	1	1	0
26	2	1993/2	2	0	0	0	2
27	2	1990/4	5	0	0	2	3
28	3	2003/4	1	0	1	0	0
29	1	1998/4	1	0	0	1	0
30	2	2000/4	1	0	0	1	0
31	2	1999/3	1	0	1	0	0
32	1	1999/1	3	0	0	3	0
33	1	1993/3	7	0	1	6	0
34	5	1997/2	4	0	3	1	0

[1]This is a number that we assigned to 83 of the top 150 brand-name drugs that contained at least one new version with a market date more than 1 year after the earliest versions. It does not indicate rank within the top 150.

Drug Number	Number of Earliest Versions	Base Calendar Year/ Quarter	Number of New Versions	Less Than 2 Years	2 Years Through Less Than 5 Years	5 Years Through Less Than 10 Years	10 or More Years
35	1	1995/1	2	0	2	0	0
36	3	1994/3	1	0	1	0	0
37	2	1994/2	2	0	1	1	0
38	1	1993/2	8	0	4	0	4
39	1	1995/4	1	1	0	0	0
40	2	1999/2	2	0	1	1	0
41	1	1993/1	1	0	0	1	0
42	1	1995/3	3	0	3	0	0
43	1	1998/3	4	0	1	3	0
44	2	2001/4	1	1	0	0	0
45	4	1991/3	1	0	0	0	1
46	1	1996/2	1	0	1	0	0
47	1	1990/4	2	0	1	1	0
48	1	2003/1	1	1	0	0	0
49	1	2000/3	1	1	0	0	0
50	2	1996/1	4	1	0	3	0
51	1	1996/4	2	0	2	0	0
52	2	1998/3	2	0	2	0	0
53	1	2003/2	1	0	1	0	0
54	1	2001/4	1	0	1	0	0
55	2	1992/2	2	0	0	2	0
56	2	1997/3	2	0	2	0	0
57	1	2000/4	1	0	0	1	0
58	5	1990/4	6	0	0	0	6
59	5	2002/1	31	4	27	0	0
60	1	1991/2	4	0	2	2	0
61	3	1998/4	1	0	1	0	0
62	1	2001/3	7	0	7	0	0
63	3	1991/2	1	0	0	1	0
64	1	1996/3	1	0	0	1	0
65	2	1998/2	3	0	1	2	0
66	5	1997/4	2	0	0	2	0
67	1	1996/2	11	1	10	0	0
68	3	1992/2	1	0	0	1	0
69	3	1995/4	3	0	0	1	2
70	4	1990/4	4	0	0	0	4
71	3	1990/4	3	0	0	3	0
72	2	1993/2	6	0	2	4	0
73	2	1995/3	1	0	1	0	0

Drug Number	Number of Earliest Versions	Base Calendar Year/ Quarter	Number of New Versions	Less Than 2 Years	2 Years Through Less Than 5 Years	5 Years Through Less Than 10 Years	10 or More Years
74	2	1998/2	1	0	0	1	0
75	1	1990/4	8	0	0	8	0
76	4	1992/2	1	0	0	1	0
77	2	1997/1	2	0	0	2	0
78	1	1990/4	1	0	0	1	0
79	1	2002/2	4	2	2	0	0
80	2	1990/4	2	0	0	1	1
81	5	1997/4	2	1	1	0	0
82	1	1990/4	6	0	0	6	0
83	2	2002/2	1	0	1	0	0

APPENDIX B: POTENTIAL ADDITIONAL REBATES

Drug Number[1]	Base Calendar Year/Quarter	Number of New Versions	Quarters Affected	Monetary Impact Through 2007
27	1990/4	5	129	$428,918,065
8	1996/2	16	246	410,346,160
1	1994/2	11	173	299,327,309
7	1990/4	2	47	254,679,454
2	1998/1	3	39	104,145,429
72	1993/2	6	184	89,788,212
75	1990/4	8	259	89,370,136
19	1994/2	3	117	82,650,997
38	1993/2	8	210	61,741,263
47	1990/4	2	101	60,103,070
5	1996/4	5	107	58,471,434
50	1996/1	4	109	55,303,210
20	1998/2	4	60	48,941,698
11	1998/4	2	15	44,254,869
66	1997/4	2	16	34,916,357
13	1997/2	3	83	34,685,216
26	1993/2	2	16	33,154,904
78	1990/4	1	38	29,823,675
70	1990/4	4	73	26,479,218
32	1999/1	3	16	26,108,176
58	1990/4	6	52	20,295,054
41	1993/1	1	20	18,926,261
23	2002/2	4	31	17,219,244
4	1998/2	2	47	15,167,289
62	2001/3	7	64	13,632,326
56	1997/3	2	54	10,804,166
65	1998/2	3	31	10,145,857
63	1991/2	1	37	10,136,646
52	1998/3	2	37	9,398,876
21	2000/3	3	25	8,795,362
10	2000/4	1	21	8,638,831
71	1990/4	3	131	7,682,184
68	1992/2	1	22	6,483,317
29	1998/4	1	9	6,439,137
80	1990/4	1	43	6,136,552
36	1994/3	1	34	5,612,525
33	1993/3	3	73	4,425,987
73	1995/3	1	32	4,345,518

[1]The drug numbers correspond to the numbers in Appendix A.

Drug Number	Base Calendar Year/Quarter	Number of New Versions	Quarters Affected	Monetary Impact Through 2007
12	1995/2	2	72	4,072,641
64	1996/3	1	16	3,792,787
28	2003/4	1	3	2,204,026
42	1995/3	3	99	2,184,221
51	1996/4	2	63	2,118,642
9	2001/3	3	9	2,105,706
25	1999/3	2	32	2,003,783
3	2003/1	6	31	1,736,493
17	2003/1	2	12	1,401,704
74	1998/2	1	15	1,297,436
6	1995/3	2	39	1,046,419
39	1995/4	1	41	1,027,900
53	2003/2	1	4	820,411
49	2000/3	1	23	683,626
81	1997/4	2	57	560,107
45	1991/3	1	9	507,275
60	1991/2	2	66	444,588
54	2001/4	1	8	432,951
18	2001/2	1	12	388,215
79	2002/2	4	38	263,282
16	2002/4	1	11	170,356
83	2002/2	1	10	163,316
34	1997/2	1	11	41,314
55	1992/2	1	26	17,447
77	1997/1	2	16	15,641
24	2005/2	1	1	6,533
40	1999/2	1	2	508

APPENDIX C: BASELINE AVERAGE MANUFACTURER PRICE ADJUSTMENT METHODOLGY

We adjusted the baseline average manufacturer prices (AMP) of the new drug versions in our review when the AMPs of the earliest versions exceeded their inflation-adjusted AMPs. Following is a hypothetical example that demonstrates our methodology. When there was more than one earliest version, we lowered the baseline AMP of the new version by the average percentage that the AMPs for the earliest versions exceeded their inflation-adjusted AMPs.

	Earliest Version	**New Version**
Market date	09/30/1990	12/31/1996
Baseline quarter/calendar year (CY)	4/1990	1/1997
Baseline AMP	$1.00	$3.00
Baseline CPI-U	132.7	158.6
AMP for first quarter CY 1997	$2.00	$3.00
Earliest version inflation-adjusted AMP as of first quarter CY 1997		
($1.00 / 132.7) × 158.6		$1.20
Amount in excess of inflation-adjusted AMP for earliest version		
$2.00 – $1.20		$0.80
Percentage earliest version AMP exceeds inflation-adjusted AMP		
$0.80 / $2.00		40%
Adjusted baseline AMP for new version		
$3.00 – ($3.00 × 0.40)		$1.80

Under current law, the additional rebate for the new version is $0.00. Using the modified baseline AMP, the additional rebate would be $1.20 per unit.

CPI-U = consumer price index for urban consumers

APPENDIX D: CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: JAN 08 2010

TO: Daniel R. Levinson
Inspector General

FROM: Charlene Frizzera
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Review of Additional Rebates for Brand-Name Drugs with Multiple Versions" (A-06-09-00033)

Thank you for the opportunity to review and comment on the subject OIG draft report. In this draft report, the OIG determines the number of the top 150 brand-name drugs, ranked by Medicaid reimbursement, that have multiple dosage forms and strengths (versions) and their potential impact on the additional rebate component of the Medicaid drug rebate program.

Rebates, including additional rebates, are calculated separately for each different version of a drug. Manufacturers are required to pay an additional rebate when the average manufacturer price (AMP) for a brand-name drug increases more than inflation. 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. When a manufacturer owes an additional rebate on a drug, it could circumvent paying the additional rebate by developing a new version of an existing brand name drug and introducing the new version to the market at a higher price. The baseline AMP is reset to the new version of the drug and the manufacturer would not have to pay additional rebates unless subsequent price increases exceed inflation.

The OIG notes that the President's budget request for fiscal year 2010 and the 2008 Congressional Budget Office's Budget Options acknowledge this apparent loophole. Pending legislation seeks to address this issue.

OIG Findings

The OIG found that of the top 150 brand-name drugs for calendar year (CY) 2007 ranked by Medicaid reimbursement, 114 drugs had more than one version. Additionally, the OIG found that for 65 of the 114 brand name drugs, the prices of the earliest versions of the drug exceeded their inflation-adjusted prices when the new versions entered the market. The prices of the earliest versions average 18.8 percent more than their inflation-adjusted prices. For nine of the 65 brand-name drugs with new versions marketed more than 10 years later, the prices of the earliest versions exceeded their inflation adjusted prices by an average of nearly of 42 percent.

The OIG calculated that for CYs 1993 through 2007, States could have collected approximately $2.5 billion in additional rebates for the 65 brand-name drugs if the baseline AMPs of the new versions had been reduced to reflect price increases in excess of inflation for the earliest version. The additional $2.5 billion represented what would have been a nearly 42 percent increase in rebates for the new versions.

Recommendation

The OIG recommends that the Centers for Medicare & Medicaid Services (CMS) continue to seek legislative authority to modify the present rebate formula calculation to ensure that manufacturers cannot circumvent paying additional rebates by bringing new versions of existing brand-name drugs to market.

CMS Response

We concur. CMS will continue to work with Congress to seek a legislative change.

We appreciate the work of the OIG in this report and hope that the findings of this report will encourage Congress to close this potential loophole.