DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

OCT - 6 2011

The Honorable Herb Kohl
Chairman, Special Committee on Aging
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

I am writing in response to your September 7, 2011, letter in which you requested that the Office of Inspector General identify the potential savings associated with requiring manufacturers of Medicare Part B drugs to pay rebates similar to those under Medicaid. As your letter states, under the Omnibus Budget Reconciliation Act of 1990, pharmaceutical manufacturers are required to pay rebates for prescription drugs covered under Medicaid. However, a comparable rebate program does not exist for Medicare Part B.

On the basis of our analysis of 20 high-dollar Part B drugs, we estimate that Medicare and its beneficiaries would have potentially saved between $1.9 billion and $2.4 billion in 2010 if manufacturers of Part B drugs had been required to pay rebates similar to those under Medicaid for these 20 drugs. These savings represent 21 to 26 percent of the $9.2 billion that Medicare and its beneficiaries paid for the 20 drugs that year. These 20 drugs represent approximately 60 percent of Medicare Part B expenditures. Our estimates exclude any rebates that may have already been owed under Medicaid for drugs dispensed to beneficiaries covered under both programs (i.e., dual eligibles).

We have enclosed a document that provides background, methodology, and scope that need to be taken into account when interpreting our results. We also have included two tables showing the potential amounts that would have been owed in 2010 under each of the four different methods we used to estimate rebates. Two of the methods used the unit rebate amounts already determined under Medicaid, which are based on average manufacturer prices and best prices. The other two methods used unit rebate amounts that we calculated using manufacturer-reported average sales prices, which are the primary benchmarks used to set reimbursement under Medicare Part B.

If you have any questions or comments, please contact me or your staff may contact Chris Hinkle, Director of Congressional and Regulatory Affairs, at (202) 401-2206 or christina.hinkle@oig.hhs.gov.

Sincerely,

Daniel R. Levinson

Daniel R. Levinson
Inspector General

Enclosures

BACKGROUND, METHODOLOGY, AND SCOPE

Background

- Medicaid beneficiaries typically obtain covered drugs from pharmacies. In 2010, Medicaid drug expenditures totaled approximately $29 billion (not including rebates).

- In general, drug manufacturers must pay quarterly rebates to States for their drugs to be eligible for the Federal share of Medicaid payment. The unit rebate amount (URA) for a generic drug is 13 percent of the average manufacturer price (AMP). The basic URA for a brand-name drug is the greater of 23.1 percent of the AMP or the difference between the AMP and the best price. If the AMP for a brand-name drug has risen faster than inflation, then the manufacturer must also pay an additional URA besides the basic URA.

- Under Federal law, Medicaid should receive the full rebate from a manufacturer if it pays any portion of the drug claim, as may be the case with dual-eligible beneficiaries (i.e., beneficiaries covered by both Medicare and Medicaid).

- Part B-covered drugs generally fall into the following categories: drugs furnished incident to physicians' services (e.g., injectable drugs for treating cancer or macular degeneration); drugs explicitly covered by statute (e.g., some vaccines and oral anticancer drugs); and drugs used in conjunction with durable medical equipment (e.g., inhalation drugs).

- Medicare beneficiaries can receive Part B-covered drugs in several settings or from various sources, including physicians' offices and hospital outpatient departments, and from durable medical equipment suppliers. Medicare and its beneficiaries spent approximately $16 billion for all Part B drugs in 2010.

- Medicare Part B pays for most covered outpatient drugs using a reimbursement methodology based on manufacturer-reported average sales prices (ASP).

Methodology and Scope

- We purposively selected 20 drugs for our analysis, representing approximately 60 percent of Medicare Part B expenditures for prescription drugs in the fourth quarter of 2010. To estimate total Part B expenditures for each drug over the entire year, we assumed that expenditures were consistent from quarter to quarter and therefore multiplied fourth quarter expenditure figures by four.

- All 20 drugs are single-source (i.e., brand-name only) products. Part B drugs are billed and paid using Healthcare Common Procedure Coding System (HCPCS) codes, which do not identify the manufacturer. Therefore, we could not examine any HCPCS code representing a drug produced by more than one manufacturer (i.e., a multiple-source drug) because we would not have been able to determine the portion of the rebate owed by each manufacturer.

- Even for single-source drugs, a HCPCS code may represent multiple versions (i.e., dosages, package sizes) of a product marketed by the same manufacturer. We calculated rebate estimates using the lowest unit URA among all versions that matched the HCPCS code definition, as well as the volume-weighted average URA for the same versions.

- URAs based on AMPs were calculated by the Centers for Medicare & Medicaid Services (CMS) using manufacturer-reported AMP and best price data from the fourth quarter of 2010. The AMP-based URA includes the CMS-calculated additional rebate owed by a manufacturer if a drug's AMP increases faster than inflation.

- We calculated ASP-based rebates using manufacturer-reported ASP and best price data from the fourth quarter of 2010, employing the same method that CMS uses when calculating AMP-based URAs. We calculated an additional rebate based on inflation for the ASP-based URA. However, in certain cases, this additional rebate may have been nonexistent or considerably smaller than the AMP-based additional rebates. This could have occurred because a drug was already on the market prior to the implementation of ASPs in 2005 and therefore no ASP data were available for the drug's initial quarter of sales (the period from which an inflation-based rebate under Medicaid is calculated).

- To estimate the total rebates owed for each drug in the fourth quarter of 2010, we multiplied the quarterly URA calculated under each method by the fourth quarter 2010 Part B utilization. Any claims that we identified as being related to dual-eligible beneficiaries were removed from the Part B utilization figures under the assumption that rebates for these claims had already been paid. As previously stated, Medicaid should receive the full rebate from a manufacturer if it pays any portion of the drug claim, as may be the case with dual-eligibles.

- To estimate total rebates owed for each drug for the entire year, we multiplied the total rebates owed in the fourth quarter of 2010 under each method by four. The total rebates figure applies only to the 20 drugs under review; we did not calculate an estimate for all Part B drugs.

Table 1: Estimated 2010 Part B Rebates Using Lowest Unit Rebate Amounts (URA) for 20 High-Dollar Drugs

HCPCS Code	Drug Name	Total 2010 Part B Expenditures (Estimated)[1]	2010 Rebates Using Lowest AMP-Based URAs (Estimated)[2]	Percentage of Part B Dollars	2010 Rebates Using Lowest ASP-Based URAs (Estimated)[3]	Percentage of Part B Dollars
J2778	Ranibizumab, 0.1 mg inj	$1,281,367,527	$265,919,672	20.8%	$264,763,904	20.7%
J9310	Rituximab, 100 mg inj	$1,246,033,306	$561,171,541	45.0%	$273,798,209	22.0%
J9035	Bevacizumab, 10 mg inj	$995,870,105	$195,771,356	19.7%	$194,000,814	19.5%
J1745	Infliximab, 10 mg inj	$892,372,941	$169,924,641	19.0%	$165,707,238	18.6%
J2505	Pegfilgrastim, 6 mg inj	$858,571,747	$173,708,331	20.2%	$173,432,188	20.2%
J0881	Darbepoetin alfa, 1 mcg inj	$444,463,212	$81,892,999	18.4%	$79,908,516	18.0%
J9305	Pemetrexed, 10 mg inj	$419,152,874	$108,459,308	25.9%	$101,564,478	24.2%
J9355	Trastuzumab, 10 mg inj	$375,640,612	$132,120,684	35.2%	$69,796,601	18.6%
J9171	Docetaxel, 1 mg inj	$360,952,714	$76,755,221	21.3%	$73,010,639	20.2%
J3487	Zoledronic acid (Zometa), 1 mg inj	$326,334,712	$63,247,405	19.4%	$62,776,373	19.2%
J9041	Bortezomib, 0.1 mg inj	$284,116,717	$113,288,537	39.9%	$97,367,255	34.3%
J9055	Cetuximab, 10 mg inj	$241,931,065	$45,533,167	18.8%	$44,615,438	18.4%
J3488	Zoledronic acid (Reclast), 1 mg inj	$239,067,511	$47,550,108	19.9%	$46,935,903	19.6%
J0129	Abatacept, 10 mg inj	$227,913,161	$47,190,510	20.7%	$45,672,003	20.0%
J2353	Octreotide, 1 mg depot inj	$208,398,869	$106,746,042	51.2%	$42,430,538	20.4%
J9033	Bendamustine hcl, 1 mg inj	$186,877,280	$38,090,191	20.4%	$37,258,124	19.9%
J2469	Palonosetron hcl, 25 mcg inj	$182,109,591	$29,582,552	16.2%	$31,785,416	17.5%
J9025	Azacitidine, 1 mg inj	$173,704,021	$59,486,283	34.2%	$36,069,461	20.8%
J2785	Regadenoson, 0.1 mg inj	$173,354,063	$46,687,651	26.9%	$38,490,390	22.2%
J3285	Treprostinil, 1 mg inj	$112,861,036	$16,702,311	14.8%	$16,368,658	14.5%
Total for 20 High-Dollar Drugs		**$9,231,093,062**	**$2,379,828,511**	**25.8%**	**$1,895,752,144**	**20.5%**

Source: OIG analysis of Part B claims data, CMS Medicaid rebate data, and ASPs, 2011.

[1] Total Part B expenditures were calculated using fourth quarter 2010 figures for physician, outpatient hospital, and durable medical equipment claims and then extrapolated to the entire year.

[2] AMP-based rebates were calculated using CMS-calculated fourth quarter 2010 URAs and then extrapolated to the entire year.

[3] ASP-based rebates were calculated using OIG-calculated fourth quarter 2010 URAs and then extrapolated to the entire year.

Table 2: Estimated 2010 Part B Rebates Using Volume-Weighted Unit Rebate Amounts (URA) for 20 High-Dollar Drugs

HCPCS Code	Drug Name	Total 2010 Part B Expenditures (Estimated)[1]	2010 Rebates Using Average AMP-Based URAs (Estimated)[2]	Percentage of Part B Dollars	2010 Rebates Using Average ASP-Based URAs (Estimated)[3]	Percentage of Part B Dollars
J2778	Ranibizumab, 0.1 mg inj	$1,281,367,527	$265,919,672	20.8%	$264,763,904	20.7%
J9310	Rituximab, 100 mg inj	$1,246,033,306	$561,261,300	45.0%	$274,096,678	22.0%
J9035	Bevacizumab, 10 mg inj	$995,870,105	$195,928,541	19.7%	$194,028,687	19.5%
J1745	Infliximab, 10 mg inj	$892,372,941	$169,924,641	19.0%	$165,707,238	18.6%
J2505	Pegfilgrastim, 6 mg inj	$858,571,747	$173,708,331	20.2%	$173,432,188	20.2%
J0881	Darbepoetin alfa, 1 mcg inj	$444,463,212	$93,295,291	21.0%	$87,466,752	19.7%
J9305	Pemetrexed, 10 mg inj	$419,152,874	$124,381,206	29.7%	$115,479,207	27.6%
J9355	Trastuzumab, 10 mg inj	$375,640,612	$132,120,684	35.2%	$69,796,601	18.6%
J9171	Docetaxel, 1 mg inj	$360,952,714	$83,807,269	23.2%	$83,608,976	23.2%
J3487	Zoledronic acid (Zometa), 1 mg inj	$326,334,712	$63,247,405	19.4%	$62,776,373	19.2%
J9041	Bortezomib, 0.1 mg inj	$284,116,717	$113,288,537	39.9%	$97,367,255	34.3%
J9055	Cetuximab, 10 mg inj	$241,931,065	$45,581,110	18.8%	$44,665,664	18.5%
J3488	Zoledronic acid (Reclast), 1 mg inj	$239,067,511	$47,550,108	19.9%	$46,935,903	19.6%
J0129	Abatacept, 10 mg inj	$227,913,161	$47,190,510	20.7%	$45,672,003	20.0%
J2353	Octreotide, 1 mg depot inj	$208,398,869	$106,891,771	51.3%	$49,212,295	23.6%
J9033	Bendamustine hcl, 1 mg inj	$186,877,280	$38,103,013	20.4%	$37,273,905	19.9%
J2469	Palonosetron hcl, 25 mcg inj	$182,109,591	$36,217,162	19.9%	$35,662,110	19.6%
J9025	Azacitidine, 1 mg inj	$173,704,021	$59,486,283	34.2%	$36,069,461	20.8%
J2785	Regadenoson, 0.1 mg inj	$173,354,063	$46,687,651	26.9%	$38,490,390	22.2%
J3285	Treprostinil, 1 mg inj	$112,861,036	$31,696,604	28.1%	$16,369,841	14.5%
Total for 20 High-Dollar Drugs		**$9,231,093,062**	**$2,436,287,091**	**26.4%**	**$1,938,875,428**	**21.0%**

Source: OIG analysis of Part B claims data, CMS Medicaid rebate data, and ASPs, 2011.

[1] Total Part B expenditures were calculated using fourth quarter 2010 figures for physician, outpatient hospital, and durable medical equipment claims and then extrapolated to the entire year.

[2] AMP-based rebates were calculated using CMS-calculated fourth quarter 2010 URAs and then extrapolated to the entire year.

[3] ASP-based rebates were calculated using OIG-calculated fourth quarter 2010 URAs and then extrapolated to the entire year.