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MEDICARE COULD COLLECT BILLIONS IF PHARMACEUTICAL MANUFACTURERS WERE REQUIRED TO PAY REBATES FOR PART B DRUGS

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EXECUTIVE SUMMARY: MEDICARE COULD COLLECT BILLIONS IF PHARMACEUTICAL MANUFACTURERS WERE REQUIRED TO PAY REBATES FOR PART B DRUGS
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WHY WE DID THIS STUDY

Statutorily mandated rebates enabled Medicaid to recoup a substantial percentage of the $28 billion spent on prescription drugs in 2011. That same year, Medicare Part B expenditures exceeded $16 billion on prescription drugs; however, no similar rebate authority exists for Part B to reduce the costs of drugs to the program. In response to a congressional request, the Office of Inspector General (OIG) estimated in 2011 that if pharmaceutical manufacturers had been required to pay rebates similar to those under Medicaid for 20 high-expenditure Part B brand-name drugs, Medicare could have collected up to $2.4 billion in rebates, representing as much as 26 percent of expenditures for those drugs in 2010. Whereas our original analysis was limited to 20 brand-name drugs, this current study provides a more thorough examination of the potential collections associated with Part B rebates, as well as implementation issues.

HOW WE DID THIS STUDY

For each of the 60 Healthcare Common Procedure Coding System codes that represented 85 percent ($13.9 billion) of total 2011 Part B drug expenditures, we calculated how much manufacturers would have owed in rebates based on average manufacturer prices (AMP-based rebates) and average sales prices (ASP-based rebates). We reviewed previous OIG work and documented the methodological challenges we encountered in this study to identify issues that would need to be addressed before implementing a rebate program under Medicare Part B.

WHAT WE FOUND

Medicare could have collected $3.1 billion if pharmaceutical manufacturers had been required in 2011 to pay AMP-based rebates for 60 high-expenditure Part B drugs, representing 22 percent of spending for those drugs. Requiring manufacturers to pay ASP-based rebates for the same 60 drugs could have garnered Medicare $2.7 billion in rebate payments, representing 20 percent of spending. However, several implementation issues related to claims and data would need to be addressed if such a rebate program were implemented.

WHAT WE RECOMMEND

We recommend that the Centers for Medicare & Medicaid Services (CMS) examine the additional potential impacts of establishing a prescription drug rebate program under Medicare Part B and, if appropriate, seek legislative change. As part of its consideration, CMS should address administrative issues that may hinder rebate collections. CMS did not concur with our recommendation.

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OBJECTIVES

1. To calculate the total rebates that could have been collected in 2011 if manufacturers had been required to pay rebates for drugs covered under Medicare Part B.
2. To identify implementation issues that would need to be addressed if such rebates were required.

BACKGROUND

The Medicaid Drug Rebate Program was created to reduce State and Federal Medicaid expenditures for prescription drugs. In general, States cover prescription drugs produced by manufacturers that have entered into rebate agreements, and in turn, manufacturers are required to provide rebates on these drugs to the States. Under this program, Federal and State governments recouped $13 billion of the $28 billion spent by Medicaid on prescription drugs in 2011.[1] Medicare Part B spent $16.4 billion on prescription drugs that same year. However, unlike Medicaid, Medicare has no requirement for manufacturers to pay rebates, despite the fact that Medicare accounts for a substantial share of the market for the types of drugs covered under Part B.[2]

In 2011, Senator Herb Kohl requested that the Office of Inspector General (OIG) identify the potential savings associated with requiring manufacturers of Medicare Part B drugs to pay rebates similar to those under Medicaid. OIG responded to Senator Kohl in a letter dated October 6, 2011.[3] In this response, we estimated that a Part B rebate program could have recouped between 21 and 26 percent of expenditures in 2010 (up to $2.4 billion) for just 20 brand-name drugs. This current study provides a more current and complete picture by encompassing a larger number of drugs, including multiple-brand and generic products; updating rebate calculations based on 2011 data; and discussing possible implementation issues.

[1] Medicaid expenditures were calculated using data from the Centers for Medicare & Medicaid Services' (CMS) Medicaid Budget and Expenditures System.

[2] In 2010, Medicare spending accounted for the majority of total U.S. spending for 35 of the 55 highest-expenditure Part B drugs. See Government Accountability Office (GAO), *Medicare: High-Expenditure Part B Drugs*, GAO-13-46R, October 2012.

[3] Letter from Inspector General Daniel R. Levinson to Senator Herb Kohl, Chairman, Senate Special Committee on Aging. Accessed at http://www.aging.senate.gov/HHSOIG.pdf on October 11, 2012.

Medicare Part B Coverage of Prescription Drugs

Although Medicare Part D covers most outpatient prescription drugs, Medicare continues to cover a limited number of drugs and biologicals (hereinafter referred to collectively as drugs) under its Part B benefit. Part B-covered drugs generally fall into the following three categories: drugs furnished incident to a physician's service (e.g., injectable drugs used in connection with the treatment of cancer); 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).[4] Medicare beneficiaries can receive Part B drugs through physician offices; hospital outpatient departments; durable medical equipment (DME) suppliers; and, in certain specific instances, pharmacies.

Medicare Part B Payments for Prescription Drugs

CMS contracts with private companies to process and pay Medicare Part B claims, including those for prescription drugs. To obtain payment for covered drugs, providers submit claims to their Medicare contractors using Healthcare Common Procedure Coding System (HCPCS) codes. HCPCS codes provide a standardized system for describing specific items and services provided in the delivery of health care. In the case of prescription drugs, each HCPCS code defines the drug's name and the amount of drug represented by one unit of the HCPCS code but does not specify manufacturer or package size information.

Medicare and its beneficiaries spent $16.4 billion for Part B drugs in all settings in 2011.[5] Although Part B paid for more than 700 outpatient prescription drug HCPCS codes that year, most spending was concentrated on a relatively small subset, with 72 HCPCS codes accounting for 90 percent of total expenditures.

Payments in the physician office, supplier, and pharmacy settings. Medicare pays physicians, DME suppliers, and pharmacies for most Part B drugs using a methodology based on average sales prices (ASP).[6, 7]

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[4] 42 CFR § 414.900(b) and *Medicare Benefit Policy Manual*, Pub. No. 100-2, ch. 15, § 50.

[5] This estimate does not include Part B drugs used to treat end-stage renal disease because Medicare now pays for these drugs using a bundled rate.

[6] Several Part B drugs, including certain vaccines and blood products, are not paid on the basis of ASPs. Sections 1847A(a)(1) and 1842(o)(1) of the Social Security Act (the Act). See also *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 17, § 20.1.3.

[7] Section 1847A(c) of the Act defines "ASP" as a manufacturer's sales of a drug (with certain exceptions) to all purchasers in the United States in a quarter divided by the number of units of the drug sold by the manufacturer in that same quarter. The ASP is net of any price concessions, such as volume discounts, "prompt pay" discounts, cash discounts, free goods contingent on purchase requirements, chargebacks, and rebates other than those obtained through the Medicaid drug rebate program.

Manufacturers provide CMS with the ASP and volume of sales for their drugs on a quarterly basis, with submissions due 30 days after the close of each quarter.[8] Payment amounts for most Part B prescription drugs are equal to 106 percent of the volume-weighted ASPs for the individual drugs represented by the HCPCS code (or the actual charge billed on the claim, if that amount is lower). Medicare beneficiaries are responsible for 20 percent of this amount in coinsurance.

Payments in the hospital outpatient setting. Medicare also pays hospital outpatient departments for Part B-covered drugs on the basis of ASPs, but only when the drugs are considered "separately payable." A drug is separately payable when (1) its estimated per-drug, per-day costs are greater than $70 (for 2011), or (2) it has been granted "pass-through" status by CMS, regardless of whether the cost exceeds the $70 per day packaging threshold.[9, 10] In contrast, "packaged drugs" are inexpensive Part B drugs that do not exceed the packaging threshold and are also not pass-through drugs. CMS does not make separate payments for packaged drugs; it includes payment for these drugs as part of the payment for the treatment during which the drugs are administered.

Unlike for other Part B drugs, the Act does not define a set payment methodology (e.g., 106 percent of ASP) for certain separately payable drugs administered in a hospital outpatient setting. Rather, through the rulemaking process, CMS annually updates the ASP-based payment methodology for separately payable drugs that are not pass-through drugs. For 2011, CMS set the Medicare payment amount for non-pass-through separately payable drugs at 105 percent of ASP (see Table 1). The payment method for pass-through drugs is the same as the payment method for drugs in physician office settings (i.e., 106 percent of ASP).[11]

[8] Sections 1847A(f) and 1927(b)(3) of the Act.

[9] 75 Fed. Reg. 71800, 71939 (Nov. 24, 2010).

[10] Section 1833(t)(6)(A) of the Act provides for temporary additional payments, or "transitional pass-through payments," for certain drugs, including new drugs and orphan drugs. Section 1833(t)(6)(A)(i) of the Act defines "orphan drugs" as drugs that are used for a rare disease or condition with respect to which the drug has been designated as an orphan drug under section 526 of the Federal Food, Drug and Cosmetic Act.

[11] 75 Fed. Reg. 71800, 71932 (Nov. 24, 2010).

Table 1: Medicare Part B Payment Methodologies for Covered Drugs

Drug Type	Medicare Payment Methodology for 2011
Drugs administered in physicians' offices or dispensed by suppliers/pharmacies	106 percent of ASP
Drugs administered in hospital outpatient settings that exceed the $70 threshold	105 percent of ASP
Drugs administered in hospital outpatient settings that are considered pass-through	106 percent of ASP
Packaged drugs	Not applicable; payment included in related service

Source: OIG analysis of Medicare payment methodologies (Feb. 13, 2012).

Medicaid Payment for Prescription Drugs

Medicaid beneficiaries typically receive covered drugs through pharmacies, which are reimbursed by State Medicaid agencies. Federal regulations require, with certain exceptions, that each State Medicaid agency's reimbursement for a covered outpatient drug not exceed (in the aggregate) the lower of (1) the estimated acquisition cost plus a reasonable dispensing fee or (2) the provider's usual and customary charge to the public for the drug.[12] CMS gives States flexibility to define "estimated acquisition cost"; most States base their calculation on list prices published in national compendia.[13, 14] For certain multiple-source drugs (i.e., generic drugs and brand-name drugs for which generic alternatives are available), States also use the Federal upper limit program and/or State maximum allowable cost programs in setting reimbursement amounts. The Medicaid law limits cost-sharing for beneficiaries, and the Medicaid program generally imposes lower cost-sharing requirements for beneficiaries than does Medicare.[15]

Medicaid Drug Rebate Program

The Omnibus Budget Reconciliation Act of 1990 created the Medicaid drug rebate program to reduce State and Federal Medicaid expenditures for prescription drugs. For Federal financial participation to be available

[12] 42 CFR § 447.512(b). CMS issued a proposed rule in February 2012 that would replace estimated acquisition cost with actual acquisition cost as the basis of Medicaid pharmacy reimbursement. See 77 Fed. Reg. 5318, 5320 (Feb. 2, 2012).

[13] Historically, the majority of States have used average wholesale prices (AWP) or wholesale acquisition costs (WAC) to set reimbursement and had obtained these data from the publisher First DataBank. First DataBank stopped publishing AWPs as of September 2011. AWPs and WACs are derived from manufacturer-reported list prices.

[14] CMS, *Medicaid Covered Outpatient Prescription Drug Reimbursement Information by State—Quarter Ending June 2012*. Accessed at http://www.medicaid.gov on November 16, 2012.

[15] Sections 1916 and 1916A of the Act.

for covered outpatient drugs provided under Medicaid, manufacturers must enter into rebate agreements with the Secretary of Health and Human Services and pay quarterly rebates to State Medicaid agencies.[16] Fifty States and the District of Columbia, as well as approximately 600 pharmaceutical companies, participate in the Medicaid drug rebate program.[17] From 2005 to 2011, the Medicaid program collected approximately $9.7 billion per year, on average, in prescription drug rebates.

Under their rebate agreements and pursuant to section 1927(b)(3) of the Act, manufacturers must provide CMS with the average manufacturer price (AMP) for each of their national drug codes (NDC) on a monthly and quarterly basis.[18, 19] In the Medicaid drug rebate program, drugs are generally categorized as one of three types: single-source, innovator multiple-source, or noninnovator multiple-source. In general terms, a single-source drug would typically be a brand-name product with no available generic versions. An innovator multiple-source drug would typically be a brand-name product that has available generic versions. A noninnovator multiple-source drug would be a generic version of any innovator product. Manufacturers provide CMS with the drug category for each of their NDCs in conjunction with AMP data.

Manufacturers of single-source and innovator multiple-source drugs must also provide CMS with the "best price" for each NDC.[20] Manufacturers of noninnovator multiple-source drugs are not required to provide best prices for those NDCs.

Medicaid Drug Rebate Calculation

Basic Rebate. For rebate purposes, manufacturers must provide AMP and best-price data to CMS within 30 days of the end of each quarter. CMS uses this information to calculate a unit rebate amount (URA) every quarter for each NDC included in the Medicaid drug rebate program.

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[16] Sections 1927(a)(1) and (b)(1) of the Act.

[17] CMS, *Medicaid Drug Rebate Program.* Accessed at http://www.medicaid.gov/ on November 16, 2012.

[18] Effective October 2010, the Patient Protection and Affordable Care Act revised the definition of "AMP" to be the average price paid to the manufacturer for the drug in the United States by (1) wholesalers for drugs distributed to retail community pharmacies and (2) retail community pharmacies that purchase drugs directly from the manufacturer.

[19] The NDC is an 11-digit code that is divided into three segments identifying (1) the firm that manufactures, distributes, or repackages the drug product; (2) the specific strength, dosage form, and formulation of the product for a particular firm; and (3) the product's package size.

[20] Section 1927(b)(3)(A)(i)(II) of the Act. "Best price" is defined in 1927(c)(1)(C) of the Act as the lowest price available from the manufacturer during the rebate period to any wholesaler, nonprofit entity, or governmental entity within the United States, with certain exceptions.

Pursuant to section 1927(c) of the Act, the formula used to calculate the URA depends on the drug category reported by the manufacturer. The basic URA for a noninnovator multiple-source drug is 13 percent of the AMP. The basic URA for a single-source or innovator multiple-source drug is the greater of 23.1 percent of the AMP or the difference between the AMP and best price.[21] In addition, for drugs approved exclusively for pediatric indications and certain blood-clotting factors, the basic rebate is the greater of 17.1 percent of AMP or the difference between the AMP and the best price.

If the AMP for a brand-name drug has risen faster than inflation, the drug's manufacturer must pay an additional rebate over and above the basic URA.[22] Prior OIG work has demonstrated that this aspect of the rebate program helps protect Medicaid from rising drug costs; substantial increases in prices for Medicaid brand-name drugs (about three times the rate of inflation) between 2005 and 2010 were largely offset by rebate payments.[23]

CMS provides the URA (basic and additional) for each NDC to State Medicaid agencies each quarter. Within 60 days after the end of the quarter, State Medicaid agencies must send each manufacturer an invoice with the URA and number of units reimbursed for each NDC. To determine the total rebate due from manufacturers for each NDC, the URA is multiplied by the total number of units of the NDC reimbursed by the State during the quarter. This utilization figure should include all units for which Medicaid paid a portion of the claim, including Part B claims for beneficiaries who are eligible for both Medicare and Medicaid (hereinafter referred to as dual eligibles) for which Medicaid covered any Part B coinsurance or deductible. Manufacturers must pay rebates to States within 30 days of the date on the rebate invoices.

The 340B Program and Prohibition of Duplicate Discounts. The Veterans Health Care Act of 1992 established the 340B Program in section 340B of

[21] Section 1927(c) of the Act.

[22] Section 1927(c)(2) of the Act. To determine whether a brand-name drug is subject to the increased rebate amount, CMS compares the reported AMP for a given quarter to its inflation-adjusted baseline AMP. The baseline AMP for a drug is the AMP for the first quarter after the drug's initial market date. To adjust the baseline AMP for inflation, CMS first divides the baseline AMP by the baseline consumer price index for all urban consumers (consumer price index), which is the consumer price index for the first month prior to the first quarter after the drug's initial market date. The result of that calculation is then multiplied by the quarterly consumer price index, which is the consumer price index for the month prior to the quarter being calculated. If the reported AMP is greater than the inflation-adjusted baseline AMP, then the difference is added to the URA.

[23] OIG, *Medicaid Brand-Name Drugs: Rising Prices Are Offset by Manufacturer Rebates*, OEI-03-10-00260, August 2011.

the Public Health Service Act. The 340B Program requires drug manufacturers to provide discounted outpatient drugs to certain eligible health care entities, known as covered entities.[24] Covered entities serve the underinsured or uninsured and include disproportionate share hospitals[25], family planning clinics, and federally qualified health centers, among others. As of January 2013, approximately 20,451 entities were participating in the 340B Program.

In general, State Medicaid agencies are responsible for ensuring that manufacturers do not provide "duplicate discounts" for drugs purchased under the 340B program. Manufacturers provide duplicate discounts when they pay Medicaid rebates to States for drugs sold at discounted prices through the 340B Program. Duplicate discounts are prohibited by law.[26] To prevent subjecting drug manufacturers to duplicate discounts when claiming Medicaid rebates, States need to exclude claims for drugs purchased under the 340B program (340B claims) from the utilization data that they send to manufacturers.

METHODOLOGY

Data Collection

Total Part B Expenditures and Utilization. We obtained all paid claims (i.e., physician claims, DME claims, and hospital outpatient claims) for Part B drug HCPCS codes from the 2011 National Claims History (NCH) file to determine quarterly utilization and spending.[27]

NDCs. We obtained from CMS the 2011 quarterly "crosswalk" files that link HCPCS codes to the related NDCs included in the ASP calculation, including a determination of how many units of a given NDC are represented by the HCPCS code.[28]

Medicaid Rebate Amounts. We obtained from CMS the Medicaid URAs for all NDCs associated with the relevant HCPCS codes in each quarter of 2011.

[24] Covered entities do not necessarily purchase all of their drugs at 340B prices.

[25] A disproportionate share hospital is a hospital with a disproportionately large share of low-income patients. CMS, *Medicare Disproportionate Share Hospital*, ICN 006741. January 2013.

[26] 42 U.S.C. § 256b(a)(5)(A).

[27] Claims are added to NCH files on a rolling basis. Therefore, the 2011 NCH files did not include 100 percent of claims when OIG analyzed the files in May 2012.

[28] Because Medicare Part B reimbursement for outpatient drugs is based on HCPCS codes rather than on NDCs and more than one NDC may meet the definition of a particular HCPCS code, CMS has developed a file that "crosswalks" manufacturers' NDCs to HCPCS codes. CMS uses information in this crosswalk file to calculate volume-weighted ASPs for covered HCPCS codes.

ASP Data. We obtained from CMS the quarterly ASPs and number of units sold as reported by manufacturers for all NDCs associated with the relevant HCPCS codes in each quarter of 2011.

Dual-Eligible Data. We obtained the 2011 beneficiary enrollment database from CMS, which includes a variable noting whether a beneficiary is enrolled in both Medicare and Medicaid.

340B Data. We obtained the database of 340B-covered entities from the Health Resources and Services Administration (HRSA) on June 7, 2012, to identify providers eligible for 340B pricing.

Previous OIG Work. We reviewed prior OIG work on the Medicaid rebate program to identify issues that would affect the implementation of a similar rebate program in Medicare Part B.

Data Analysis

Selection of Drugs. Using data from the NCH file, we summarized Medicare expenditures and utilization by HCPCS code for all Part B drugs in all settings in 2011. We selected the 72 HCPCS codes with the highest total expenditures (constituting 90 percent of Medicare Part B total spending) for review.

We removed 3 of the 72 HCPCS codes from our analysis because the codes represented Not Otherwise Classified (NOC) drugs, meaning that the drugs being billed could not be readily identified. We also removed five additional HCPCS codes because they were not paid on the basis of ASPs in 2011.[29] We then removed four additional HCPCS codes from our analysis because they did not meet the definition of a covered outpatient drug under Medicaid and manufacturers were therefore not subject to rebate agreements requiring them to report AMP or ASP data.[30] We then used CMS's ASP files to identify all NDCs that are crosswalked to the remaining 60 HCPCS codes. These 60 codes accounted for 85 percent ($13.9 billion) of Part B drug expenditures in 2011 (see Table 2).

[29] Four of the five HCPCS codes represented vaccines—drugs for which manufacturers are not required to submit ASP data to CMS. The fifth code represented a newly approved drug that was not included in CMS's ASP pricing file in 2011, but was paid on the basis of ASPs in 2012.

[30] Three HCPCS codes represent hyaluronan (Synvisc or Synvisc-One, Hyalgan or Supartz, and Orthovisc) and the fourth represents Apligraf skin substitute. All of these products are considered "devices" and not drugs by Medicaid and the U.S. Food and Drug Administration (FDA).

Table 2: Summary of Part B Drug HCPCS Codes Included in Analysis

Number of HCPCS Codes	2011 Part B Spending	Percentage of Total
712 (All Part B HCPCS codes)	$16.4 billion	100%
72 (Codes with the highest Part B expenditures)	$14.8 billion	90%
69 (After 3 NOC codes removed)	$14.4 billion	88%
64 (After 4 vaccines and 1 newly approved drug removed)	$14.2 billion	87%
60 (After 4 devices removed)	$13.9 billion	85%

Source: OIG analysis of 2011 NCH file (Feb. 13, 2012).

Categorization of Drugs. Using CMS's fourth-quarter ASP file, we categorized the 60 HCPCS codes as representing a single-brand drug, multiple-brand drug, or generic drug (see Appendix A for a list of the 60 HCPCS codes and their respective categorizations). A single-brand HCPCS code represents only one brand-name drug (and no generics) produced by a single manufacturer. We classified 48 of the 60 HCPCS codes as single brand. A multiple-brand HCPCS code represents two or more brand-name drugs produced by more than one manufacturer. We classified 5 of the 60 HCPCS codes as multiple brand. A generic HCPCS code represents either a combination of brand-name and generic drugs or of generic drugs only. Generic drugs are also produced by more than one manufacturer. We classified 7 of the 60 HCPCS codes as generic.[31]

Calculation of AMP-Based Rebate Amounts. We calculated a rebate amount for each NDC within a HCPCS code using the Medicaid URAs (which include basic and additional rebates) reported for the associated NDCs in each quarter of 2011. AMPs (and URAs) are calculated for the lowest identifiable quantity of the drug contained in that NDC (e.g., 1 milliliter, one tablet). In contrast, Part B payment amounts and utilization are reported by HCPCS code for the entire amount of the drug contained in the NDC (e.g., 50 milliliters, 100 tablets). To ensure that the rebate amount is representative of the correct number of units for the HCPCS code, we used CMS's crosswalk file to convert the URA of each NDC so that it would represent the amount of the drug specified by the HCPCS code.

Determination of ASP-Based Rebate Amounts. Because Part B payments for most covered drugs are based on ASPs, we also calculated an

[31] Two of the generic HCPCS codes represented brand-name drugs of which generic versions become available at some point in 2011.

estimated rebate based on those amounts in each quarter of 2011. We first calculated a basic URA for each crosswalked NDC by substituting ASP for AMP in the rebate formula (i.e., for single-source and innovator multiple-source drugs, the greater of 23.1 percent of ASP or the difference between ASP and best price; for noninnovator multiple-source drugs, 13 percent of ASP; and for drugs approved exclusively for pediatric indications and certain blood-clotting factors, the greater of 17.1 percent of ASP or the difference between ASP and best price). For brand-name drugs, we then calculated the additional inflation-based rebate using the same method that CMS uses to calculate the additional rebate for Medicaid drugs (i.e., using the base-date ASP to track changes in ASPs against inflation).[32] We then added the basic rebate amount to any additional inflation-based rebate amount to calculate the ASP-based URA for each NDC.

Removing Claims for Which Manufacturers Would Not Owe Rebates. Before calculating the total potential Part B rebate amounts, we removed Part B claims for dual-eligible beneficiaries from our analysis because those claims should have already been subject to Medicaid rebates. We identified all Part B drug claims for dual eligibles by matching the Part B drug claims against the beneficiary enrollment file.

We also removed 340B claims from our analysis because duplicate discounts are prohibited by law.[33] Using HRSA's file of 340B-covered entities from June 7, 2012, we identified and removed any Part B drug claims submitted by covered entities. We then summarized the utilization for the remaining claims to determine the total units of each HCPCS code that would have been subject to rebates in 2011.

Claims associated with dual eligibles or with 340B-covered entities represented 29 percent of expenditures and 36 percent of utilization for the 60 HCPCS codes included in our review. In other words, $4 billion of the $13.9 billion spent on these 60 HCPCS codes in 2011 would not have been subject to rebates, and any associated claims were therefore removed from our rebate calculations.[34]

Total Rebate Calculations. After removing dual-eligible and 340B claims, we apportioned the remaining utilization among the individual NDCs within each HCPCS code. Because NDC-level utilization is not tracked under Part B, we used CMS's ASP files to determine the percentage of total sales of a HCPCS code represented by each NDC (i.e., one NDC

[32] We defined "base-date ASP" as the drug's ASP in the first reported quarter or, for older drugs, the drug's ASP when the ASP-based payment went into effect in 2005.

[33] 42 U.S.C. § 256b(a)(5)(A).

[34] Among the individual HCPCS codes, between 10 percent and 77 percent of spending and between 10 percent and 96 percent of utilization was removed from our analysis.

represented 10 percent of total sales, and another NDC represented 15 percent). We then multiplied these percentages by the total quarterly utilization of each HCPCS code to estimate utilization for each NDC.[35] To determine total rebate amounts, we multiplied the estimated utilization of each NDC by its AMP-based and ASP-based rebate amounts and summarized the NDC-level figures by HCPCS code (see Appendix B for total rebate calculations). Rebate calculations are based on historical pricing and utilization data. These calculations do not attempt to account for potential changes in pricing or utilization that might result from implementation of a rebate requirement.

Implementation Issues Related to Calculating and Collecting Rebates for Part B. We reviewed previous OIG work involving Medicaid rebates, manufacturer-reported AMP and ASP data, and the 340B Program to identify potential issues that would need to be addressed before implementing a Part B rebate program. We also reviewed issues that we encountered during the analysis of this study, such as identifying claims for drugs purchased at 340B prices and obtaining information to calculate drug rebates.

Limitations

We did not review Part B claims for accuracy. We also did not review manufacturer-reported drug data or the CMS crosswalk files for accuracy. Because there is no identifier in the NCH claims data indicating that a drug was purchased at 340B prices, we removed all claims submitted by 340B-covered entities from our analysis. We identified these entities using HRSA's database of covered entities, which prior OIG work has found to contain inaccuracies.[36, 37] Given the problems with this database and issues with identifying 340B drugs in NCH claims data, we may have inadvertently removed claims for drugs *not* purchased at 340B prices, possibly resulting in underestimating potential collections associated with a Part B rebate program.

Furthermore, our rebate estimates apply only to the 60 drugs in our sample that represent 85 percent of expenditures; the estimates cannot be

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[35] We determined that the number of units listed in the 2011 NCH file for two HCPCS codes (representing factor viii recombinant and factor viia, which are used to treat hemophilia) underrepresented the actual number of HCPCS units reimbursed by a substantial margin. We calculated the correct number of Medicare units by dividing the total Part B spending (after removing dual-eligible and 340B claims) by the Part B payment amount in each quarter.

[36] OIG, *Deficiencies in the 340B Drug Discount Program's Database*, OEI-05-02-00071, June 2004.

[37] OIG, *State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs*, OEI-05-09-00321, June 2011.

generalized to all drug HCPCS codes paid under Part B. Our analysis did not address how implementation of Part B rebates could affect beneficiary cost-sharing, i.e., potential fluctuations in drug pricing and resulting copay obligations or the possibility that any of the potential rebate collections could be passed on to beneficiaries. Our analysis also did not examine the impact that the implementation of a Part B rebate program could have on provider acquisition costs, beneficiary access to useful therapies, and Medicare drug prices; on prices for uninsured patients and for other payers; on the pharmaceutical market in general; on supplemental insurance premiums; or on the administrative costs of establishing and operating a rebate program.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

Medicare could have collected at least $2.7 billion in 2011 if manufacturers of Part B drugs had been required to pay rebates similar to those under Medicaid

Medicare and its beneficiaries spent $13.9 billion in 2011 for the 60 selected high-expenditure Part B drugs. If Medicare had applied an AMP-based methodology, it could have collected $3.1 billion in rebates from pharmaceutical manufacturers for the 60 drugs that year, which represents 22 percent of expenditures on those drugs. If Medicare had applied an ASP-based methodology, it could have collected $2.7 billion in rebates from pharmaceutical manufacturers, which represents 20 percent of expenditures on those drugs.

If Medicare had used an AMP-based methodology for rebates, the program could have potentially recouped 22 percent of expenditures for the 60 drugs under review

Under an AMP-based rebate program (i.e., using the same rebate benchmark as Medicaid), manufacturers would potentially have owed $3.1 billion in rebates for the 60 drugs included in this review. As a result, Medicare could have recouped 22 percent of the $13.9 billion in expenditures for these drugs. AMP-based rebates for just 10 of the 60 HCPCS codes accounted for 55 percent of the total projected rebate amounts. As shown in Table 3, most of the total projected rebate amounts were attributable to the 48 single-brand HCPCS codes, which represented $2.6 billion of the total rebates (and $11.8 billion of total expenditures).

If Medicare had used an ASP-based methodology for rebates, the program could have potentially recouped 20 percent of expenditures for the 60 drugs under review

Under an ASP-based rebate program, manufacturers would have potentially owed $2.7 billion in rebates for the 60 drugs included in this review. As a result, Medicare could have recouped 20 percent of the $13.9 billion in expenditures for these drugs. ASP-based rebates for just 10 of the 60 HCPCS codes accounted for 57 percent of total projected rebate amounts. Once again, most of the total projected rebate amounts were attributable to single-brand HCPCS codes, which represented $2.4 billion of the total rebates.

Table 3: Potential Rebates Associated With Each Drug Type

HCPCS Classification	AMP-Based Rebates	ASP-Based Rebates
Single-Brand (n=48)	$2,648,759,293	$2,353,138,619
Multiple-Brand (n=5)	$159,580,380	$144,661,408
Generic (n=7)	$273,240,243	$237,125,619
TOTAL	**$3,081,579,916**	**$2,734,925,646**

Source: OIG analysis of CMS's 2011 AMP and ASP files and the 2011 NCH file (Nov. 20, 2012).

Several implementation issues related to claims and data would need to be addressed if Congress were to establish a comprehensive drug rebate program for Medicare Part B

The lack of NDC-level information on Part B claims, issues involving manufacturer-reporting of drug data, and difficulties in identifying drugs purchased under the 340B Program would all affect CMS's ability to calculate accurate rebates and invoice the appropriate manufacturers for drug claims. OIG has identified many of these issues in prior reports and has made relevant recommendations.

The use of HCPCS codes for Part B drugs would present challenges when identifying the manufacturer responsible for rebates

The use of HCPCS codes rather than NDCs to bill for Part B drugs would need to be addressed before Medicare could effectively collect rebates for multiple-brand and generic drugs. For 12 of the 60 HCPCS codes under review, CMS's crosswalk file lists NDCs from more than 1 manufacturer and multiple manufacturers reported sales during the quarters under review. Therefore, without an NDC on the claim, CMS would not be able to determine the appropriate manufacturer to invoice.

For many years, Medicaid faced a similar problem in collecting rebates for physician-administered drugs, i.e., the principal type of drug also covered under Medicare Part B. In 2004, OIG reported that only 17 States collected Medicaid rebates from manufacturers for physician-administered drugs in 2001.[38] At that time, many States did not have a system to identify the manufacturer responsible for paying the rebates for these drugs, as most were using HCPCS codes rather than NDCs for physician-administered drug claims.

[38] OIG, *Medicaid Rebates for Physician-Administered Drugs,* OEI-03-02-00660, April 2004.

Following the release of that OIG report, the Deficit Reduction Act of 2005 (DRA) specifically required States to collect rebates for certain physician-administered drugs for Federal financial participation to be available.[39] To assist States in meeting this requirement, the DRA also mandated that claims for certain physician-administered drugs include the NDC for the drug being billed. In a followup report released in 2011, OIG found that as of June 30, 2009, all States but one reported collecting at least a portion of the rebates owed for physician-administered drugs, and 86 percent of States reported that they required NDCs on all physician-administered drug claims.[40]

Even if providers billed Medicare with NDCs, information needed to calculate and collect Part B rebates may be unavailable or inaccurate

Only manufacturers with Medicaid drug rebate agreements in effect are required to report ASPs and AMPs, among other drug information, to CMS.[41] However, manufacturers of certain Part B drugs may not have Medicaid drug rebate agreements in effect. For example, four high-expenditure Part B HCPCS codes were associated with products that FDA and Medicaid classified as devices (rather than drugs). For that reason, the manufacturers are not required to pay Medicaid drug rebates, and they did not report any AMP data to CMS for the products.[42]

A previous OIG study found that for certain Part B HCPCS codes, none of the associated drugs were manufactured by companies with Medicaid drug rebate agreements.[43] Therefore, if these manufacturers chose not to report ASPs or AMPs, the missing pricing data would prevent Medicare from calculating and collecting rebates for the relevant drugs. This barrier to a Part B drug rebate program would be addressed if CMS were to require all manufacturers of Part B drugs to report pricing data as OIG has recommended in the past.

Furthermore, even if providers were required to report both NDCs and HCPCS codes on physician-administered drug claims, the information may be inaccurate. In our June 2011 report on physician-administered drugs, OIG found that Medicaid providers incorrectly convert HCPCS

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[39] Section 1927(a)(7) of the Act, as added by section 6002 of the DRA.

[40] OIG, *States' Collection of Medicaid Rebates for Physician-Administered Drugs*, OEI-03-09-00410, June 2011.

[41] Section 1927 of the Act.

[42] Although they were not required to do so, the manufacturers reported ASP data to CMS for their products.

[43] OIG, *Average Sales Prices: Manufacturer Reporting and CMS Oversight*, OEI-03-08-00480, February 2010.

code units to NDC units on claims and that providers list NDCs that do not correspond to the same drug as the HCPCS code.[44] Because manufacturers are invoiced for rebates on the basis of the number of units billed, inaccurate conversions and incorrect codes may cause States to request substantially more or less than they are actually owed. HCPCS/NDC coding and conversion issues were cited by many States as a primary cause of manufacturer rebate disputes.

Drugs purchased at 340B prices have proven challenging to identify

If a Part B rebate program were implemented, Medicare would be responsible for ensuring that manufacturers do not provide duplicate discounts for drugs purchased under the 340B Program. Like Medicaid, Medicare would need to exclude claims for drugs purchased at 340B prices from the utilization data sent to drug manufacturers when collecting rebates. However, OIG has found that it is challenging for States to prevent duplicate discounts in Medicaid because they cannot identify 340B claims with current billing and claims policies. A 2011 OIG study found that 31 States did not have an edit (i.e., a computerized system process) to identify physician-administered drug claims submitted by covered entities and/or did not require NDCs on 340B claims for physician-administered drugs.[45]

Another OIG study found that 38 percent of sampled entities were incorrectly listed in the covered-entity database as participating in the 340B Program.[46] Because of potential inaccuracies, 30 States have established alternative files or processes to prevent duplicate discounts.[47] For example, nine of these States instruct covered entities to use the National Council for Prescription Drug Plan (NCPDP) Telecommunication Standard, an electronic standard used in pharmacies' prescription drug transactions, to identify 340B claims. Issues with 340B claims are another frequent source of rebate disputes in Medicaid.

Problems with identifying drugs purchased at 340B prices could affect the accuracy of Part B rebates. For example, to be conservative in Part B rebate calculations, CMS could elect to exclude all claims submitted by covered entities because drugs that were purchased at 340B prices cannot

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[44] OIG, *States' Collection of Medicaid Rebates for Physician-Administered Drugs*, OEI-03-09-00410, June 2011.

[45] Ibid.

[46] OIG, *Deficiencies in the 340B Drug Discount Program's Database*, OEI-05-02-00071, June 2004.

[47] OIG, *State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs*, OEI-05-09-00321, June 2011.

be identified. This might result in unnecessarily excluding claims for drugs not purchased at 340B prices. In this case, Medicare would not collect the full amount manufacturers owe in rebates. On the other hand, if CMS could not identify claims submitted by covered entities, Medicare could exclude too few claims, and manufacturers would be billed in excess of the amounts owed in rebates.

CONCLUSION AND RECOMMENDATIONS

The results of this current study build upon our original 2011 work and help inform analysis of the potential impact of a Part B rebate program. Our findings show that a Part B rebate program similar to the Medicaid rebate program could have yielded Medicare as much as $3.1 billion in rebates (representing 22 percent of spending) for 60 high-expenditure outpatient prescription drugs in 2011.

Therefore, we recommend that CMS:

Examine the additional potential impacts of establishing a prescription drug rebate program under Medicare Part B and, if appropriate, seek legislative change

In evaluating the potential impact of establishing a prescription drug rebate program under Medicare Part B, CMS should take into account numerous factors that could influence drug pricing and utilization that would alter the expected rebate collections and net impact thereof. Such analysis should consider how a rebate program might affect drug prices in Medicare and other markets, beneficiary access to useful therapies, beneficiary cost-sharing, provider acquisition costs, and administrative costs.

As part of its consideration of a Medicare Part B prescription drug rebate program, address administrative issues that may hinder rebate collections in Part B

Any consideration of a Part B rebate program must address the data- and claims-related issues described in our findings. Many of the issues that impede rebate collection are similar to ones previously faced by Medicaid when collecting rebates for physician-administered drugs, and OIG recommendations have helped reduce (if not eliminate) existing problems. The following measures could help facilitate implementation of a Medicare Part B prescription drug rebate program:

Require providers to include NDCs on Part B claims.

Medicare would be able to effectively collect rebates for multiple-brand and generic Part B drugs only if NDCs were included on claims. Prior to the implementation of new NDC-related requirements mandated by the DRA, most State Medicaid programs also had major issues collecting rebates for physician-administered drugs as claims for these products typically included only HCPCS codes. However, because the DRA requires providers to include NDCs on certain physician-administered

drug claims, all States but one now collect Medicaid rebates for physician-administered drugs.[48]

Require all manufacturers of Part B drugs to submit ASPs for their products.

Pricing information for some Part B drugs may be unavailable because the manufacturers of those drugs do not have Medicaid drug rebate agreements in effect and are therefore not required to report ASPs and AMPs for their drugs. Without this pricing data, CMS would be unable to calculate and collect rebates for these drugs.

Make claims for drugs purchased under the 340B Program readily identifiable.

To prevent duplicate discounts for drugs purchased under the 340B Drug Pricing Program and to ensure the accuracy of Part B rebates, CMS should modify claims submission requirements for covered entities. If drugs purchased under the 340B Drug Pricing Program are unidentifiable, CMS could incorrectly include or exclude these drugs when invoicing manufacturers. Among other options, CMS could address this issue by requiring covered entities to use the NCPDP Telecommunication Standard to identify 340B claims.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In its comments on the draft report, CMS stated that although it appreciates our analysis of a potential Part B rebate program, a legislative change would be necessary to establish a Part B rebate program and that the annual President's Budget does not include such a proposal. In addition, CMS stated that a comprehensive examination of the impact of a Part B rebate program would require significant resources. CMS stated that given current priorities, it is unable to devote these resources for a proposal that neither is a provision of current law nor is actively under consideration. OIG recognizes the challenges of assessing a rebate program. However, because of the potential to collect billions of dollars, we believe that a rebate program warrants further deliberation.

[48] OIG, *States' Collection of Medicaid Rebates for Physician-Administered Drugs,* OEI-03-09-00410, June 2011.

APPENDIX A

Drug Descriptions

HCPCS Code	Description	HCPCS Dosage	HCPCS Classification
J0129	Abatacept injection	10 mg	Single-Brand
J0152	Adenosine injection	30 mg	Single-Brand
J0256	Alpha 1 proteinase inhibitor	10 mg	Multiple-Brand
J0583	Bivalirudin	1 mg	Single-Brand
J0585	Botulinum toxin type a	1 unit	Single-Brand
J0878	Daptomycin injection	1 mg	Single-Brand
J0881	Darbepoetin alfa	1 mcg	Single-Brand
J0885	Epoetin alfa	1000 units	Multiple-Brand
J0894	Decitabine injection	1 mg	Single-Brand
J1300	Eculizumab injection	10 mg	Single-Brand
J1440	Filgrastim injection	300 mcg	Single-Brand
J1441	Filgrastim injection	480 mcg	Single-Brand
J1459	Immune globulin (privigen) injection	500 mg	Single-Brand
J1559	Hizentra injection	100 mg	Single-Brand
J1561	Gamunex injection	500 mg	Single-Brand
J1566	Immune globulin powder	500 mg	Multiple-Brand
J1569	Gammagard liquid injection	500 mg	Single-Brand
J1572	Flebogamma injection	500 mg	Single-Brand
J1745	Infliximab injection	10 mg	Single-Brand
J2260	Milrinone lactate injection	5 mg	Generic
J2323	Natalizumab injection	1 mg	Single-Brand
J2353	Octreotide depot injection	1 mg	Single-Brand
J2357	Omalizumab injection	5 mg	Single-Brand
J2469	Palonosetron hydrochloride injection	25 mcg	Single-Brand
J2505	Pegfilgrastim injection	6 mg	Single-Brand
J2778	Ranibizumab injection	0.1 mg	Single-Brand
J2785	Regadenoson injection	0.1 mg	Single-Brand
J2796	Romiplostim injection	10 mcg	Single-Brand
J3262	Tocilizumab injection	1 mg	Single-Brand
J3285	Treprostinil injection	1 mg	Single-Brand
J3487	Zoledronic acid	1 mg	Single-Brand
J3488	Reclast injection	1 mg	Single-Brand
J7189	Factor viia	1 mcg	Single-Brand
J7192	Factor viii recombinant	1 IU	Multiple-Brand
J7507	Tacrolimus oral	1mg	Generic
J7517	Mycophenolate mofetil oral	250 mg	Generic
J7518	Mycophenolic acid	180 mg	Single-Brand
J7520	Sirolimus oral	1 mg	Single-Brand
J7605	Arformoterol inhalation solution	15 mcg	Single-Brand
J7606	Formoterol fumarate inhalation solution	20 mcg	Single-Brand
J7620	Albuterol and ipratropium bromide	2.5 mg/0.5 mg	Generic
J7626	Budesonide inhalation solution	Up to 0.50 mg	Generic
J7686	Treprostinil inhalation solution	1.74 mg	Single-Brand

HCPCS Code	Description	HCPCS Dosage	HCPCS Classification
J9001	Doxorubicin hydrochloride injection	10 mg	Single-Brand
J9025	Azacitidine injection	1 mg	Single-Brand
J9033	Bendamustine injection	1 mg	Single-Brand
J9035	Bevacizumab injection	10 mg	Single-Brand
J9041	Bortezomib injection	0.1 mg	Single-Brand
J9055	Cetuximab injection	10 mg	Single-Brand
J9171	Docetaxel injection	1 mg	Generic
J9201	Gemcitabine hydrochloride injection	200 mg	Generic
J9217	Leuprolide acetate suspension	7.5 mg	Multiple-Brand
J9263	Oxaliplatin	0.5 mg	Single-Brand
J9264	Paclitaxel protein bound	1 mg	Single-Brand
J9303	Panitumumab injection	10 mg	Single-Brand
J9305	Pemetrexed injection	10 mg	Single-Brand
J9310	Rituximab injection	100 mg	Single-Brand
J9355	Trastuzumab injection	10 mg	Single-Brand
J9395	Fulvestrant injection	25 mg	Single-Brand
Q4074	Iloprost inhalation solution	Up to 20 mcg	Single-Brand

Source: OIG analysis of the CMS average sales price file for the fourth quarter of 2011.

APPENDIX B

Estimated 2011 AMP-Based and ASP-Based Part B Rebates for 60 High-Expenditure Drugs

HCPCS Code	Total 2011 Part B Expenditures	2011 AMP-Based Rebates	Percentage of Part B Spending	2011 ASP-Based Rebates	Percentage of Part B Spending
J0129	$242,621,080	$45,296,356	19%	$43,779,195	18%
J0152	$39,187,453	$3,263,977	8%	$5,472,800	14%
J0256	$38,814,546	$4,736,155	12%	$4,699,193	12%
J0583	$55,106,985	$19,129,757	35%	$26,903,046	49%
J0585	$136,604,360	$21,421,964	16%	$10,740,628	8%
J0878	$48,882,977	$17,725,069	36%	$17,601,790	36%
J0881	$383,226,086	$72,213,146	19%	$68,910,997	18%
J0885	$315,462,628	$59,300,246	19%	$59,477,785	19%
J0894	$115,821,603	$29,031,868	25%	$24,664,456	21%
J1300	$56,786,248	$6,791,565	12%	$6,791,570	12%
J1440	$49,660,422	$16,744,905	34%	$13,522,406	27%
J1441	$102,526,925	$37,565,814	37%	$31,102,949	30%
J1459	$105,355,271	$12,893,068	12%	$12,622,376	12%
J1559	$89,229,433	$8,026,938	9%	$7,867,661	9%
J1561	$152,594,293	$19,301,268	13%	$18,757,028	12%
J1566	$54,839,875	$17,580,557	32%	$14,804,736	27%
J1569	$183,952,086	$45,185,976	25%	$42,602,018	23%
J1572	$73,565,788	$9,862,168	13%	$9,280,857	13%
J1745	$884,009,825	$155,456,677	18%	$144,971,468	16%
J2260	$77,197,786	$1,091,377	1%	$637,550	1%
J2323	$164,272,185	$42,947,863	26%	$41,798,801	25%
J2353	$218,148,095	$89,026,417	41%	$60,291,334	28%
J2357	$116,626,156	$23,912,385	21%	$23,295,927	20%
J2469	$184,722,551	$32,873,614	18%	$33,685,830	18%
J2505	$905,463,334	$151,635,833	17%	$163,101,441	18%
J2778	$1,378,203,139	$270,198,840	20%	$268,932,149	20%
J2785	$194,402,526	$28,154,653	14%	$26,689,641	14%
J2796	$72,036,293	$13,341,727	19%	$12,325,109	17%
J3262	$47,296,258	$7,578,172	16%	$7,482,382	16%
J3285	$137,058,446	$39,577,422	29%	$20,624,506	15%
J3487	$271,797,552	$44,719,164	16%	$44,376,478	16%
J3488	$211,617,887	$31,604,846	15%	$31,207,799	15%
J7189	$116,085,003	$8,129,573	7%	$8,091,974	7%
J7192	$158,214,783	$8,347,292	5%	$8,173,610	5%
J7507	$216,943,580	$25,408,192	12%	$16,802,379	8%
J7517	$76,360,922	$25,710,172	34%	$20,442,909	27%
J7518	$87,389,642	$28,006,887	32%	$22,674,893	26%
J7520	$47,168,605	$13,322,350	28%	$12,606,792	27%
J7605	$88,787,349	$40,268,808	45%	$17,797,374	20%

HCPCS Code	Total 2011 Part B Expenditures	2011 AMP-Based Rebates	Percentage of Part B Spending	2011 ASP-Based Rebates	Percentage of Part B Spending
J7606	$45,028,692	$26,030,126	58%	$11,092,184	25%
J7620	$42,317,828	$7,878,310	19%	$15,954,183	38%
J7626	$188,089,307	$32,743,303	17%	$31,186,158	17%
J7686	$85,265,114	$15,011,054	18%	$15,370,787	18%
J9001	$68,417,727	$26,547,997	39%	$10,622,135	16%
J9025	$183,229,371	$52,110,919	28%	$36,989,197	20%
J9033	$205,375,262	$34,202,115	17%	$33,510,321	16%
J9035	$916,856,239	$148,664,574	16%	$147,132,358	16%
J9041	$314,484,519	$105,721,054	34%	$97,312,473	31%
J9055	$237,004,599	$37,443,123	16%	$36,687,839	15%
J9171	$361,874,603	$89,950,074	25%	$98,110,554	27%
J9201	$255,099,464	$90,458,815	35%	$53,991,886	21%
J9217	$259,416,825	$69,616,130	27%	$57,506,084	22%
J9263	$444,619,885	$86,212,530	19%	$81,153,644	18%
J9264	$111,742,094	$17,878,362	16%	$17,777,030	16%
J9303	$49,123,947	$7,464,960	15%	$7,337,807	15%
J9305	$415,627,110	$105,889,772	25%	$102,565,013	25%
J9310	$1,242,467,898	$458,527,642	37%	$354,825,987	29%
J9355	$378,059,453	$108,019,246	29%	$89,910,401	24%
J9395	$116,516,160	$19,180,875	16%	$19,004,330	16%
Q4074	$58,966,632	$14,645,874	25%	$11,273,438	19%
Totals	**$13,877,622,705**	**$3,081,579,916**	**22%**	**$2,734,925,646**	**20%**

Notes: Total Part B expenditures were calculated using 2011 figures for physician, outpatient hospital, and durable medical equipment claims. Rebates based on average manufacturer price and average sale price for 2011 were calculated after removing claims for drugs purchased at 340B prices and claims for beneficiaries enrolled in both Medicare and Medicaid.

Source: OIG analysis of 2011 National Claims History files, Centers for Medicare & Medicaid Services (CMS) 2011 Medicaid unit rebate amounts files, and CMS's 2011 ASP files.

APPENDIX C

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

200 Independence Avenue SW
Washington, DC 20201

DATE: JUL 25 2013

TO: Daniel R. Levinson
Inspector General

/S/

FROM: Marilyn Tavenner
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Medicare Could Collect Billions If Pharmaceutical Manufacturers Were Required To Pay Rebates for Part B Drugs" OEI-12-12-00260

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and respond to the above subject draft report. The objectives for this report are to (1) Calculate the total rebates that could have been collected in 2011 had manufacturers been required to pay rebates for drugs covered under Medicare Part B; and (2) Identify implementation issues that would need to be addressed if such rebates were required. The OIG found that Medicare could have collected $3.1 billion if pharmaceutical manufacturers had been required in 2011 to pay average manufacturer prices (AMP) based rebates for 60 high-expenditure Part B drugs, representing 22 percent of spending for those drugs. Requiring manufacturers to pay ASP-based rebates for the same 60 drugs could have garnered Medicare $2.7 billion in rebate payments, representing 20 percent of spending. However, several implementation issues related to claims and data would need to be addressed if such a rebate program were implemented.

The study also identified single-brand drugs (one brand-name drug produced by a single manufacturer and no generics) as the source for the majority of the estimated savings. However, the study did not estimate the administrative costs of implementing and maintaining such a program, or the impact on providers, manufacturers, or beneficiaries.

The OIG recommendation and CMS response to the recommendation are discussed below.

OIG Recommendation

The OIG recommends that CMS examine the additional potential impacts of establishing a prescription drug rebate program under Medicare Part B and, if appropriate, seek legislative change. As part of its consideration of a Medicare Part B prescription drug rebate program, address administrative issues that may hinder rebate collections in Part B.

CMS Response

The CMS does not concur with this recommendation. We appreciate the OIG's analysis of the situation and the clear identification of several significant issues that would require resolution before a Part B rebate program could be implemented. As indicated by the OIG, a legislative change would be necessary for a Part B rebate program to be implemented. The President's Budget does not currently include such a proposal. Moreover, a comprehensive examination and analysis of the impact of a Part B rebate program, including the effects of making a fundamental change to the Part B claims payment system to include national drug codes (NDCs), the impact on providers, and the impact on access to care, would require significant resources. With all of the existing priorities of the agency that are currently in statute, CMS is unable to devote significant administrative resources at this time to a proposal that is neither a provision of current law or actively under consideration.

The CMS thanks the OIG for the opportunity to review and comment on this report.

ACKNOWLEDGMENTS

This report was prepared under the direction of David Tawes, Regional Inspector General for Evaluation and Inspections in the Baltimore regional office; Patricia Wheeler, Regional Inspector General for Audit Services in the Dallas regional office; Michael Armstrong, Regional Inspector General for Audit Services in the Boston regional office; and Stephen Conway, Director of Advanced Auditing Techniques.

Office of Audit Services staff from the Dallas regional office who conducted this study include Paul Chesser and Kelsey Mitchell. Office of Audit Services staff from the Boston regional office who conducted this study include Robert Broadhurst, Amy Harriman, Karen Lowe, Judith Reilly, and Leah Scott. Office of Audit Services staff from the Centers for Medicare & Medicaid Audits Division who conducted this study include Jeffrey Cohen. Office of Evaluation and Inspections staff from the Baltimore regional office who conducted the study include Bahar Adili. Central office staff who provided support include Clarence Arnold, Mandy Walz, Meghan Kearns, and Christine Moritz.

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