Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

CALCULATION OF POTENTIAL INFLATION-INDEXED REBATES FOR MEDICARE PART B DRUGS

Suzanne Murrin
Deputy Inspector General for
Evaluation and Inspections

August 2017
OEI-12-17-00180

Report in Brief
August 2017
Report No. OEI-12-17-00180

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

Calculation of Potential Inflation-Indexed Rebates for Medicare Part B Drugs

Why OIG Did This Review

OIG conducted this review to respond to a congressional request asking us to update our earlier rebate calculations using only the inflation-indexed portion of the Medicaid rebate methodology. This report is part of OIG efforts to provide relevant data for policymakers in their discussions related to Medicare Part B drug spending.

Statutorily mandated rebates, which include both basic rebates and inflation-indexed rebates (additional rebates owed when drug prices rise faster than inflation), amount to a substantial percentage of spending on Medicaid prescription drugs. Medicare does not have the authority to collect rebates for Part B drugs and biologicals (i.e., "Part B drugs"). In an earlier report, OIG found that a rebate program for Part B drugs could have resulted in at least $2.7 billion in rebates (both basic rebate and inflation-indexed rebate segments) in 2011.

How OIG Did This Review

Applying the same formula that Medicaid uses to determine inflation-indexed rebates, we calculated how much in inflation-indexed rebates could have been associated with 64 high-expenditure Part B drugs in 2015. We performed separate calculations using both average sales prices (ASPs) and average manufacturer prices (AMPs). We also identified claims issues and coding-related issues that would need to be addressed before establishing a rebate program under Part B, should Congress choose to do so.

What OIG Found

An ASP-based rebate program for Medicare Part B drugs could have resulted in $1.4 billion in inflation-indexed rebates in 2015 for 64 high-expenditure drugs. An AMP-based rebate program for the same 64 drugs could have resulted in $1.8 billion in inflation-indexed rebates that same year. Several implementation issues related to claims and data would need to be addressed should Congress decide to establish a rebate program under Part B.

What OIG Concludes

Inflation-indexed rebates are intended to help protect State Medicaid programs and the Federal Government from significant drug price increases. Medicare Part B does not have similar rebate authority. The results of this current study build upon our original 2011 analysis. This analysis did not take into account how implementation of a Part B rebate requirement could affect beneficiary coinsurance obligations, beneficiary access to prescription drugs, and the overall pharmaceutical marketplace. Furthermore, we did not address the operational burden of implementing such a requirement.

Any consideration of a rebate program should address the following administrative issues that may hinder rebate collections: the use of Healthcare Common Procedure Coding System codes, incorrect coding conversions, unavailable drug pricing data, and difficulties in identifying 340B-purchased drugs.

TABLE OF CONTENTS

OBJECTIVES

1. To estimate the amount of rebates in 2015 if pharmaceutical manufacturers had been required to pay inflation-indexed rebates for Part B drugs.
2. To identify implementation issues that would need to be addressed if such rebates were required.

BACKGROUND

Rationale

To protect Medicaid from significant price increases, Federal law requires drug manufacturers to pay additional rebates (i.e., inflation-indexed rebates) on drugs whose average manufacturer prices (AMPs) rise faster than inflation.[1, 2] According to previous Office of Inspector General (OIG) work, these inflation-indexed rebates accounted for more than half of all the statutory rebates collected for selected brand-name drugs in 2012.[3, 4] No similar rebate authority exists for Medicare for Part B drugs and biologicals.[5]

On August 30, 2016, OIG received a congressional request asking us to update our earlier calculations of potential rebates for Part B drugs using only the inflation-indexed portion of the rebate methodology. This report presents an independent analysis to inform the ongoing congressional and administration discussions related to Medicare Part B drug spending.

Medicare Part B Payments for Prescription Drugs

Medicare coverage for outpatient prescription drugs is primarily provided under the Part D benefit. However, Medicare also covers specific categories of outpatient drugs under its Part B benefit, including injectable drugs used in the treatment of cancer, certain vaccines, and inhalation and

[1] Section 1927(k)(1) of the Act defines AMP.

[2] Prior to January 2017, manufacturers were required to pay inflation-indexed rebates for only their brand-name drugs (i.e., single-source and innovator multiple-source drugs). Manufacturers are now required to pay inflation-indexed rebates for both their brand-name and generic drugs (i.e., noninnovator multiple source) pursuant to section 1927(c)(3) of the Social Security Act (the Act) as amended by the Bipartisan Budget Act of 2015.

[3] OIG, *Medicaid Rebates for Brand-Name Drugs Exceeded Part D Rebates by a Substantial Margin*, OEI-03-13-00650, April 2015.

[4] Collectively, "State Medicaid programs and the Federal Government" will hereinafter be referred to as "Medicaid."

[5] Part B drugs and biologicals will hereinafter be referred to as "Part B drugs."

infusion drugs used with durable medical equipment (DME).[6] Medicare beneficiaries receive Part B drugs through physician offices; hospital outpatient departments; DME suppliers; and, in certain instances, pharmacies.

To obtain payment for Part B drugs, providers submit claims to Medicare using Healthcare Common Procedure Coding System (HCPCS) codes (see Appendix A for a glossary that describes HCPCS codes and other technical terms used in this report). Medicare pays for most Part B drug HCPCS codes at 106 percent of their volume weighted average sales prices (ASPs).[7, 8] Beneficiaries are responsible for 20 percent of these payments in coinsurance. Medicare and its beneficiaries spent a total of $25.8 billion for Part B drugs in 2015. Although Part B paid for more than 700 prescription drug HCPCS codes that year, spending was concentrated on a relatively small subset, with 64 HCPCS codes accounting for 81 percent of total expenditures.

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 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.[9] In 2015, Medicaid spent $47 billion on prescription drugs. Federal and State governments received $23 billion in statutorily-mandated rebates, which include both the inflation-indexed rebate and basic rebate segments of the rebate formula, that same year.

Under their rebate agreements and pursuant to section 1927(b)(3) of the Social Security Act (the Act), manufacturers must provide the Centers for Medicare & Medicaid Services (CMS) with the AMP and drug category for each of their covered outpatient drugs on a quarterly basis. For rebate purposes, drugs are generally categorized as one of three types: single-source, innovator multiple-source, or noninnovator multiple-

---

[6] 42 CFR § 414.900(b); Medicare Benefit Policy Manual, ch. 15 § 50.

[7] 79 Fed. Reg. 66770, 66874 (Nov. 10, 2014) and section 1847A of the Act. Part B claims dated on or after April 1, 2013, incur a 2-percent reduction in payment in accordance with the Budget Control Act of 2011 and the American Taxpayer Relief Act of 2012 (i.e., sequestration). This mandatory payment reduction is applied after the beneficiary's coinsurance has been determined.

[8] Section 1847A(c) of the Act defines ASP.

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

source.[10] Manufacturers of single-source and innovator multiple-source drugs must also provide CMS with the "best price" for each covered outpatient drug.[11] Manufacturers of noninnovator multiple-source drugs are not required to provide best prices.

Medicaid Drug Rebate Calculation

Under section 1927 of the Act, manufacturers are responsible for accurately calculating and paying rebates to the States. To assist States, CMS uses the pricing and drug category data reported by manufacturers to calculate by national drug code (NDC) a unit rebate amount (URA) every quarter for each covered outpatient drug included in the Medicaid drug rebate program. In general, the URA equals the sum of the basic rebate and the inflation-indexed rebate (if any).

Basic Rebate. 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. 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.

Inflation-Indexed Rebate. If the AMP for a drug has risen faster than the Consumer Price Index-Urban (CPI-U), the drug's manufacturer must pay an additional rebate over and above the basic URA.[12] The formula in section 1927(c) of the Act requires adjusting the original AMP reported for an NDC by inflation and comparing the result to the AMP reported in a given quarter. See Appendix B for a detailed description of the inflation-indexed rebate calculation

Total Rebate. CMS provides the URA for each NDC to State Medicaid agencies each quarter. 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

---

[10] 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.

[11] Section 1927(b)(3)(A)(i)(II) of the Act. Section 1927(c)(1)(C) of the Act defines "best price."

[12] Section 1927(c)(2) of the Act.

portion of the claim, including Part B claims for beneficiaries who also have coverage under Medicare (hereinafter referred to as dual eligibles) for which Medicaid covered any Part B coinsurance or deductible.

The 340B Program and Prohibition of Duplicate Discounts. The 340B Drug Discount Program (340B program) requires drug manufacturers to provide discounted outpatient drugs to certain eligible health care entities—known as covered entities— that serve the underinsured or uninsured and include disproportionate share hospitals.[13] 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 under Medicaid are prohibited by law.[14] 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) when calculating the total rebates owed.

Previous OIG Work

In 2011, a member of Congress requested that OIG quantify the potential rebates that could be associated with a rebate program for Medicare Part B drugs, similar to that under Medicaid. In response, OIG estimated that requiring manufacturers to pay full rebates (i.e., both basic and inflation-indexed rebates) could have resulted in rebates amounting to between $1.9 billion and $2.4 billion in 2010 for 20 brand-name drugs.[15]

In 2013, OIG conducted a study estimating the amount of rebates that could be associated with a rebate program, similar to that under Medicaid, for Part B drugs.[16] OIG found that implementing a Part B rebate program could have resulted in at least $2.7 billion in rebates in 2011 for 60 high-expenditure Part B drugs (note: this estimate was based on both segments of the rebate calculation – basic rebates and inflation-indexed rebates). We recommended that CMS examine the potential impacts of establishing a prescription drug rebate program under Medicare Part B and, if appropriate, seek legislative change. CMS did not concur with this recommendation because the annual President's Budget did not include a proposal to establish a Part B rebate program. In addition, CMS stated

---

[13] Covered entities do not necessarily purchase all of their drugs at 340B prices. Family planning clinics, disproportionate share hospitals, and federally qualified health centers are other examples of covered entities.

[14] 42 U.S.C. § 256b(a)(5)(A).

[15] https://oig.hhs.gov/newsroom/spotlight/2011/rebate-letter.pdf

[16] OIG, *Medicare Could Collect Billions If Pharmaceutical Manufacturers Were Required To Pay Rebates for Part B Drugs*, OEI-12-12-00260, September 2013.

that a comprehensive examination of the impact of such a rebate program would require significant resources.

METHODOLOGY

Data Analysis

Selection of Drugs. We identified 498 HCPCS codes for which we could determine both ASP- and AMP-based rebate amounts (hereinafter referred to as "rebatable drugs"). Using Medicare claims data, we summarized 2015 Medicare expenditures and utilization in all settings and selected the 64 HCPCS codes with the highest total expenditures.[17] Spending for these 64 HCPCS codes constituted 81 percent of total 2015 Part B drug expenditures and 90 percent of expenditures for rebatable drugs.

Calculation of ASP-Based and AMP-Based Inflation-Indexed Rebate Amounts. Because Part B payments for most covered drugs are based on ASPs, we calculated inflation-indexed rebates using this benchmark in each quarter of 2015. We also calculated inflation-indexed rebates based on AMPs—the pricing benchmark used to determine Medicaid rebates. The distinct statutory definitions of ASP and AMP (see Appendix A) mean that certain sales may be included in one benchmark but not the other, and sometimes result in meaningful differences between the two figures.

For all NDCs associated with each of the 64 HCPCS included in our review, we calculated the inflation-indexed rebate using the same method that CMS uses to calculate the inflation-indexed rebate for Medicaid drugs (i.e., we substituted ASPs for AMPs in the statutory formula). We then converted each NDC's inflation-indexed rebate amount so that it represented the amount of the drug specified by the HCPCS code.

Removing Claims for Which Manufacturers Would Not Owe Rebates. We presumed that, similar to Medicaid, duplicate discounts would also be prohibited by law under Medicare if a rebate program were established for Part B drugs. Therefore, before calculating the total Part B inflation-indexed rebate amounts, we removed claims for dual-eligible beneficiaries and claims submitted by 340B-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 2015.

[17] We excluded claims for hospitals that are paid at cost rather than under the hospital outpatient prospective payment system (e.g., critical access hospitals, hospitals of the Indian Health Service). Furthermore, our review includes only drugs that were separately paid for by Medicare (i.e., we did not include drugs for which Medicare bundles payment with associated services).

Total Rebate Calculations. We apportioned the remaining utilization among the NDCs within each HCPCS code using quarterly sales data reported by manufacturers (i.e., one NDC represents 10 percent of total sales, and another NDC represents 15 percent). To determine total inflation-indexed rebate amounts, we multiplied the estimated utilization of each NDC by its ASP-based and AMP-based inflation-indexed rebate amounts and summarized the NDC-level figures by HCPCS code.

Implementation Issues Related to Calculating and Collecting Rebates for Part B. We reviewed previous OIG work involving Medicaid rebates, ASP and AMP 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 current analysis of this study.

See Appendix C for a detailed description of our methodology.

Limitations

We did not review Part B claims or pricing data for accuracy. Because there is no 340B identifier on Part B claims, we removed all claims submitted by 340B-covered entities from our analysis. Therefore, 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 64 drugs in our sample that represent 81 percent of total 2015 Part B drug expenditures; the estimates cannot be generalized to all drug HCPCS codes paid under Part B.

This analysis did not consider how manufacturers might adjust their pricing strategies in response to new rebates. We also did not explore how such rebates may affect beneficiaries. Furthermore, we did not address the operational burden of implementing such a requirement.

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

A rebate program for Medicare Part B drugs could have resulted in at least $1.4 billion in inflation-indexed rebates in 2015

Medicare and its beneficiaries spent $20.8 billion in 2015 for the 64 selected high-expenditure Part B drugs included in our review. That same year, a rebate program for Part B drugs could have resulted in $1.4 billion in inflation-indexed rebates when ASPs rose faster than inflation (see Exhibit 1). Inflation-indexed rebates when AMPs rose faster than inflation could have resulted in $1.8 billion in rebates (see Appendix E for a summary of potential rebates by HCPCS code).

Exhibit 1: Potential Inflation-Indexed Rebates

Rebate Methodology	Actual Part B Drug Expenditures	Potential Inflation-Indexed Rebates	Percentage
ASP-based	$20,816,953,325	$1,421,459,195	7%
AMP-based	$20,816,953,325	$1,812,830,465	9%

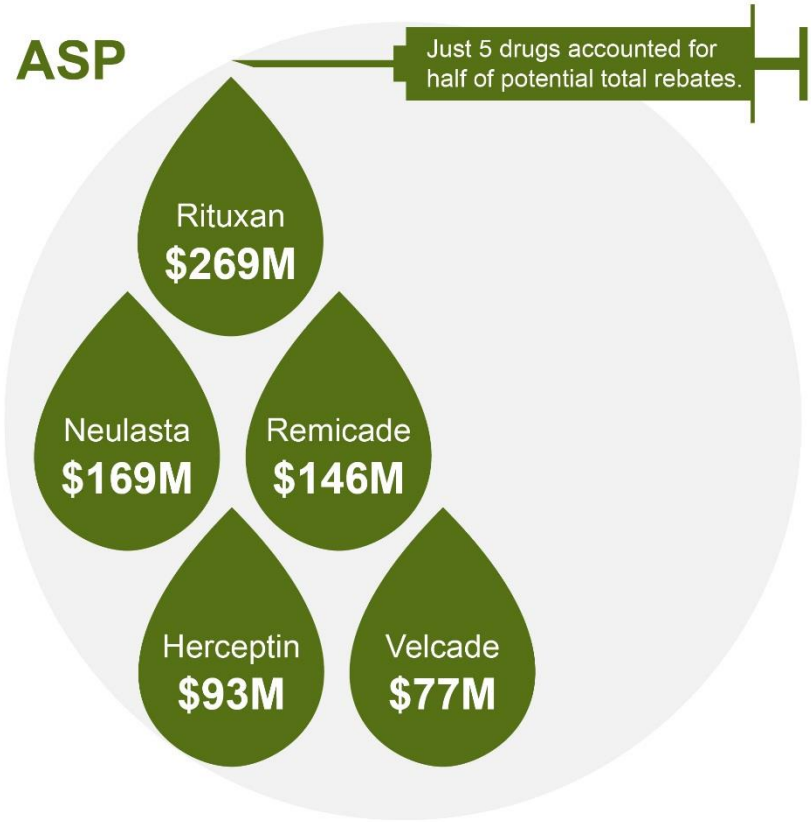
Source: OIG analysis of CMS's 2015 ASP and AMP files and the 2015 National Claims History file

An ASP-based rebate program for Medicare Part B drugs could have resulted in $1.4 billion in inflation-indexed rebates for drugs with ASPs that rose faster than inflation

An ASP-based inflation-indexed rebate program could have resulted in $1.4 billion (7 percent) in rebates for the 64 drugs included in this review. Almost all of the total projected rebates were attributable to single-brand HCPCS codes (i.e., codes associated with one brand-name drug produced by a single manufacturer), which represented $1.3 billion of the total potential rebates and $18.5 billion of the total expenditures (see Appendix F).

In 2015, a rebate program could have resulted in inflation-indexed rebates for 50 of the 64 drugs. ASP-based rebates for just 20 of these 50 HCPCS codes accounted for 89 percent of the $1.4 billion in total projected rebates; just 5 drugs accounted for half of total projected rebates (see Exhibit 2). In contrast, there would have been no inflation-indexed rebates for 14 of the 64 drugs in 2015 because their associated ASPs did not rise faster than inflation. For example, there would have been no inflation-indexed rebates for 2 of the 5 highest-expenditure drugs (aflibercept and ranibizumab), as their ASPs have remained unchanged or have decreased since their introduction to the market.

Exhibit 2: Drugs with the highest potential inflation-indexed rebates using ASP

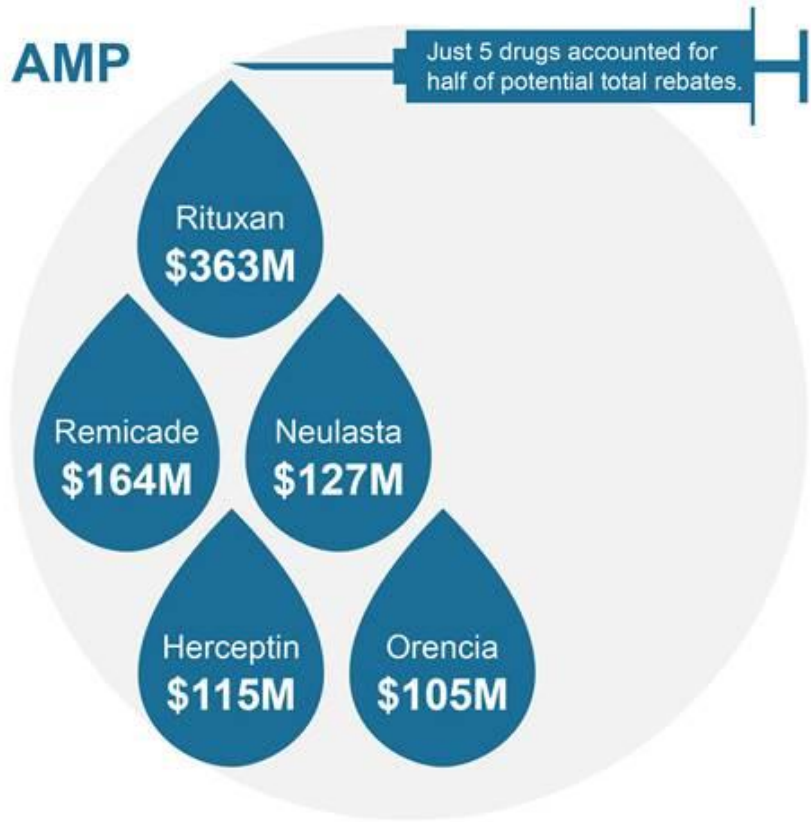


An AMP-based rebate program for Medicare Part B drugs could have resulted in $1.8 billion in inflation-indexed rebates for drugs with AMPs that rose faster than inflation

An AMP-based inflation-indexed rebate program (i.e., using the same rebate formula and pricing data used in Medicaid) could have resulted in $1.8 billion (9 percent) in rebates for the 64 drugs included in this review. Once again, almost all of the total projected rebates were attributable to single-brand HCPCS codes.

In 2015, a rebate program could have resulted in inflation-indexed rebates for 56 of the 64 drugs. AMP-based rebates for just 19 of the 56 HCPCS codes accounted for 89 percent of the $1.8 billion in total projected rebates; just 5 drugs account for nearly half of total projected rebates (see Exhibit 3). In contrast, there would have been no rebates for 8 of the 64 drugs in 2015 because their associated AMPs did not rise faster than inflation.

Exhibit 3: Drugs with the highest potential inflation-indexedrebates using AMP



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

The use of HCPCS codes, incorrect coding conversions, unavailable drug pricing 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 that have improved the Medicaid drug rebate program.

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

Because NDCs are not typically listed on Part B drug claims, CMS would not be able to determine the appropriate manufacturer to invoice in certain instances. Therefore, 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 15 of the 64 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.

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. To address this issue, the Deficit Reduction Act of 2005 mandated that claims for certain physician-administered drugs include the NDC for the drug being billed.

Incorrect unit conversions related to HCPCS codes could cause CMS to improperly invoice manufacturers

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 converted HCPCS code units to NDC units on claims and that providers listed NDCs that do not correspond to the same drug as the HCPCS code.[18] Because manufacturers are invoiced for rebates on the basis of the number of units billed by providers, inaccurate conversions and incorrect codes may cause States to request substantially more or less than they are actually owed. HCPCS/NDC coding and subsequent unit conversion issues were cited by many States as a primary cause of manufacturer rebate disputes. To ensure that manufacturers are invoiced for the correct number of units under a Part B rebate program, CMS would need to verify that providers accurately convert HCPCS units to NDC units on Part B claims.

Unreported drug pricing data would prevent Medicare from collecting rebates for all Part B drugs

A previous OIG study found that for a small number of Part B HCPCS codes, none of the associated drugs were manufactured by companies with Medicaid drug rebate agreements.[19] 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 legislation were enacted that requires all manufacturers of Part B drugs to report the necessary pricing data, as OIG has recommended in the past. CMS did not concur with this recommendation and stated that a proposal

---

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

[19] OIG, *Limitations in Manufacturer Reporting of Average Sales Price Data for Part B Drugs*, OEI-12-13-00040, July 2014.

to require manufacturers of Part B drugs to submit ASPs was not included in the annual President's budget.

Drugs purchased at 340B prices have proven challenging to identify and exclude from rebates

If a Part B rebate program were implemented, Medicare would likely be responsible for ensuring that manufacturers do not provide duplicate discounts for drugs purchased under the 340B program.[20] 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 always identify 340B claims with current billing and claims policies. A 2011 OIG study found that 31 States had not implemented steps necessary for collecting rebates on all eligible physician-administered drugs purchased by 340B-covered entities.[21]

A 2016 OIG study also highlighted the challenge faced by States when identifying 340B-purchased drugs.[22] OIG found that fewer than half of the States included in the review use claim-level methods to identify 340B drug claims. They instead use provider-level methods to identify 340B drug claims, which may not accurately identify all individual 340B drug claims.[23] Provider-level methods generally treat all drug claims from a given covered entity in the same way—that is, as either 340B claims or non-340B claims—and do not allow covered entities to differentiate among specific claims. In practice, however, a covered entity may submit both 340B claims and non-340B claims to Medicaid. OIG recommended that CMS require States to use claim-level methods to identify 340B claims. CMS did not concur with our recommendation, noting that while it agrees with the importance of claim-level methods, the statute does not contemplate such a requirement for States.

---

[20] OIG found that Medicare Part B and its beneficiaries spent $3.5 billion for 340B-purchased drugs in 2013, representing nearly one-fifth of the $19 billion that Part B spent that year on the HCPCS codes included in our review. OIG, *Part B Payments for 340B-Purchased Drugs*, OEI-12-14-00030, November 2015.

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

[22] OIG, *State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates*, OEI-05-14-00430, June 2016.

[23] Provider-level methods identify covered entities that use 340B-purchased drugs for their Medicaid patients and exclude all drug claims billed by those entities when determining total rebates owed. The most prominent provider-level method is HRSA's Medicaid Exclusion File. Claim-level methods exclude individual drug claims that covered entities have explicitly identified on the claim as a 340B-purchased drug.

Because there is no 340B identifier on Part B claims, 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 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 inappropriately billed in excess of the amounts owed in rebates. Requiring claim-level methods to identify 340B-purchased drugs on Part B claims, as OIG has recommended for Medicaid, could resolve this challenge.

CONCLUSION

Each year, manufacturers pay statutorily-mandated Medicaid drug rebates amounting to a substantial percentage of the billions spent on Medicaid prescription drugs. A considerable portion can be attributed to the inflation-indexed portion of the rebate methodology, triggered when manufacturers significantly increase drug prices. Medicare does not have the authority to collect rebates from manufacturers when the cost of Part B drugs increases faster than inflation.

We found that prices for most of the high-expenditure Part B drugs included in our study rose faster than inflation in 2015 and that an inflation-indexed rebate program for Part B could have resulted in at least $1.4 billion in inflation-indexed rebates for 64 high-expenditure outpatient prescription drugs in 2015. However, we did not address the operational burden of implementing such a rebate program or related issues, such as how such a program could affect beneficiary coinsurance obligations, beneficiary drug access, and the overall pharmaceutical marketplace.

This report presents an independent analysis to inform the ongoing congressional and administration discussions related to Medicare Part B drug spending. The results of this current study build upon our original 2013 work and help inform analysis of the potential impact of a Part B rebate program. In implementing a rebate program under Medicare Part B, it would be essential that the data- and claims-related issues described in our findings be addressed.

APPENDIX A

Glossary

340B claim: Claims for drugs purchased under the 340B Drug Discount Program. To prevent subjecting drug manufacturers to duplicate discounts when claiming Medicaid rebates, States need to exclude 340B claims when calculating the total rebates owed by manufacturers.

Average manufacturer price (AMP): 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. CMS uses AMPs to calculate Medicaid rebate amounts.

Average sales price (ASP): 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, net of certain price concessions and discounts. Medicare pays for most Part B drug codes at 106 percent of their ASPs.

Best price: The lowest price available from the manufacturer to any wholesaler, retailor, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, with certain exceptions. CMS uses best price to calculate Medicaid rebate amounts for certain categories of drugs.

Healthcare Common Procedure Coding System (HCPCS) code: Procedure codes used by providers to submit claims to Medicare and to obtain payment for Part B drugs. 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.

National drug code (NDC): An 11-digit code that is divided into three segments identifying (1) the firm that manufactures, distributes, or repackages the drug product; (2) the strength, dosage form, and formulation of the product; and (3) the product's package size. CMS calculates rebate amounts for each NDC representing a Medicaid-covered outpatient drug.

Unit rebate amount (URA): CMS uses the pricing and drug category data reported by manufacturers to calculate a URA every quarter for each NDC included in the Medicaid drug rebate program. The URA equals the sum of the basic rebate and the inflation-indexed rebate (if any).

APPENDIX B

Inflation-Indexed Rebate Calculation

If the AMP for a brand-name drug (i.e., single-source or innovator multiple-source drug) has risen faster than inflation, the drug's manufacturer must pay an additional rebate over and above the basic URA. 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 either the AMP for the calendar quarter beginning July 1, 1990, or, for drugs approved by the Food and Drug Administration after October 1, 1990, 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, which is the consumer price index for September 1990 or the consumer price index for the first month before 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 before the quarter being calculated. The resulting figure is known as the inflation-adjusted baseline AMP.

If the reported AMP is greater than the inflation-adjusted baseline AMP, the difference is added to the basic rebate when determining the URA. Manufacturers are also required to pay inflation-indexed rebates for their generic (i.e., noninnovator multiple-source) drugs as of January 2017.[24]

[24] Section 1927(c)(3) of the Act as amended by the Bipartisan Budget Act of 2015.

APPENDIX C

Detailed Methodology

Data Analysis

Selection of Drugs. Medicare paid providers for 765 Part B drug HCPCS codes in 2015. We removed 267 of the HCPCS codes that year because (1) the associated products were not subject to Medicaid rebates under current rules, or (2) rebate amounts could not be determined for various reasons (see Exhibit 4). The former group includes supplies, vaccines, and products classified as devices by the Food and Drug Administration and Medicaid. The latter group includes products for which rebates could not be determined (e.g., diagnostic agents).

For the remaining 498 HCPCS codes (hereinafter referred to as "rebatable drugs"), we used the National Claims History (NCH) file to summarize 2015 Medicare expenditures and utilization in all settings (i.e., physician offices, and hospital outpatient departments, durable medical equipment suppliers) and selected the 64 HCPCS codes that accounted for 90 percent of 2015 expenditures for rebatable Part B drugs.[25] Spending for these 64 codes constituted 81 percent of total 2015 Part B drug expenditures.

Exhibit 4: Summary of Part B Drug HCPCS Codes Included in Analysis

Number of HCPCS Codes	Drugs Removed	2015 Part B Spending	Percentage of Total
765 (All Part B Drug HCPCS codes)	None	$25.8 billion	100%
664 (After removing drugs not subject to rebates)	38 devices 4 supplies 59 vaccines	$24 billion	93%
498 (After removing drugs for which we could not calculate rebates)	4 blood products 66 diagnostic agents 14 Not Otherwise Classified codes 82 other drugs without pricing data	$23.2 billion	90%
64 (Remaining codes with the highest Part B expenditures)		$20.8 billion	81%

Source: OIG analysis of CMS's 2015 ASP and AMP files and the 2015 NCH file.

[25] We excluded claims for hospitals that are paid at cost rather than under the hospital outpatient prospective payment system (e.g., critical access hospitals, hospitals of the Indian Health Service). Furthermore, our review includes only drugs that were separately paid for by Medicare (i.e., we did not include drugs for which Medicare bundles payment with associated services).

Categorization of Drugs. Using CMS's quarterly 2016 ASP files, we categorized the 64 HCPCS codes as representing a single-brand drug, multiple-brand drug, or generic drug (see Appendix D for a list of the 64 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 50 of the 64 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 64 HCPCS codes as multiple brand. A generic HCPCS code represents either a combination of brand-name and generic drugs or generic drugs only. We classified 9 of the 64 HCPCS codes as generic.

Calculation of ASP-Based Inflation-Indexed Rebate Amounts. We calculated inflation-indexed rebates based on ASPs—the pricing benchmark used to determine Medicare Part B payments—for each of the 64 HCPCS codes included in our review. For all NDCs included in our review (i.e., single-source, innovator multiple-source drug, and noninnovator multiple-source NDCs), we calculated the quarterly ASP-based inflation-indexed rebate using the same method that CMS uses to calculate the inflation-indexed rebate for Medicaid drugs.

Specifically, for each drug, we calculated its inflation-adjusted baseline ASP.[26] We then compared the drug's inflation-adjusted baseline ASP to its ASP in a given quarter. If the ASP was greater than the inflation-adjusted baseline ASP, the manufacturer would have owed the difference as the drug's inflation-indexed rebate amount.

Calculation of AMP-Based Inflation-Indexed Rebate Amounts. We also calculated inflation-indexed rebates based on AMPs—the pricing benchmark used to determine Medicaid rebates—for each of the 64 HCPCS codes included in our review. We calculated the inflation-indexed rebate amount for each single-source and innovator multiple-source drug NDC within a HCPCS code in our sample using Medicaid URAs reported for the associated NDCs in each quarter of 2015. A Medicaid URA includes basic and inflation-indexed rebates. Therefore, to calculate the inflation-indexed portion of the rebate for single-source

[26] Similar to base-date AMP, 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. Similar to CMS's inflation-adjusted AMP methodology, we adjusted the baseline ASP for inflation by first dividing the baseline ASP by the baseline consumer price index for all urban consumers (consumer price index), which is the consumer price index for the first month before the first reported quarter. The result of that calculation is then multiplied by the quarterly consumer price index, which is the consumer price index for the month before the quarter being calculated.

and innovator multiple-source drugs, we reduced each NDC's URA by its basic rebate amount, which, for single-source or innovator multiple-source drugs is the greater of 23.1 percent of the AMP or the difference between the AMP and best price.[27]

Manufacturers are required to pay inflation-indexed rebates for their generic (i.e., noninnovator multiple-source) drugs beginning in January 2017.[28] Because these requirements were not in effect during our study period, the Medicaid URA for these NDCs did not include the inflation-indexed portion of the rebate. Therefore, for generic drugs, we calculated the inflation-indexed rebate using the same method that CMS uses to calculate the inflation-indexed rebate for Medicaid drugs. For each drug, we calculated its inflation-adjusted baseline AMP.[29] We then compared the drug's inflation-adjusted baseline AMP to its AMP in a given quarter. If the AMP was greater than the inflation-adjusted baseline AMP, the manufacturer would have owed the difference as the drug's inflation-indexed rebate amount.

The AMP and URA are calculated for the lowest identifiable quantity of the drug contained in that NDC (e.g., 1 milliliter). In contrast, ASPs and utilization are reported by manufacturers for the entire amount of the drug contained in the NDC (e.g., 50 milliliters). When calculating Part B payment amounts, CMS converts the ASPs and utilization so that they represent the amount of the drug contained in the HCPCS code (e.g., 5 milliliters). To ensure that each NDC's inflation-indexed rebate amount was representative of the correct number of units for the HCPCS code, we converted the inflation-indexed rebate amount so that it represents the amount of the drug specified by the HCPCS code.

Removing Claims for Which Manufacturers Would Not Owe Rebates. Before calculating the total potential Part B inflation-indexed rebate amounts, we removed from our analysis claims for which manufacturers would not owe rebates. First we excluded claims associated with dual eligible beneficiaries because those claims should have already been

---

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

[28] Section 1927(c)(3) of the Act as amended by the Bipartisan Budget Act of 2015.

[29] Base-date AMP is the AMP for the first quarter after the drug's market date. We used CMS's methodology to adjust the baseline AMP for inflation. We first divided 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 before the first quarter after the drug's initial market date. We then multiplied the result of that calculation by the quarterly consumer price index, which is the consumer price index for the month before the quarter being calculated.

subject to Medicaid rebates. We identified Part B drug claims for dual eligibles by matching beneficiaries' health care identifier numbers listed on Part B drug claims against the beneficiary enrollment file.

Next, we removed 340B claims from our analysis because duplicate discounts are prohibited by law.[30, 31] Using the Health Resources and Services Administration's 340B-covered entities file accessed on November 16, 2016, we identified and removed any Part B drug claims submitted by 340B-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 2015.

Total Rebate Calculations. After removing claims associated with dual eligible beneficiaries and/or 340B entities, we apportioned the remaining utilization among the 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 units sold of a drug represented by each NDC (i.e., one NDC represents 10 percent of total sales, and another NDC represents 15 percent). We then multiplied these percentages by the total quarterly utilization of each HCPCS code to estimate utilization for each NDC.[32] To determine total inflation-indexed rebate amounts, we multiplied the estimated utilization of each NDC by its AMP-based and ASP-based inflation-indexed rebate amounts and summarized the NDC-level figures by HCPCS code.

We also summarized HCPCS codes' ASP-based and AMP-based rebates by whether they represented a single-brand, multiple-brand drug, or generic drug in 2015.

Implementation Issues Related to Calculating and Collecting Rebates for Part B. We reviewed previous OIG work involving Medicaid rebates, 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

---

[30] Manufacturers provide duplicate discounts when they pay Medicaid rebates to States for drugs sold at discounted prices through the 340B Drug Pricing Program (i.e., 340B program). 42 U.S.C. § 256b(a)(5)(A).

[31] We presumed that similar to Medicaid, duplicate discounts would also be prohibited by law under Medicare if a rebate program were established for Part B drugs.

[32] We determined that the number of units listed in the 2015 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 estimated 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.

study, such as identifying claims for drugs purchased at 340B prices and obtaining information to calculate drug rebates.

APPENDIX D

Drug Descriptions

HCPCS Code	HCPCS Code Description	HCPCS Dosage	HCPCS Classification
A9606	Radium ra-223 dichloride	1 microCurie	Single-Brand
C9027	Pembrolizumab injection	1 mg	Single-Brand
C9453	Nivolumab injection	1 mg	Single-Brand
J0129	Abatacept injection	10 mg	Single-Brand
J0178	Aflibercept injection	1 mg	Single-Brand
J0256	Alpha 1 proteinase inhibitor injection	10 mg	Multiple-Brand
J0490	Belimumab injection	10 mg	Single-Brand
J0585	Onabotulinumtoxina injection	1 unit	Single-Brand
J0717	Certolizumab pegol injection	1 mg	Single-Brand
J0878	Daptomycin injection	1 mg	Single-Brand
J0881	Darbepoetin alfa injection	1 mcg	Single-Brand
J0885	Epoetin alfa injection	1000 units	Multiple-Brand
J0894	Decitabine injection	1 mg	Generic
J0897	Denosumab injection	1 mg	Single-Brand
J1300	Eculizumab injection	10 mg	Single-Brand
J1442	Filgrastim (g-csf) injection	1 mcg	Single-Brand
J1453	Fosaprepitant injection	1 mg	Single-Brand
J1459	Immune globulin (privigen) injection	500 mg	Single-Brand
J1559	Immune globulin (hizentra) injection	100 mg	Single-Brand
J1561	Immune globulin (gamunex-c/gammaked) injection	500 mg	Multiple-Brand
J1568	Immune globulin (octagam) injection	500 mg	Single-Brand
J1569	Immune globulin (gammagard liquid) injection	500 mg	Single-Brand
J1602	Golimumab injection	1 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 hcl 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
J7189	Factor viia	1 mcg	Single-Brand
J7192	Factor viii	1 IU	Multiple-Brand
J7507	Tacrolimus oral	1 mg	Generic

HCPCS Code	HCPCS Code Description	HCPCS Dosage	HCPCS Classification
J7517	Mycophenolate mofetil oral	250 mg	Generic
J7518	Mycophenolic acid oral	180 mg	Generic
J7605	Arformoterol inhalation solution	15 mcg	Single-Brand
J7606	Formoterol fumarate inhalation solution	20 mcg	Single-Brand
J7626	Budesonide inhalation solution	up to 0.50 mg	Generic
J7686	Treprostinil inhalation solution	1.74 mg	Single-Brand
J9025	Azacitidine injection	1 mg	Generic
J9033	Bendamustine hcl injection	1 mg	Single-Brand
J9035	Bevacizumab injection	10 mg	Single-Brand
J9041	Bortezomib injection	0.1 mg	Single-Brand
J9043	Cabazitaxel injection	1 mg	Single-Brand
J9047	Carfilzomib injection	1 mg	Single-Brand
J9055	Cetuximab injection	10 mg	Single-Brand
J9070	Cyclophosphamide	100 mg	Generic
J9217	Leuprolide acetate suspension	7.5 mg	Multiple-Brand
J9228	Ipilimumab injection	1 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
J9306	Pertuzumab injection	1 mg	Single-Brand
J9310	Rituximab injection	100 mg	Single-Brand
J9354	Ado-trastuzumab emtansine injection	1 mg	Single-Brand
J9355	Trastuzumab injection	10 mg	Single-Brand
J9395	Fulvestrant injection	25 mg	Single-Brand
Q2043	Sipuleucel-T auto CD54+	minimum 50 million cells	Single-Brand
Q2050	Doxorubicin hydrochloride injection	10 mg	Generic

Note: A single-brand HCPCS code represents only one brand-name drug (and no generics) produced by a single manufacturer. A multiple-brand HCPCS code represents two or more brand-name drugs produced by more than one manufacturer. A generic HCPCS code represents either a combination of brand-name and generic drugs or of generic drugs only.

Source: OIG analysis of Centers for Medicare & Medicaid Services (CMS) 2015 average sales price files.

APPENDIX E

ASP-Based and AMP-Based 2015 Part B Inflation-Indexed Rebates for 64 High-Expenditure Drugs

HCPCS Code	Total 2015 Part B Expenditures	2015 ASP-Based Rebates	Percentage of Part B Spending	2015 AMP-Based Rebates	Percentage of Part B Spending
A9606	$126,060,515	$686,707	1%	$9,979,200	8%
C9027	$96,225,452	$33,347	0%	$14,458	0%
C9453	$134,717,544	$0	0%	$95	0%
J0129	$464,998,446	$71,652,810	15%	$105,177,314	23%
J0178	$1,850,750,116	$0	0%	$0	0%
J0256	$68,144,898	$1,323,129	2%	$636,142	1%
J0490	$67,602,924	$119,485	0%	$538,212	1%
J0585	$262,433,507	$0	0%	$24,940,558	10%
J0717	$178,260,140	$41,824,518	23%	$63,602,222	36%
J0878	$104,716,722	$36,529,223	35%	$37,093,622	35%
J0881	$298,442,136	$24,863,038	8%	$46,356	0%
J0885	$294,837,423	$13,427,498	5%	$454,505	0%
J0894	$104,703,502	$0	0%	$5,710	0%
J0897	$932,095,376	$0	0%	$7,702,712	1%
J1300	$236,251,083	$6,217,949	3%	$6,217,935	3%
J1442	$129,494,396	$20,038,850	15%	$29,785,084	23%
J1453	$75,973,914	$0	0%	$0	0%
J1459	$210,002,809	$1,418,328	1%	$2,402,977	1%
J1559	$184,215,806	$4,260,100	2%	$7,723,456	4%
J1561	$293,809,820	$2,371,386	1%	$2,883,989	1%
J1568	$169,329,971	$17,017,136	10%	$8,354,829	5%
J1569	$268,543,924	$12,189,481	5%	$22,190,634	8%
J1602	$129,747,902	$698,440	1%	$1,282,215	1%
J1745	$1,279,370,904	$145,620,900	11%	$163,857,900	13%
J2260	$141,554,000	$2,241,982	2%	$0	0%
J2323	$303,571,226	$20,836,852	7%	$74,719,833	25%
J2353	$386,650,822	$24,871,621	6%	$101,442,449	26%
J2357	$275,915,288	$57,429,253	21%	$58,054,607	21%
J2469	$181,237,603	$10,084,267	6%	$144	0%
J2505	$1,279,584,855	$168,676,519	13%	$127,404,160	10%
J2778	$1,173,915,082	$0	0%	$0	0%
J2785	$120,262,495	$4,032,133	3%	$4,443,601	4%
J2796	$161,439,429	$16,174,907	10%	$15,822,414	10%
J3262	$162,852,165	$4,270,842	3%	$4,377,919	3%
J3285	$177,698,758	$0	0%	$22,950,051	13%

HCPCS Code	Total 2015 Part B Expenditures	2015 ASP-Based Rebates	Percentage of Part B Spending	2015 AMP-Based Rebates	Percentage of Part B Spending
J7189	$99,806,682	$3,772,769	4%	$7,587,084	8%
J7192	$234,401,062	$635,056	0%	$0	0%
J7507	$97,729,530	$491,592	1%	$8,484,148	9%
J7517	$80,073,907	$20,675,247	26%	$24,359,190	30%
J7518	$119,606,568	$13,889,331	12%	$16,302,289	14%
J7605	$181,724,396	$47,922,668	26%	$88,510,116	49%
J7606	$81,036,463	$31,725,224	39%	$46,664,659	58%
J7626	$233,792,529	$15,062,458	6%	$15,298,228	7%
J7686	$213,630,146	$22,404,754	10%	$16,335,484	8%
J9025	$144,225,592	$364,107	0%	$16,809	0%
J9033	$314,863,267	$5,598,500	2%	$5,364,896	2%
J9035	$1,139,264,181	$0	0%	$54	0%
J9041	$514,529,558	$76,994,382	15%	$87,838,026	17%
J9043	$75,335,126	$620,586	1%	$77,510	0%
J9047	$231,980,278	$5,493,153	2%	$5,788,165	2%
J9055	$247,660,653	$0	0%	$232	0%
J9070	$86,196,664	$14,926,623	17%	$16,886,218	20%
J9217	$283,102,959	$17,286,231	6%	$17,883,963	6%
J9228	$218,882,552	$6,892,938	3%	$5,701,862	3%
J9264	$281,360,889	$0	0%	$0	0%
J9303	$80,409,421	$1,577,667	2%	$1,929,033	2%
J9305	$555,401,558	$57,123,938	10%	$59,978,718	11%
J9306	$169,153,658	$0	0%	$0	0%
J9310	$1,592,316,822	$269,255,495	17%	$362,766,151	23%
J9354	$107,447,525	$0	0%	$0	0%
J9355	$654,609,456	$93,306,028	14%	$114,588,997	18%
J9395	$189,303,156	$2,337,083	1%	$31	0%
Q2043	$173,648,618	$4,192,665	2%	$4,546,123	3%
Q2050	$90,049,156	$0	0%	$1,817,177	2%
Totals	**$20,816,953,325**	**$1,421,459,195**	**7%**	**$1,812,830,465**	**9%**

Notes: Total Part B expenditures were calculated using 2015 figures for physician, outpatient hospital, and durable medical equipment claims. Rebates based on average manufacturer prices and average sales prices for 2015 were calculated after removing claims for drugs purchased at 340B prices and claims for beneficiaries enrolled in both Medicare and Medicaid. Totals may not equal the sum of individual numbers due to rounding.

Source: OIG analysis of 2015 National Claims History files, Centers for Medicare & Medicaid Services (CMS) 2015 Medicaid unit rebate amounts files, and CMS's 2015 average sales price files.

APPENDIX F

Potential Inflation-Indexed Rebates Associated With Each Drug Type

HCPCS Classification	ASP-Based Rebates	AMP-Based Rebates
Single-Brand (n=50)	$1,318,764,556	$1,707,802,095
Multiple-Brand (n=5)	$35,043,299	$21,858,600
Generic (n=9)	$67,651,339	$83,169,770
TOTAL	**$1,421,459,195**	**$1,812,830,465**

Source: OIG analysis of CMS's 2015 ASP and AMP files and the 2015 NCH file.
Note: The total does not equal the sum of the individual rebates due to rounding.

ACKNOWLEDGMENTS

This report was prepared under the direction of Dave Tawes, Regional Inspector General for Evaluation and Inspections in the Baltimore regional office, and Louise Schoggen, Assistant Regional Inspector General.

Bahar Adili served as team leader for this study. Central office staff who provided support include Clarence Arnold, Berivan Demir Neubert, Meghan Kearns, and Christine Moritz. Office of Management and Policy Staff who provided support include Jessica Swanstrom.

Office of Inspector General

http://oig.hhs.gov

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of individuals served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and individuals. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.