

U.S. Department of Health and Human Services
Office of Inspector General



Technical Assistance Brief: Implementation of Inflation-Indexed Rebates for Part B Drugs

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February 2023, OEI-BL-23-00170





Why OIG Did This Review

The IRA requires CMS to calculate inflation indexed rebates for certain Part B drugs beginning in 2023. Prior OIG work estimated that Medicare could collect billions of dollars in inflation indexed rebates similar to those authorized by the IRA. OIG faced several methodological challenges when conducting this past work that could be informative for CMS and stakeholders as the agency implements the new rebate provisions. This technical assistance brief is intended as technical assistance for CMS to consider as it implements these new provisions.

How OIG Did This Review

This technical assistance brief compiles insights on potential challenges in implementing inflation indexed rebates for Part B drugs. The insights provided are drawn from OIG's prior evaluations of Part B drug rebates and our larger body of prescription drug work.

Challenges That OIG Identified

On the basis of our prior oversight work, we anticipate that unless CMS takes action to remedy several administrative issues, the agency will face the following challenges in implementing rebates:

- Identifying products subject to Part B rebates; and
- Excluding claims from Part B rebate calculations that were already subject to:
 - Rebates under the Medicaid Drug Rebate Program, and
 - Discounts under the 340B Drug Discount Program.

We propose potential solutions to mitigate each administrative issue.

Technical Assistance Brief: Implementation of Inflation-Indexed Rebates for Part B Drugs

The Inflation Reduction Act of 2022 (IRA) directs drug manufacturers to pay quarterly rebates to the U.S. Department of Health and Human Services (HHS) for certain drugs and biologicals (hereinafter referred to as "drugs") covered under Medicare Part B. Manufacturers owe rebates if the Part B payment amount for their drug rises faster than inflation. Rebate provisions took effect in January 2023.¹

Over the past decade, OIG has issued three reports projecting how much Medicare could save if manufacturers paid rebates for Part B drugs similar to those owed under Medicaid. Our most recent work estimated that Medicare could have collected \$1.4 billion in 2015 had manufacturers been required to pay inflation-indexed rebates for 64 high-expenditure Part B drugs.²

OIG faced several methodological challenges when conducting the analysis for our past work on Part B rebates. This technical assistance brief compiles insights from this work specifically, as well as from our extensive body of prescription drug work in general. We summarize significant administrative challenges that CMS will face in implementing Part B rebate provisions and also identify potential solutions to mitigate these challenges. The potential solutions are not official recommendations to CMS; rather, they are rooted in findings from prior OIG evaluations and offer summary-level technical assistance to the agency. OIG is also providing more detailed technical assistance on these issues to CMS staff in conjunction with this technical assistance brief. Other solutions may be identified as the new rebate program is implemented.

CHALLENGE #1

Identifying products subject to Part B rebates

Requirement in IRA

Only single source drugs are subject to Part B rebates. Single source drugs are typically brand name products with no available generic versions.

Challenge

Rebates are calculated on the basis of increases in Part B payment amounts, which are set at the HCPCS code level. However, in a small number of cases, a single HCPCS code may represent several single source drugs from different manufacturers.

For these codes, CMS would find it difficult to determine which manufacturer(s) owe rebates, as well as the number of units and amount of rebates associated with each drug.

Potential Solutions

- 1) Require providers to include on claims national drug codes (NDCs) identifying the specific drug administered and the manufacturer of the drug; or
- 2) For HCPCS codes associated with single source drugs from multiple manufacturers, develop a method to apportion the number of units and amount of rebates to each manufacturer.

Rebates are calculated on the basis of HCPCS-level payment amounts. However, a small number of HCPCS codes represent single-source drugs from multiple manufacturers.

The IRA requires that only single-source drugs (or biologicals, including biosimilars) may be “rebateable”—i.e., subject to Part B rebates.³ In general terms, a single-source drug would typically be a brand-name product with no available generic versions.⁴

Medicare pays for Part B drugs at the HCPCS code level.⁵ A HCPCS code defines a drug’s name and the amount of drug represented by one unit of the code but does not specify manufacturer or package size information. Drugs from multiple manufacturers may meet the definition of a HCPCS code.

As required by the IRA, CMS must calculate any inflation-indexed rebates for Part B drugs for each calendar quarter by multiplying (1) the amount by which the HCPCS code’s payment amount in that quarter exceeds its inflation-adjusted payment amount (i.e., the inflation-adjusted payment amount in the benchmark quarter) and (2) the total number of Part B units furnished for the HCPCS code for that quarter.⁶ If the HCPCS code’s payment amount—which is

calculated on the basis of manufacturer-reported average sales prices—rises faster than inflation, then rebates are owed for that drug. If a HCPCS code is associated with single source drug(s) produced by just one manufacturer, rebate calculations will be relatively straightforward. However, in a small number of cases, a HCPCS code may be associated with single-source drugs produced by multiple manufacturers. For example, 5 of the 60 HCPCS codes for which OIG calculated potential Part B rebates in a past study represented 2 or more single-source drugs produced by more than 1 manufacturer.⁷ For HCPCS codes associated with multiple manufacturers, CMS will face the following challenges in calculating rebates:

Determining how many units to invoice for each manufacturer. Part B claims generally do not include a drug code (i.e., NDC) identifying the specific drug administered and the manufacturer of the drug.⁸ As a result, for HCPCS codes associated with single-source drugs from multiple manufacturers, CMS cannot determine the exact number of units for which each manufacturer owes rebates.

Determining the rebate amount owed by each manufacturer. CMS calculates payment amounts by averaging pricing data for all drugs that meet the definition of the HCPCS code. As a result, price increases for just one drug may disproportionately cause the HCPCS code's payment amount to rise faster than inflation and therefore require manufacturer(s) to pay rebates for the HCPCS code.

For HCPCS codes crosswalked to single-source drugs from more than one manufacturer, a manufacturer may raise concerns about CMS's rebate requests if its drug's price remained relatively steady and thus is not the product which triggered the rebate.⁹

To address these challenges, CMS could choose among the following options:

Require providers to include NDCs on Part B claims

CMS could explore requiring providers to include NDCs on claims, thus enabling the agency to identify the number of units and rebate amount owed by each manufacturer. A similar requirement for Medicaid drug claims has helped State Medicaid agencies collect additional Medicaid rebates on physician-administered drugs.¹⁰

Develop a methodology to apportion units and rebates to each manufacturer

If CMS does not require providers to include NDCs on claims, the agency would need to apportion the units to each associated single-source drug and, thereby, to each manufacturer. OIG developed a similar methodology for its past work calculating potential rebates for Part B drugs, using nonpublic sales data reported to CMS for each NDC to estimate the percentage of Part B-paid units represented by each NDC (i.e., one manufacturer's product represented 70 percent of total sales, and another manufacturer's product represented 30 percent).¹¹

CMS would also need to develop a method to apportion the rebate amount to the appropriate single-source drug and its manufacturer. The calculation could be based on the change in each single-source drug's ASP.

CHALLENGE #2

Identifying units that would be subject to Medicaid drug rebates

Requirement in IRA

CMS must exclude from Part B rebate calculations units subject to Medicaid rebates.

Units on a Part B claim would be subject to Medicaid rebates if Medicaid pays a portion of a claim, which could be the case if the claim is for an individual enrolled in both Medicare and Medicaid (known as a dual eligible enrollee).

Challenge

There are no fields on Part B claims that indicate whether Medicaid will pay a portion of the claim and that, as a result, the units would be subject to Medicaid rebates.

Potential Solutions

- 1) Use the MMA File to identify whether a Part B claim is for a dual eligible enrollee;
- 2) Add a field to Part B claims to indicate whether Medicaid will pay a portion of the claim; or
- 3) Develop an automated mechanism to identify Part B claims for which Medicaid will pay a portion.

Part B claims do not indicate whether the units on the claim would be subject to Medicaid rebates

The IRA requires CMS to exclude from Part B rebate calculations units that are already subject to discounts from the 340B Drug Discount Program or the Medicaid Drug Rebate Program.^{12, 13}

Units on a Part B claim would be subject to Medicaid rebates if Medicaid pays any portion of the claim, which could be the case if the claim was for a dual-eligible enrollee. Dual-eligible enrollees are typically individuals with low income who are enrolled in both Medicare and Medicaid.

Integration and coordination between Medicare and Medicaid is an ongoing issue and a key area of focus for CMS and State Medicaid agencies.¹⁴ Medicare and Medicaid were originally created as distinct programs, and claims are generally processed separately. There are no fields on a Part B claim that would allow CMS to determine whether the units on the claim will be subject to Medicaid rebates.

To address these challenges, CMS could explore the following solutions:

Use the MMA File to identify whether a Part B claim is for a dual-eligible enrollee

Currently, CMS may be limited to using existing enrollment data to identify Part B claims for dual-eligible enrollees. CMS's MMA File in the Integrated Data Repository contains Medicare enrollee identification numbers for dual-eligible enrollees.¹⁵ After a claim is paid, CMS could match Medicare enrollee identification numbers in the MMA File for dual-eligible enrollees to Medicare identification numbers on Part B claims, and subsequently exclude any associated claims from rebate consideration if the claim date falls within the period of dual enrollment. Due to the limited availability of Medicaid claims data at the time of OIG's previous work related to Part B rebates, we used a similar matching process to identify Part B claims for dual-eligible enrollees.¹⁶ However, systematically excluding all Part B drug claims for dual-eligible enrollees, even if Medicaid did not pay a portion of the claim, would result in Medicare not receiving all the rebates it is owed.

Add a field to Part B claims to indicate whether Medicaid will pay a portion of the claim

In general, a patient enrolled in both Medicaid and Medicare Part B would notify their provider of their dual-eligibility status. If CMS adds a field to Part B claims indicating dual-eligible status, providers could specify on the claim whether the patient is enrolled in both Medicaid and Medicare Part B. CMS could use information from the provider to exclude all Part B claims for dual-eligible enrollees. However, as with the aforementioned solution, using this method would also result in Medicare not receiving all the rebates it is owed.

Develop an automated mechanism to identify Part B claims for which Medicaid will pay a portion

CMS could develop a mechanism that automatically flags in the agency's system, upon receipt, Part B claims for which Medicaid will pay a portion. To automate the process and effectively exclude these claims from rebate calculations, CMS may need to integrate (1) Medicare claims processing systems; (2) Medicaid claims processing systems; and (3) real-time enrollment data.

CHALLENGE #3

Identifying units purchased at discount prices under the 340B Drug Discount Program

Requirement in IRA

CMS must exclude from Part B rebate calculations units that were already subject to discounts for drugs purchased by covered entities at discount prices under the 340B Drug Discount Program.

Challenge

CMS recently announced that modifiers indicating that a drug was purchased at 340B discount prices will be required on all Part B claims for these drugs effective January 2024.

The modifier requirement is new for non hospital covered entities, as well as affiliated physicians and suppliers. It may take time for these covered entities, providers, and suppliers to adjust their billing systems to the new requirement.

Potential Solution

Monitor the use of 340B modifiers, especially among covered entities that had not used the modifier prior to the new program guidance.

CMS must exclude units for drugs purchased at 340B discount prices from rebate calculations

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. Covered entities generally serve a disproportionate share of patients with low incomes.¹⁷ A covered entity may not necessarily purchase all of its drugs at 340B discount prices.

The IRA requires CMS to exclude from Part B rebate calculations units that were already subject to discounts for drugs purchased by covered entities (i.e., 340B-purchased drugs).¹⁸ A previous OIG study found that Medicare spent \$3.5 billion on 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.¹⁹

Some Part B claims for 340B-purchased drugs may not be readily identifiable in 2023

As of 2018, hospitals that participate in the 340B Program are required to include modifiers on Part B claims indicating that the claim is for a drug purchased at a discounted 340B price.²⁰ CMS instituted this requirement to implement a distinct payment policy (that has since been rescinded) for drugs purchased at 340B prices by hospitals.²¹

In recent rulemaking, CMS requires hospitals participating in the 340B Program to continue using modifiers in 2023 to identify 340B-purchased drugs for informational purposes.²² CMS also recently released guidance requiring (1) hospitals participating in the 340B Program to continue using modifiers beyond 2023 and (2) covered entities that are not hospitals, such as Ryan White clinics and hemophilia clinics, as well as individual providers and suppliers affiliated with covered entities, to include such modifiers on claims for 340B-purchased drugs effective no later than January 1, 2024.²³

For 2023, CMS may not be able to solely rely on 340B modifiers to identify Part B claims for 340B-purchased drugs. CMS encourages—but does not require—covered entities that are not hospitals as well as affiliated providers and suppliers to “begin using the appropriate modifier as soon as possible.” Some of these covered entities, providers, and suppliers may use 340B modifiers for a portion of 2023—or not at all—because the modifier requirement is new for these entities and will require changes to billing systems that could take time to operationalize. A previous OIG study found that Part B expenditures for 340B-purchased drugs provided by covered entities that are not hospitals, as well as providers and suppliers affiliated with covered entities, accounted for 3 percent of total associated Part B drug expenditures.²⁴

CMS should consider monitoring the use of 340B modifiers, especially among covered entities that had not used the modifier prior to the new program guidance

Had CMS not required modifiers, the agency would not be able to exclude claims for 340B-purchased drugs specifically, and would likely instead need to exclude all claims submitted by covered entities. OIG faced this challenge in previous work and needed to use an extremely burdensome process of matching provider identifiers on Part B claims to the Health Resources and Services Administration’s covered entities database.²⁵

Most covered entities have been using 340B modifiers on Part B claims since 2018. However, covered entities that are not hospitals, as well as providers and suppliers affiliated with covered entities, have not been required to use the 340B modifiers. CMS should consider monitoring the use of 340B modifiers, especially among these covered entities, providers, and suppliers. For 2023 rebate calculations in particular, CMS may need to take steps to identify claims for 340B-purchased drugs that are submitted without a 340B modifier.

CONCLUSION

Medicare's new authority to collect rebates for certain Part B drugs has the potential to recoup billions of dollars for Medicare and its enrollees. Our most recent work estimated that Medicare could have collected \$1.4 billion had manufacturers been required in 2015 to pay inflation-indexed rebates for 64 high-expenditure Part B drugs.²⁶

However, several administrative issues hinder the implementation of a comprehensive rebate program. The challenges and solutions we identify are rooted in findings from our past work on Part B rebates as well as from our extensive body of prescription drug work in general. OIG looks forward to working with CMS as it navigates the complexities of the IRA Part B rebate provisions and ensures that Medicare appropriately collects all the rebates that are owed to the program.

ACKNOWLEDGMENTS AND CONTACT

Acknowledgments

Bahar Adili served as the team leader for this study. Office of Evaluation and Inspections headquarters staff who provided support include Melissa Baker and Christine Moritz.

This report was prepared under the direction of Dave Tawes, Regional Inspector General for Evaluation and Inspections in the Baltimore Regional Office; Heather Barton, Deputy Regional Inspector General; and Louise Schoggen, Assistant Regional Inspector General.

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ENDNOTES

¹ The Centers for Medicare & Medicaid Services (CMS) has until September 30, 2025, to invoice manufacturers for 2023 and 2024 rebates. For each Part B rebatable drug, CMS is required to include on invoices the total number of units for which manufacturers owe rebates, the difference between the payment amount and the inflation-adjusted payment amount (i.e., the inflation-adjusted payment amount in the benchmark quarter), and the rebate amount. Manufacturers must pay rebates within 30 days of receiving the invoice. Rebates will be deposited into the Medicare Trust Fund. 42 U.S.C. §1395w-3a(i)(1) and (i)(6).

² This study estimated two inflation-indexed rebate calculations—one based on average sales prices (ASPs), and another based on average manufacturer prices (AMPs). ASPs are used to calculate Part B drug payment amounts and AMPs are used to calculate rebate amounts under the Medicaid Drug Rebate Program. 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. OIG, *Calculation of Potential Inflation-Indexed Rebates for Medicare Part B Drugs*, OEI-12-17-00180, August 2017. OIG also conducted the following work calculating potential Part B drug rebates had manufacturers been required to pay rebates similar to those under Medicaid (i.e., both basic rebates and inflation-indexed rebates): OIG, *Medicare Could Collect Billions If Pharmaceutical Manufacturers Were Required To Pay Rebates for Part B Drugs*, OEI-12-12-00260, September 2013. Finally, in response to a Congressional request, OIG issued a letter to the member of Congress in 2011 estimating potential Part B rebates for 20 HCPCS codes representing brand-name drugs produced by a single manufacturer.

³ 42 U.S.C. §1395w-3a(i)(2)(A).

⁴ Generic products and brand-name drugs for which there is a generic version available are not subject to Part B rebates.

⁵ To calculate HCPCS code payment amounts, CMS averages pricing data by sales volume for all national drug codes (NDCs) crosswalked to a HCPCS code. Medicare pays for most Part B drugs at 106 percent of the volume-weighted average sales prices. 42 U.S.C. §1395w-3a(b)(1).

⁶ The components and calculation of the rebate amount are set forth in 42 U.S.C. §1395w-3a(i)(3).

⁷ For that same study, 48 of the 60 HCPCS codes represented single-source drugs produced by a single manufacturer, and 7 of the 60 HCPCS codes represented either a combination of brand-name and generic drugs or of generic drugs only. OIG, *Medicare Could Collect Billions If Pharmaceutical Manufacturers Were Required To Pay Rebates for Part B Drugs*, OEI-12-12-00260, September 2013.

⁸ An 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 strength, dosage form, and formulation of the product; and (3) the product's package size.

⁹ The IRA does not contain a mechanism for manufacturers to dispute rebate invoices. 42 U.S.C. §1395w-3a(i)(8).

¹⁰ For many years, Medicaid faced problems 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. Following the release of that OIG report, the Deficit Reduction Act of 2005 (DRA), Pub. L. No. 109-171, specifically required States to collect rebates for certain physician-administered drugs for Federal financial participation to be available. 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. See Section 1927(a)(7) of the Social Security Act, as added by section 6002 of the DRA; OIG, *Medicaid Rebates for Physician-*

Administered Drugs, OEI-03-02-00660, April 2004; and OIG, *States' Collection of Medicaid Rebates for Physician-Administered Drugs*, OEI-03-09-00410, June 2011.

¹¹ For two of OIG's previous studies estimating potential Part B rebates, we developed a methodology to apportion HCPCS code units to the individual NDCs crosswalked to each HCPCS code. Because NDC-level utilization is not tracked under Part B, we used CMS's nonpublic ASP files to determine the percentage of total sales of a HCPCS code represented by each NDC (i.e., one NDC represented 70 percent of total sales, and another NDC represented 30 percent). We then multiplied these percentages by the total quarterly utilization of each HCPCS code to estimate utilization for each NDC. OIG, *Medicare Could Collect Billions If Pharmaceutical Manufacturers Were Required To Pay Rebates for Part B Drugs*, OEI-12-12-00260, September 2013. OIG, *Calculation of Potential Inflation-Indexed Rebates for Medicare Part B Drugs*, OEI-12-17-00180, August 2017.

¹² 42 U.S.C. §1395w-3a(i)(3)(B)(ii)(I).

¹³ The Medicaid Drug Rebate Program (MDRP) was created in 1990 to reduce State and Federal Medicaid expenditures for prescription drugs. Manufacturers pay quarterly rebates to State Medicaid agencies under MDRP in exchange for Medicaid coverage of the manufacturer's drugs. Fifty states and the District of Columbia, as well as approximately 780 drug manufacturers, participate in this program. Sections 1927(a)(1) and (b)(1) of the Social Security Act. Also, see CMS, *Medicaid Drug Rebate Program*. Accessed at <https://www.medicare.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html> on November 21, 2022.

¹⁴ For example: CMS, *SMDL #18-012 RE: Ten Opportunities to Better Serve Individuals Dually Eligible for Medicaid and Medicare*. Accessed at <https://www.medicare.gov/federal-policy-guidance/downloads/smd18012.pdf> on November 21, 2022.

¹⁵ CMS, *Defining Medicare-Medicaid Dually Enrolled Beneficiaries in CMS Administrative Data March 2021*.

Accessed at https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/MMCO_DualEligibleDefinition.pdf on November 21, 2022. CMS, *Medicare Advantage Prescription Drug State User Guide, Version 10.1, July 18, 2022*. Accessed at <https://www.cms.gov/files/document/mapd-state-user-guide-version-101.pdf> on December 2, 2022.

¹⁶ OIG, *Medicare Could Collect Billions If Pharmaceutical Manufacturers Were Required To Pay Rebates for Part B Drugs*, OEI-12-12-00260, September 2013. OIG, *Calculation of Potential Inflation-Indexed Rebates for Medicare Part B Drugs*, OEI-12-17-00180, August 2017.

¹⁷ To have their drugs covered by Medicaid, manufacturers must agree to sell covered outpatient drugs at or below statutorily defined discount prices (340B ceiling prices) to covered entities. Examples of covered entities are disproportionate share hospitals, federally qualified health centers, and critical access hospitals. As of November 2022, approximately 55,000 covered entity sites participate in the 340B Program. Covered entities may have multiple sites (i.e., covered entity sites) for health care delivery. 42 U.S.C. §§ 256b(a)(1) and (a)(4). HRSA, *Covered Entity Database*. Accessed at <https://340bopais.hrsa.gov/> on November 18, 2022.

¹⁸ 42 U.S.C. §1395w-3a(i)(3)(B)(ii)(I).

¹⁹ OIG, *Part B Payments for 340B-Purchased Drugs*, OEI-12-14-00030, November 2015. Expenditures for 340B-purchased drugs were concentrated among hospital outpatient settings rather than associated physicians' offices and durable medical equipment suppliers. In total, payments for 340B-purchased drugs accounted for almost half (\$3.2 billion) of Part B hospital outpatient drug expenditures. We determined how much Part B spent on 340B-purchased drugs in 2013 by identifying paid Medicare Part B claims from covered entities.

²⁰ 82 Fed. Reg. 59216, 59369 (Dec. 14, 2017). CMS required modifiers "JG" and "TB" on Part B claims for 340B-purchased drugs effective January 1, 2018. The JG modifier triggered a payment adjustment, whereas the TB modifier was used for informational purposes. CMS also published the following document outlining the modifier(s) each type of hospital covered entity should use, and addressing frequently asked questions: CMS, *Medicare-FFS Program, Billing 340B Modifiers under the Hospital Outpatient Prospective Payment System (OPPS)*. Accessed at <https://www.cms.gov/medicare/medicare-fee-for-service->

[payment/hospitaloutpatientpps/downloads/billing-340b-modifiers-under-hospital-oppo.pdf](https://www.cms.gov/files/document/payment/hospitaloutpatientpps/downloads/billing-340b-modifiers-under-hospital-oppo.pdf) on November 30, 2022.

²¹ Beginning in calendar year (CY) 2018, CMS paid for 340B-purchased drugs under Part B's hospital outpatient prospective payment system (OPPS) at ASP minus 22.5 percent to approximate a minimum average discount for 340B-purchased drugs. This policy has been the subject of significant litigation, including the Supreme Court's recent decision in *American Hospital Association v. Becerra*, 142 S. Ct. 1896 (2022). On June 15, 2022, the Supreme Court ruled that HHS cannot vary payment rates for drugs and biologicals by different hospital groups if HHS has not conducted a survey of hospitals' acquisition costs as required by sections 1833(t)(14)(A)(iii)(I) and (t)(14)(D) of the Social Security Act. CMS stated that due to the Supreme Court's decision, the agency will pay for 340B-purchased drugs at ASP plus 6 percent (i.e., the default payment rate under OPPS) in CY 2023. 87 Fed. Reg. 71748, 71976 (Nov. 23, 2022); 82 Fed. Reg. 59216, 59369 (Dec. 14, 2017).

²² CMS requires that the "JG" modifier be used by hospitals (except for rural sole community hospitals, children's hospitals, and OPPS-exempt cancer hospitals) to identify 340B-purchased drugs for informational purposes, rather than to trigger a payment adjustment. Rural sole community hospitals, children's hospitals, and OPPS-exempt cancer hospitals will continue to use the "TB" modifier to identify 340B drugs for informational purposes. 87 Fed. Reg. 71748, 71976 (Nov. 23, 2022).

²³ CMS, *Part B Inflation Rebate Guidance: Use of the 340B Modifiers, December 20, 2022*. Accessed at <https://www.cms.gov/files/document/part-b-inflation-rebate-guidance340b-modifierfinal.pdf>, on December 23, 2022.

²⁴ This study was conducted prior to CMS's implementation of modifiers for 340B-purchased drugs. Therefore, we assumed that all drug claims submitted by covered entities were for 340B-purchased drugs. We identified claims for covered entities by crosswalking provider identifiers associated with covered entities to Part B claims. OIG, *Part B Payments for 340B-Purchased Drugs*, OEI-12-14-00030, November 2015.

²⁵ OIG, *Part B Payments for 340B-Purchased Drugs*, OEI-12-14-00030, November 2015.

²⁶ This study estimated two inflation-indexed rebate calculations—one based on average sales prices (ASPs), and another based on average manufacturer prices (AMPs). ASPs are used to calculate Part B drug payment amounts and AMPs are used to calculate rebate amounts under the Medicaid Drug Rebate Program. 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. OIG, *Calculation of Potential Inflation-Indexed Rebates for Medicare Part B Drugs*, OEI-12-17-00180, August 2017.