Published on *The National Law Review* https://natlawreview.com

CMS Releases Guidance on Implementation of Rebate Programs for Certain Medicare Part B and Part D Drugs

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On February 9, 2023, the Centers for Medicare and Medicaid Services ("CMS") released two highly-anticipated guidance documents (the "Guidance") detailing the agency's proposed implementation of the Medicare Part B ("Part B") and Medicare Part D ("Part D") Prescription Drug Inflation Rebate Programs (each, a "Rebate Program" and, collectively, the "Rebate Programs"). The Rebate Programs are administered as part of the prescription drug affordability provisions of the Inflation Reduction Act (the "IRA"), which is aimed at "lower[ing] out-of-pocket drug costs for people with Medicare and improv[ing] the sustainability of the Medicare program for current and future generations."[1] The IRA represents the most sweeping healthcare legislation passed by Congress since the Affordable Care Act.[2] Please refer to our previous blog post on the IRA.

Overview of Key Guidance Provisions

Below is a summary of key provisions of CMS' proposed implementation of the Rebate Programs. However, industry participants, especially those who seek to submit public comment on solicited topics, are encouraged to read the Guidance in its entirety, as it includes significant intricacies related to a vast scope of implementation topics that will impact manufacturers who market, as well as providers who furnish, Part B and Part D drugs.

What are the Rebate Programs?

Sections 11101 and 11102 of the IRA amended the Social Security Act (the "Act") to establish the Rebate Programs. Under the Rebate Programs, manufacturers of certain Part B drugs (*i.e.,* drugs covered by Medicare that are typically obtained and administered by a provider) and Part D drugs (*i.e.,* drugs covered by Medicare that are obtained by a Part D enrollee through a pharmacy) are required to pay rebates to Medicare if their prescription drug prices increase faster than the rate of inflation. All rebate payments will be deposited into the Medicare Prescription Drug Account in the

Federal Supplementary Medical Insurance Trust Fund.

Is the Guidance Final or Open to Comment?

Interestingly, the answer is – both. Sections 1847A(c)(5)(C) and 1860D-14B(h) of the Act permit CMS to implement the Rebate Programs without soliciting public comment but the agency is voluntarily soliciting public comment only on specified topics related to implementation of the Rebate Programs, as described below. Guidance on topics not specified for public comment is final.

Among other topics, CMS has finalized guidance on (i) its determination of which drugs qualify for the Rebate Programs, and (ii) its computation of beneficiary coinsurance for Part B rebatable drugs.

CMS is soliciting comments on, among others, the following topics related to CMS' calculation of rebate amounts under both the Part B and Part D Rebate Programs:

- The process CMS intends to use to determine the number of drug units for calculating rebates;
- The process CMS intends to use to identify and remove 340B units (*i.e.,* units of the drug for which the manufacturer provides a discount under the 340B Drug Pricing Program[3]) from the rebate calculation;
- The process CMS intends to use to identify and remove units for which a Medicaid drug rebate was paid for a covered outpatient drug;
- The processes CMS intends to use to reduce or waive the rebate amount in the case of a drug shortage or severe supply chain disruption; and
- The process CMS intends to use to ensure the integrity of the rebate determination process.

Additionally, with respect to the Part B Rebate Program, CMS is soliciting comments on (i) the extent to which CMS should consider rebatable drugs furnished to Medicare Advantage enrollees, and (ii) the process CMS should use to allocate financial responsibility for the rebate amount where there is more than one manufacturer of a rebatable drug. With respect to the Part D Rebate Program, CMS is also soliciting comments on (i) the extent to which CMS should consider rebatable drugs that are not covered under the Medicaid Drug Rebate Program, and (ii) penalties for manufacturers who fail to pay rebates.

The thirty-day public comment period ends on March 11, 2023. Interested industry participants should submit comments on solicited topics to IRARebateandNegotiation@cms.hhs.gov with the subject line, "Medicare Part B Inflation Rebate Comments" or "Medicare Part D Inflation Rebate Comments," by the March 11 deadline.

Which Drugs are Subject to Inflation Rebates?

Part B rebatable drugs include single-source drugs (*i.e.,* drugs which have no generic equivalents in the market, usually due to patent protection or regulatory exclusivity) and biologics covered under Part B, including biosimilar biologics other than those biosimilar biologics whose average sales price (the "ASP") is not more than the ASP of the reference biologic.[4] However, single-source drugs and

biologics are not considered Part B rebatable drugs–and are, thus, not subject to inflation rebates–if (i) the average total allowed charges for such drug or biologic under Part B per individual that uses the drug or biologic is less than a threshold of one hundred dollars ($100) in 2023 or, in future years, one hundred dollars ($100) increased by a formula based on the percentage increase in the Consumer Price Index for Urban Consumers (the "CPI-U"); (ii) the drug or biologic is an influenza, pneumococcal, hepatitis B, or COVID-19 vaccine, other than a COVID-19 monoclonal antibodies vaccine administered after the end of the Emergency Use Authorization period;[5] or (iii) the drug or biologic is billed under a Healthcare Common Procedure Coding System ("HCPCS") code that is unclassified or unspecified (*i.e.,* new-to-market drugs which have not yet received a specific HCPCS code).

Part D rebatable drugs include drugs and biologics covered under Part D, including single-source drugs, multiple?source drugs, biosimilar biologics, and a narrow scope of generic drugs that effectively operate as single-source generic drugs.[6] However, drugs and biologics are not considered Part D rebatable drugs–and are, thus, not subject to inflation rebates–if the average total allowed charges for such drug or biologic under Part D per individual that uses the drug or biologic is less than a threshold of one hundred dollars ($100) for the twelve-month period beginning October 1, 2022, or, in future measuring periods, one hundred dollars ($100) increased by a formula based on the percentage increase in the CPI-U.[7]

What is the Effect on Coinsurance Rates under Part B?

Beginning April 1, 2023, if the price for a Part B rebatable drug for a calendar quarter exceeds the inflation-adjusted payment for such quarter, in addition to requiring that the manufacturer pay an inflation rebate, the IRA requires that the beneficiary coinsurance rate for such drug be set at twenty percent (20%) of the inflation-adjusted payment amount for such quarter.[8] The Guidance indicates that CMS will specify whether the adjustment applies to a certain Part B rebatable drug in the quarterly pricing files posted on its website.[9]

What are Key Dates and Timelines?

Part B inflation rebates are measured on a quarterly basis, with the first quarter having begun on January 1, 2023. Although the IRA provides for a transition period, which gives CMS until September 20, 2025, to invoice manufacturers for rebates accrued during 2023 and 2024 calendar quarters, after September 20, 2025, CMS must invoice manufacturers within six (6) months of the end of the applicable measuring quarter. Each manufacturer must pay the rebate within thirty (30) days of receiving the invoice and failure to pay will result in civil monetary penalties ("CMPs"), which CMS will establish through regulations, including a penalty equal to at least one hundred twenty-five percent (125%) of the rebate amount.

Part D inflation rebates are measured on an annual basis, with the first measuring period having begun on October 1, 2022. Although the IRA provides for a transition period, which gives CMS until December 31, 2025, to invoice manufacturers for rebates accrued during the first two twelve-month measuring periods, after December 31, 2025, CMS must invoice manufacturers within nine (9) months of the end of the applicable measuring period. Each manufacturer must pay the rebate within thirty (30) days of receiving the invoice and failure to pay will result in a CMP equal to one hundred twenty-five percent (125%) of the rebate amount, with this and other potential penalties currently open to public comment.

The following chart outlines key dates relating to CMS' implementation of the Rebate Programs.

Key Dates	Description
October 1, 2022	Beginning of the first twelve-month measuring period for which manufacturers will be required to pay rebates to Medicare for prices that outpace inflation for Part D rebatable drugs.
December 20, 2022	CMS issued its first inflation rebate guidance, which required providers that receive drugs under the 340B Drug Pricing Program to include the 340B modifier when billing for drugs and biologics acquired through the 340B Drug Pricing Program.[10]
January 1, 2023	Beginning of the first quarterly measuring period for which manufacturers will be required to pay rebates for prices that outpace inflation on Part B rebatable drugs.
January 9, 2023	CMS issued this Guidance with a thirty-day comment period on key topics to implement the Rebate Programs.
March 11, 2023	The thirty-day comment period on key topics to implement the Rebate Programs closes.
April 1, 2023	Beneficiaries covered under Traditional Medicare or a Medicare Advantage plan may pay a lower coinsurance amount for Part B rebatable drugs whose prices outpace inflation during the first quarter of 2023.
4th Quarter, 2023	CMS expects to issue revised guidance on the implementation of the Rebate Programs.
September 20, 2025	The date by which CMS must invoice manufacturers for the Part B inflation rebates owed for calendar quarters in 2023 and 2024.
December 31, 2025	The date by which CMS must invoice manufacturers for the Part D inflation rebates owed for the twelve-month periods beginning October 1, 2022 and October 1, 2023.

Key Takeaways for Providers

The Part B coinsurance adjustment will have the most direct effect on providers, as it will require providers to monitor the CMS quarterly pricing files and adjust billing procedures accordingly. If the

coinsurance adjustment applies, the provider must implement the coinsurance adjustment either at the point-of-service, meaning that the beneficiary is charged no more than the dollar amount of the adjusted coinsurance percentage that applies to the specific Part B rebatable drug the beneficiary received, or through a beneficiary refund.

Additionally, since the coinsurance reductions are triggered in tandem with the manufacturer rebate requirement, providers should not lose out on reimbursement associated with the coinsurance reductions. The intent behind the joint requirements established under the Part B Rebate Program is that, when the manufacturer rebate is triggered, the value of that rebate will be passed along to the beneficiary in the form of a coinsurance reduction and the provider's reimbursement will not be affected.

Key Takeaways for Manufacturers

The Rebate Programs, overall, will have the greatest effect on drug manufacturers, as the programs place significant pricing restrictions on qualifying drugs and biologics that are reimbursable under Medicare Part B, Medicare Advantage, or Medicare Part D.

The Rebate Programs implement inflation-based rebates for the Medicare program that mirror those under the Medicaid Drug Rebate Program. The payment of these inflation-based Medicaid rebates has been vigilantly enforced (*see, e.g.,* a $260 million settlement in 2022 and a $465 million settlement in 2016[11]) and nothing indicates that the Department of Justice (the "DOJ") will be any less vigilant in enforcing rebates under the new Medicare Rebate Programs. Given the steep value of penalties at play, which would be a substantial amount if a drug experienced a significant price increase, and the fact that CMS has opened the floor to consider additional penalties, manufacturers of federally reimbursable drugs and biologics should take care to follow the detailed requirements outlined in the Guidance.

In the meantime, any manufacturers that disagree with the limitations imposed by the Rebate Programs should consider submitting comments to CMS by the March 11, 2023 deadline. The Guidance specifically indicates that CMS seeks to "benefit from manufacturer feedback."[12].

FOOTNOTES

[1] *See* Press Release – HHS Releases Initial Guidance for Medicare Prescription Drug Inflation Rebate Program, CMS (Feb. 9, 2023).

[2] The IRA, which was signed into law on August 16, 2022, addresses prescription drugs in three primary ways: (i) the Drug Negotiation Program, which allows CMS to negotiate with manufacturers for the prices of single-source drugs with the highest expenditure rates under Part B and D; (ii) the restructuring of Part D, which is intended to, among other goals, close the coverage gap, expand eligibility for low-income subsidies, and increase vaccine coverage; and (iii) the Rebate Programs, which require manufacturers to reimburse Medicare if the prices for their Medicare Part B and Part D drugs increase faster than the rate of inflation.

[3] Section 340B of the Public Health Service Act requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to health care organizations that care for many uninsured and low-income patients. The Guidance indicates that drugs already discounted under the 340B Drug Pricing Program should be excluded from the Part B rebate calculation right away and from the Part D rebate calculation beginning in 2026.

[4] Social Security Act § 1847A(i)(2)(A); CMS Guidance – Part B Inflation Rebates at p. 5.

[5] Social Security Act § 1847A(i)(2)(A)(i); CMS Guidance – Part B Inflation Rebates at pp. 5; 7-8.

[6] Generic drugs approved under an Abbreviated New Drug Application ("ANDA") are only considered Part D rebatable drugs if all of the following apply: (i) the reference drug and any authorized generic are not currently being marketed; (ii) no other drug is marketed that is therapeutically equivalent; (iii) the manufacturer is not a "first applicant" during the 180-day exclusivity window; and (iv) the manufacturer is not a "first approved applicant" for a competitive generic therapy.

[7] CMS Guidance – Part D Inflation Rebates at p. 4.

[8] CMS Guidance – Part B Inflation Rebates at p. 5.

[9] CMS Guidance – Part B Inflation Rebates at p. 12.

[10] This allows CMS to identify drugs and biologics that are already discounted under the 340B Drug Pricing Program for its inflation rebate calculation.

[11] *See* DOJ Press Release No. 22-194 (March 7, 2022); DOJ Press Release No. 17-921 (Aug. 17, 2017).

[12] *See* CMS Guidance – Part B Inflation Rebates at p. 1.

National Law Review, Volume XIII, Number 53