Issue Brief

FEDERAL ISSUE BRIEF

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Medicare Part B Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1847A(i) of the Social Security Act, and Solicitation of Comments

CMS has issued a program memorandum providing initial guidance (to be followed with revised guidance later) to manufacturers regarding the payment of inflation rebates for Part B rebatable drugs beginning January 1, 2023.

Section 11101 of the ***Inflation Reduction Act*** added a new section 1847A(i) to the ***Social Security Act***, which establishes a requirement for manufacturers to pay Medicare Part B rebates for single source drugs and biological products with prices that increase faster than the rate of inflation for a calendar quarter no later than 30 days after receiving an invoice from CMS.

Section 1847A(i)(5) of the Act also provides for an adjustment to beneficiary cost sharing in cases where the price of Part B rebatable drugs increase faster than the rate of inflation. A copy of the 36-page memorandum is available at:

https://www.cms.gov/sites/default/files/2023-02/2.9.2023%20Part%20B%20Inflation%20Rebate%20Guidance.pdf.

Part B Rebatable Drug

Section 1847A(i)(2)(A) defines a "Part B rebatable drug" to mean a single source drug or biological product (as defined section 1847A(c)(6)(D) of the Act), including a biosimilar biological product (as defined in section 1847A(c)(6)(H)), but excluding a qualifying biosimilar biological product (as defined in section 1847(b)(8)(B)(iii)), for which payment is made under Part B.

Beneficiary Coinsurance Amount

Beneficiary coinsurance will be equal to 20 percent of the inflation-adjusted payment amount for Part B rebatable drugs furnished on or after April 1, 2023, if the payment amount for the calendar quarter in which the drug was furnished exceeds the inflation-adjusted payment amount for that quarter. For example, if the inflation-adjusted payment amount is the Average Sales Price (ASP) plus 6 percent, the beneficiary coinsurance will be equal to 20 percent of ASP plus 6 percent.

Beginning with the April 2023 quarterly pricing files, the applicable beneficiary coinsurance percentage would be shown for each HCPCS code in the pricing files that are posted on the CMS website.

When a separately payable claim line for a Part B rebatable drug is processed and the coinsurance is less than 20 percent of the published payment limit, the Medicare payment to the billing healthcare provider will equal the difference between the Medicare payment limit and the applicable beneficiary coinsurance amount, after application of the Medicare Part B deductible, and prior to application of sequestration, as applicable.

Questions? Contact Andrew Wheeler, MHA's Vice President of Federal Finance, at 573-893-3700 | ext. 1336 or awheeler@mhanet.com.

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The following table is intended to provide an example of coinsurance changes.

HCPCS Code	Short Description	Code Dosage	Payment Limit	Co-Ins %	Vaccine AWP%	Vaccine Limit	Blood AWP%	Blood Limit	Clotting Factor	Scenario
Jxxx1	Drug/ biological	1 ML	348.527	20.00						Part B rebatable drug where the drug's price is not outpacing inflation and the co-insurance adjustment therefore does not apply for the calendar quarter OR drug/biological is not a Part B rebatable drug.
Jxxx2	Drug/ Biological	1 MG	3.492	19.456						Part B rebatable drug with the inflation adjusted coinsurance applied.
Jxxx3	Drug/ Biological	1 IU	1.342	16.587					1	A clotting factor that is a Part B rebatable drug with the inflation adjusted coinsurance applied and the clotting factor furnishing fee is included in the payment limit.
9xxx3	Section 1861 (s)(10) Vaccine	0.5 ML	69.941	0.000	95	69.941				Vaccines that are excluded from Part B rebatable drugs and for which beneficiaries do not pay coinsurance.

Comment

The table could be more helpful if information about the payment limits and inflation items were also presented.

Estimated Part B Drug Inflation Rebate Amount

The Part B drug inflation rebate amount is the estimated amount equal to the product of the total number of units determined in accordance with section 1847A(i)(3)(B) of the Act and the amount, if any, by which the specified amount exceeds the inflation-adjusted payment amount.

Subsequently Approved Part B Rebatable Drugs

The payment amount benchmark quarter for drugs first approved or licensed by FDA on or before December 1, 2020 is the calendar quarter beginning July 1, 2021. For drugs first approved or licensed by FDA after December 1, 2020, the payment amount benchmark quarter is the third full calendar quarter after the day on which the drug was first marketed.

Civil Monetary Penalties for Non-Payment of Rebates

Pharmaceutical manufacturers that do not comply with the requirements to pay Part B drug inflation rebates as set forth at section 1847A(i)(1)(B) of the Act are subject to civil monetary penalties (CMPs) in an amount equal to at least 125 percent of the rebate amount for a drug for an applicable calendar quarter.

Removal of 340B Units

Section 1847A(i)(3)(B)(ii)(I) of the Act specifically excludes units of drugs for which the manufacturer provides a discount under the 340B program from the units of drugs for which a manufacturer may otherwise have a Part B inflation rebate liability.

Removal of Units that Are Packaged into the Payment Amount for an Item or Service and Are Not Separately Payable

Because CMS intends to identify units for separately payable claim lines for Part B rebatable drugs only, no further action will be necessary to remove units that are packaged into the payment amount for an item or service and are not separately payable, such as drugs for which payment is packaged under the hospital outpatient prospective payment system (OPPS), Ambulatory Surgical Center (ASC) payment system, or those administered in the Federally qualified health centers (FQHC) or rural health clinics (RHC) setting.

Final Comment

From a providers perspective, it would appear that changes to beneficiary coinsurance and following such calendar updates may be the single challenge.

It is interesting that CMS has released this document with the following caveat. Releasing the document now has it in the public domain.

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CMS has also coined a new word not recognized by spell check. – "Rebatable"