Part B Inflation Rebate Guidance: Use of the 340B Modifiers
December 20, 2022

This guidance is issued in accordance with section 1847A(c)(5)(C) of the Social Security Act (the Act) and is directed to Medicare providers and suppliers who bill for separately payable Part B drugs and biologicals and participate in the 340B Drug Discount Program. **No later than January 1, 2024, in accordance with section 1847A(i) of the Act, CMS is requiring all 340B covered entities, including hospital-based and non-hospital-based entities, that submit claims for separately payable Part B drugs and biologicals to report the applicable modifier ("JG" or "TB") on claim lines for drugs acquired through the 340B Program as specified below.**

Section 1847A(i) of the Act, as added by the Inflation Reduction Act, requires the Secretary to establish a Part B inflation rebate by manufacturers of certain single source drugs[1] and biologicals with prices increasing faster than the rate of inflation. 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 otherwise may have a Part B inflation rebate liability. Effective implementation of the Part B inflation rebate requires CMS to identify units of drugs acquired through the 340B Program so they can be subtracted from the total number of otherwise rebatable units as applicable.

As finalized in the Calendar Year (CY) 2023 Outpatient Prospective Payment System (OPPS) Final Rule,[2] effective January 1, 2023, the "JG" modifier will be used by hospitals (except for rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals) to identify 340B drugs for informational purposes, rather than to trigger a payment adjustment as in previous years. Also, the CY 2023 OPPS final rule states, for CY 2023, rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals should continue to bill the modifier ''TB'' on claim lines for drugs acquired through the 340B Program. As such, the "JG" and "TB" modifiers provide an existing mechanism to identify drugs acquired through the 340B Program that is familiar to most 340B covered entities paid under the OPPS, and this guidance does not change the requirements established in the OPPS final rule.[3]

For claims with dates of service beginning no later than January 1, 2024, this guidance instructs all 340B covered entities to report the appropriate modifier, including those not currently reporting the "JG" or "TB" modifier, such as Ryan White clinics and hemophilia clinics, which should report the "JG" modifier on separately payable Part B claim lines for drugs acquired through the 340B Program.[4] Providers and suppliers who furnish drugs acquired through the 340B Program through a 340B covered entity are also required to submit the appropriate modifier on separately payable claim lines for such drugs.

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[1] As defined by Section 1847A(c)(6)(D) of the Social Security Act, a single source drug is "a drug which is not a multiple source drug and which is produced or distributed under a new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application."

[2] https://www.govinfo.gov/content/pkg/FR-2022-11-23/pdf/2022-23918.pdf.

[3] These modifiers have been in use by many 340B covered entities since 2018. https://www.govinfo.gov/content/pkg/FR-2017-12-14/pdf/R1-2017-23932.pdf

[4] We note that 340B covered entities paid under the OPPS will continue to use the "TB" modifier for pass-through drugs acquired through the 340B program.

While these modifiers have been required and utilized by 340B providers paid under the OPPS since calendar year (CY) 2018, this requirement may be new for other 340B covered entities. As this requirement will require operational changes to billing systems for some 340B covered entities (and other providers and suppliers as applicable), CMS encourages these such entities to begin using the appropriate modifier as soon as possible, and no later than January 1, 2024.

Further program instruction on the Part B inflation rebate is forthcoming and will include information on how CMS will determine rebatable units during CY 2023 for purposes of determining the Part B inflation rebate. For questions, please email IRARebateandNegotiation@cms.hhs.gov.