DEPARTMENT OF HEALTH & HUMAN SERVICES
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CENTER FOR MEDICARE

DATE: December 14, 2023

TO: Interested Parties

FROM: Meena Seshamani, M.D., Ph.D., CMS Deputy Administrator and Director of the Center for Medicare

SUBJECT: Revised Part B Inflation Rebate Guidance: Use of the 340B Modifier

This guidance is a revision to the 340B Modifier Guidance, titled *Part B Inflation Rebate Guidance: Use of the 340B Modifiers,* initially published on December 20, 2022. This guidance revises the modifiers that should be used to report drugs acquired under the 340B Program to align with the policies finalized in the Calendar Year (CY) 2024 Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System final rule with comment period.[1] However, this guidance does not revise the overall requirement for all 340B covered entities to report a 340B modifier on claim lines for separately payable Part B drugs and biologicals.

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 Program. As previously set forth in the December 20, 2022 340B Modifier Guidance, **for claims with dates of service beginning 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"[2] or "TB"[3]) on claim lines for drugs acquired through the**

[1] https://www.federalregister.gov/documents/2023/11/22/2023-24293/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment. From CY 2018 to CY 2023, certain 340B covered entities paid under the OPPS reported the "JG" and "TB" modifiers, and others reported only the "TB" modifier. In the CY 2024 OPPS/ASC final rule with comment period, CMS adopted a policy that all 340B covered entity hospitals report the "TB" modifier effective January 1, 2025. CMS explained that transitioning to a single 340B modifier will allow for greater simplicity and reduce provider burden, as only one modifier would have to be reported for all scenarios where a 340B drug is acquired. The "JG" modifier will remain effective through December 31, 2024.

[2] "JG" Modifier description: Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes.

[3] "TB" Modifier description: Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities. Note, beginning January 1, 2025, the description will not include "for select entities."

340B Program as specified below. This revised 340B Modifier Guidance further provides that, for claims with dates of service beginning no later than January 1, 2025, 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 "TB" modifier on claim lines for drugs acquired through the 340B program.

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[4] 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 program 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.

The "JG" and "TB" modifiers are an existing mechanism used to identify drugs acquired through the 340B Program and are familiar to most 340B covered entities paid under the OPPS. As finalized in the CY 2024 OPPS/ASC final rule with comment period,[5] all 340B covered entity hospitals paid under OPPS must report the "TB" modifier effective January 1, 2025, even if the hospital previously reported the "JG" modifier. That final rule gives hospitals the flexibility to transition to use of the "TB" modifier sooner than CY 2025, provided hospitals that currently report the "JG" modifier use the "TB" modifier exclusively beginning in CY 2025.

This revised guidance aligns with the CY 2024 OPPS/ASC final rule with comment period and applies the single modifier policy to all 340B covered entities to implement Section 1847A(i) of the Inflation Reduction Act. Consistent with the December 20, 2022 340B Modifier Guidance, for claims with dates of service beginning no later than January 1, 2024, this guidance instructs all 340B covered entities to report a 340B modifier on claims for separately payable Part B drugs and biologicals, including those not currently reporting the "JG" or "TB" modifier, such as critical access hospitals, hospitals located in Maryland and paid under the Maryland All-Payer or Total Cost of Care Model, Ryan White clinics, and hemophilia treatment centers. Covered entities not currently reporting a 340B modifier may use either the "JG" or "TB" modifier for claims with dates of service through December 31, 2024, but must transition to the "TB" modifier no later than January 1, 2025. 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.

While these modifiers have been required and utilized by 340B covered entities paid under the

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[4] 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."

[5] https://www.federalregister.gov/documents/2023/11/22/2023-24293/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment.

OPPS since CY 2018, this requirement may be new for other 340B covered entities, including but not limited to critical access hospitals, hospitals located in Maryland and paid under the Maryland All-Payer or Total Cost of Care Model, Ryan White clinics, and hemophilia treatment centers. As this requirement may require operational changes to billing systems for some 340B covered entities (and other providers and suppliers as applicable), CMS has encouraged these covered entities to begin using the appropriate modifier as soon as possible, and no later than January 1, 2024.

Please refer to *Medicare Part B Drug Inflation Rebates Paid by Manufacturers: Revised Guidance, Implementation of Section 1847A(i) of the Social Security Act* for further information on the Medicare Part B Inflation Rebate Program. For questions on the Part B Inflation Rebate Program, please email IRARebateandNegotiation@cms.hhs.gov.