3 March 2023

**Medicare-FFS Program**

**Billing 340B Modifiers under the Hospital Outpatient Prospective Payment System (OPPS)**

**Frequently Asked Questions**

**Overview:** The purpose of this document is to address frequently asked questions about billing modifiers for 340B-acquired drugs under the OPPS in Calendar Year (CY) 2023 and subsequent years.

## General

### 1. What modifiers should be used to report 340B-acquired drugs?

CMS established two Healthcare Common Procedure Coding System (HCPCS) Level II modifiers to identify 340B-acquired drugs. The revised descriptors for CY 2023 and subsequent years are listed below:

- Modifier "**JG**": *Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes.*
- Modifier "**TB**": *Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities*.

When applicable, providers are required to report either modifier "JG" or "TB" on OPPS claims (bill type 13X) beginning January 1, 2023. The presence of modifier "JG" or "TB" on a claim indicates that a drug has been acquired through the 340B program. The modifiers "JG" or "TB" will not trigger a payment reduction and will be used only for informational purposes, including to comply with certain requirements of the Inflation Reduction Act (IRA) of 2022 (see question 2 below for information related to the Inflation Reduction Act). Though modifiers "JG" and "TB" are informational modifiers, reporting is mandatory for providers paid under the OPPS in CY 2023.

### 2. Why does CMS continue to require the reporting of the "JG" and "TB" modifiers if the 340B drug and biological payment policy is no longer in effect?

The Inflation Reduction Act establishes a Part B inflation rebate by manufacturers for certain single source drugs[1] and biologicals with prices increasing faster than the rate of inflation. However, it also 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. Accordingly, effective implementation of the Part B inflation rebate requires the identification of units of drugs acquired through the 340B Program so those units can be subtracted from the total number of units for which a manufacturer otherwise may have a Part B inflation rebate liability.

[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."

CMS is requiring use of the "JG" and "TB" modifiers to identify drugs acquired through the 340B Program to comply with these requirements of the Inflation Reduction Act. The agency is utilizing these modifiers because they are an established mechanism that have been in use by hospitals paid under the OPPS for five years.

It is also necessary to maintain the requirement for 340B hospitals to report the ''JG'' and ''TB'' modifiers so that CMS can track the utilization of 340B-acquired drugs and biologicals for informational purposes; however, the continued use of these modifiers will have no effect on OPPS payment rates. We are allowing continued use of both modifiers to reduce provider burden compared to shifting to a single modifier, as all OPPS providers can use the same modifier (either ''JG'' or ''TB'') going forward as they have used for the past five calendar years.

More information on the health care components of the IRA can be found in this CMS fact sheet, 340B Modifiers Guidance, and Medicare Learning Network article. These FAQs and this timeline are also helpful resources.

**3. How does CMS pay for 340B-acquired drugs furnished by hospital outpatient departments paid under the OPPS?**

Beginning in CY 2023, Medicare pays for separately payable drugs and biologicals (hereinafter referred to as "drug" or "drugs") acquired through the 340B program at the same rate as drugs not acquired through the 340B program, which is generally the statutory default rate of the average sales price (ASP) plus 6 percent. For purposes of this FAQ, "acquired through the 340B Program" means any separately payable Part B drug (assigned status indicator "K"), other than vaccines, that meets the definition of "covered outpatient drug" under 1927(k) of the Act and that is purchased through the 340B Program or the Prime Vendor Program (PVP).

**Billing**

**4. Which hospital types should report modifier "JG" and which hospital types should report modifier "TB"?**

The following charts list the modifier a hospital should report depending upon its hospital type and includes the pertinent OPPS drug status indicator (SI) for the 340B-acquired drug being furnished, if applicable.[2]

| Hospitals Paid Under the OPPS | | | | |
|---|---|---|---|---|
| **Hospital Type (determined by CMS)** | **Pass-through Drug (SI "G")** | **Separately Payable Drug (SI "K")** | **Vaccine* (SI "L" or "M")** | **Packaged Drug (SI "N")** |
| Children's Hospital | TB | TB | N/A | TB or JG, Optional |
| PPS-Exempt Cancer Hospital | TB | TB | N/A | TB or JG, Optional |
| Rural Sole Community Hospital | TB | TB | N/A | TB or JG, Optional |
| DSH Hospital | TB | JG | N/A | TB or JG, Optional |
| Medicare Dependent Hospital | TB | JG | N/A | TB or JG, Optional |
| Rural Referral Center | TB | JG | N/A | TB or JG, Optional |
| Non-Rural Sole Community Hospital | TB | JG | N/A | TB or JG, Optional |

| Hospitals Not Paid under the OPPS** | |
|---|---|
| **Hospital Type (determined by CMS)** | **Drugs Acquired Under the 340B Program** |
| CAH | TB |
| Hospitals located in Maryland and paid under the Maryland All-Payer or Total Cost of Care Model | TB |

[2] No later than January 1, 2024, CMS is requiring all 340B covered entities, including hospital-based and nonhospital-based entities, that submit claims for separately payable Part B drugs and biologicals, to report modifier "JG" or "TB" on claim lines for drugs acquired through the 340B Drug Discount Program.
*https://www.cms.gov/files/document/part-b-inflation-rebate-guidance340b-modifierfinal.pdf*

| | |
|---|---|
| Non-Excepted Off-Campus PBD | JG |

N/A= Not Applicable
* COVID–19 monoclonal antibody products are currently assigned to status indicator "L," which describes vaccines that are exempt from the 340B modifiers requirement. We note that, after expiration of their EUA designations, certain COVID–19 monoclonal antibody products may be reassigned to another status indicator.
** All 340B covered entities not paid under the OPPS must report the appropriate "JG" or "TB" modifier for separately payable drugs acquired through the 340B Program with dates of service on or after January 1, 2024.

**5. Are entities that are not paid under the OPPS, such as Critical Access Hospitals (CAHs); non-excepted, off-campus provider-based departments of hospitals; and hospitals located in Maryland and paid under Maryland's All-Payer or Total Cost of Care Model, required to report informational modifier "TB"?**

Yes, all 340B covered entities not paid under the OPPS should report the appropriate "JG" or "TB" modifier for separately payable drugs acquired through the 340B Program for claims with dates of service on or after January 1, 2024. Please see *Part B Inflation Rebate Guidance: Use of the 340B Modifiers* for additional information.

**6. How does CMS define rural sole community hospitals (SCHs)?**

Rural SCHs receive a 7.1 percent add-on adjustment under the OPPS. These providers either meet the definition of an SCH under the regulations at 42 CFR § 412.92 or are EACHs (essential access community hospitals), which are considered to be SCHs under section 1886(d)(5)(D)(iii)(III) of the Act, and that meet the definition in the regulations at 42 CFR § 412.109. These providers must also be located in a rural area, as defined under section 412.64(b) of the regulations, or be treated as being located in a rural area under section 412.10 of the regulations.

If a provider is unsure of its status as a Rural SCH, it may check with its Medicare Administrative Contractor (MAC) or review the CY 2023 OPPS final rule impact file to determine whether the hospital is designated a rural SCH under the OPPS for CY 2023. Rural SCHs are defined in the impact file where Rural Sole Community and Essential Access Hospitals indicator flag is '1' [column E]. The CY 2023 OPPS impact file is available at https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientppshospital-outpatient-regulations-and-notices/cms-1772-fc.

7. **My hospital has a dual designation such that it is listed in the HRSA database as a disproportionate share hospital (DSH) but paid under the OPPS as a rural SCH. Which designation determines whether my hospital should report the "JG" modifier or the "TB" modifier for CY 2023?**

   The Medicare hospital type designation determines whether a hospital reports the "JG" modifier or the "TB" modifier, regardless of how the hospital is enrolled in the 340B Program. For example, a hospital enrolled in the 340B program as a DSH but paid under the OPPS as a rural SCH would bill the informational modifier "TB" for each 340B-acquired drug furnished to a hospital outpatient. See question 4 above for the appropriate application of the modifiers.

8. **Will CMS accept modifier "JG" on packaged drugs (i.e., status indicator "N" drugs)?**

   Yes. For administrative ease, providers may report modifier "JG" on packaged drugs (assigned status indicator "N"). However, no modifier is required to be reported for these packaged drugs.

9. **How are providers to bill using the "JG" and "TB" modifiers on claims?**

   Separately payable, non pass-through, 340B-acquired drugs should be billed on a separate claim line with the appropriate 340B modifier, which is dependent on the hospital type (see question 4 above for the appropriate application of the modifiers). As mentioned in question 4, pass-through drugs are reported with the informational modifier "TB" for all provider types.

   For a claim with multiple drug lines, the appropriate 340B modifier is required on each line of a 340B-acquired drug. A 340B modifier is not required on claim lines of a non 340B-acquired drug (regardless of status indicator), a product assigned status indicator "L" (Not paid under OPPS. Paid under reasonable cost; not subject to deductible or coinsurance), "M" (Not paid under OPPS), or "N" (a packaged drug).

10. **Are non-excepted off-campus provider-based departments of hospitals required to report modifier "JG" for 340B-acquired drugs?**

    Yes. Non-excepted off-campus provider-based departments of hospitals that are participating in the 340B Program are required to report modifier "JG" for 340B-acquired drugs in addition to modifier "PN" (Nonexcepted service provided at an off-campus, outpatient, provider-based department of a hospital).

**11. How are providers to bill for the discarded drug amount on 340B-acquired drugs?**

The discarded drug amount should be billed on a separate claim line with the "JW" (Drug amount discarded/not administered to any patient) modifier and the appropriate 340B modifier. The modifier "JZ" (Zero drug amount discarded/not administered to any patient) should also be used to attest that there were no discarded amounts.

Please refer to the Medicare Program Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Policy Frequently Asked Questions for additional information.

**12. How are providers to bill the discarded drug amount on 340B-acquired drugs for off-campus departments of a hospital?**

The off-campus department of a hospital would report:

(1) modifier "PO" or "PN," to identify that the off-campus department is either excepted or non-excepted;

(2) modifier "JG" or "TB," depending on the hospital type, to indicate that a drug was acquired through the 340B program; and

(3) modifier "JZ" or "JW" to indicate whether any amount of the drug is discarded.

For example, for a single dose 340B-acquired drug (assigned status indicator "K") that is furnished in an excepted off-campus department of a hospital and for which there is no discarded drug amount, the hospital would bill one claim line with the drug HCPCS code and the modifiers:

"JG" (Drug or biological acquired with 340b drug pricing program discount, reported for informational purposes),

"PO" (Excepted service provided at an off-campus, outpatient, provider-based department of a hospital),

"JZ" (Zero drug amount discarded/not administered to any patient).

Conversely, for a single dose 340B-acquired drug (assigned status indicator "K") that is furnished in an excepted off-campus department of a hospital and for which there is a discarded drug amount, the hospital would bill the discarded drug on a claim line with the drug HCPCS code and the modifiers:

"JG" (Drug or biological acquired with 340b drug pricing program discount, reported for informational purposes),

"PO" (Excepted service provided at an off-campus, outpatient, provider-based department of a hospital),

"JW" (Drug amount discarded/not administered to any patient). As a reminder, when multiple modifiers are reported, providers should report pricing modifiers first followed by descriptive modifiers.

**13. What happens if a provider inadvertently does not use the "JG" modifier on claims that include 340B-acquired drugs? What happens if a provider mistakenly reports modifier "JG" instead of "TB"?**

While CMS expects hospitals to submit accurate claims and utilize the correct modifiers, hospitals will not be required to correct a claim to use one informational modifier instead of another where it mistakenly reports the incorrect one.

We note that providers are required to report either modifier "JG" or "TB" on OPPS claims (bill type 13X) beginning January 1, 2023. 340B covered entities not paid under the OPPS should report the appropriate "JG" or "TB" modifier for separately payable drugs acquired through the 340B Program with dates of service on or after January 1, 2024.

**14. Do hospitals need to report a 340B modifier if the drug or biological was purchased at wholesale acquisition cost (WAC) but not through the 340B program at a discounted rate?**

We recognize that not all covered outpatient drugs acquired by a 340B hospital are purchased through the 340B Program. Participating 340B hospitals are responsible for knowing whether a 340B eligible drug was obtained under the 340B Program and for maintaining documentation. Hospitals are not required to report the applicable 340B modifier for a 340B-eligible drug that was not purchased under the 340B Program.

**15. How are providers to report the 340B modifiers for drugs administered to dual-eligible beneficiaries? Is the "UD" modifier required for Medicaid?**

When Medicare is either the primary or secondary payer, the appropriate 340B modifier is required for informational purposes and to comply with the applicable requirements of the Inflation Reduction Act. Because Medicaid billing requirements vary by state, providers should contact the applicable State Medicaid Program for guidance on billing 340B drugs. Normal CMS policy and procedures and trading partner agreement requirements for coordination of benefits (COB) claims will be followed.

**16. What if a provider fails to use or accidentally omits the modifier and needs to make a correction to a claim?**

Institutional providers may submit adjustment claims to add a modifier. Note: Institutional providers would append condition code D2 (a change to the revenue codes, HCPCS code, or HIPPS code) to the adjustment claim with the modifier.[3]

[3] Medicare Claims Processing Manual, Chapter 1 – General Billing Requirements, Section 130.1.2.1 (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c01.pdf).