

## 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 340B-acquired drugs under the OPPS in Calendar Year (CY) 2018.

#### General

#### 1. What is Medicare's payment policy for 340B-acquired drugs provided by a hospital outpatient department?

Beginning January 1, 2018, Medicare pays an adjusted amount of the average sales price (ASP) minus 22.5 percent for certain separately payable drugs or biologicals (hereafter referred to as drug or drugs) that are acquired through the 340B Program and furnished to a Medicare beneficiary by a hospital paid under the OPPS that is not excepted from the payment adjustment policy. For purposes of this policy, "acquired through the 340B Program" means the drug was purchased at or below the 340B ceiling price from the manufacturer and includes 340B drugs purchased through the Prime Vendor Program (PVP).

Medicare will continue to pay for separately payable drugs that were not acquired through the 340B Program and furnished by a hospital paid under the OPPS at ASP+6 percent.

For CY 2018, CMS designated rural sole community hospitals (SCHs), children's hospitals, and PPS-exempt cancer hospitals are excepted from the 340B payment adjustment. For more details about which hospitals are designated as rural SCHs, please refer to Question 4.

#### 2. What modifiers did CMS establish to report 340B-acquired drugs?

CMS established two Healthcare Common Procedure Coding System (HCPCS) Level II modifiers to identify 340B-acquired drugs:

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

When applicable, providers are required to report either modifier "JG" or "TB" on OPPS claims (bill type 13X) beginning January 1, 2018. Though modifier "TB" is an informational modifier, reporting is mandatory for applicable providers. See Question 8 below for additional information about these modifiers.

**3. Are Critical Access Hospitals (CAHs) subject to the 340B payment policy? Should CAHs report the informational modifier “TB”? What about hospitals located in Maryland that are paid under a cost containment waiver?**

No, CAHs are not subject to the 340B payment policy because CAHs are not paid under the OPSS. Neither modifier “JG” nor modifier “TB” is required to be reported by CAHs. However, CAHs have the option of reporting informational modifier TB on a voluntary basis for drugs that were acquired under the 340B Program.

Likewise, hospitals paid under the Maryland waiver are excluded from the OPSS and are not subject to the payment policy change. These hospitals, as well as any other hospitals that are excluded from the OPSS, are similarly not required to report the JG modifier, but have the option to report the TB modifier on a voluntary basis.

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

Rural SCHs receive a 7.1 percent add-on adjustment under the OPSS. 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 2018 OPSS final rule impact file to determine whether the hospital is designated a rural SCH under the OPSS for CY 2018. Rural SCHs are defined in the impact file where Rural Sole Community and Essential Access Hospitals indicator flag is ‘1’ [column D] and where Urban/Rural Geographic Location is ‘rural’ [column G]. The CY 2018 OPSS impact file is available at <https://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1678-FC-2018-OPSS-FR-Facility-Specific-Impacts.zip>.

**5. 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 OPSS as a rural SCH. Which designation determines whether my hospital is excepted or not excepted from the 340B payment policy in CY 2018?**

The Medicare hospital type designation determines applicability of the 340B drug payment adjustment, 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 OPSS as a rural SCH would be excepted from the 340B payment reduction in CY 2018 and would bill the informational modifier “TB” for each 340B-acquired drug furnished to a hospital outpatient.

**6. Are non-excepted off-campus provider-based departments of hospitals required to report modifier “TB” 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 “TB” for 340B-acquired drugs in addition to modifier “PN” (*Nonexcepted service provided at an off-campus, outpatient, provider-based department of a hospital*).

As stated in the CY 2018 OPPS/ASC final rule with comment, we intend to consider changes to the payment policy for 340B-acquired drugs furnished in non-excepted off-campus provider-based departments of hospitals in CY 2019 rulemaking.

**7. Are hospital-owned retail pharmacies that bill 340B eligible claims under Part B impacted by the 340B payment policy?**

No. The 340B payment policy adopted in the CY 2018 OPPS/ASC final rule with comment period applies to certain hospitals paid under the OPPS. Pharmacies do not bill under the OPPS and therefore are not affected by this policy.

**8. Which hospital types should report the modifier “JG”? Modifier “TB”?**

The following chart describes the modifier a hospital should report depending upon its hospital type and the pertinent OPPS drug status indicator (SI) for the 340B-acquired drug being furnished.

Hospital Type (determined by CMS)	Pass-through Drug (SI “G”)	Separately Payable Drug (SI “K”)	Vaccine (SI “F” “L” or “M”)	Packaged Drug (SI “N”)
<b>Not Paid under OPPS</b>				
CAH	TB, Optional	TB, Optional	N/A	TB or JG, Optional
Maryland Waiver Hospital	TB, Optional	TB, Optional	N/A	TB or JG, Optional
Non-Excepted Off-Campus PBD	TB	TB	N/A	TB or JG, Optional
<b>Paid under the OPPS, Excepted from the 340B Payment Adjustment for 2018</b>				
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
<b>Paid under the OPPS, Subject to the 340B Payment Adjustment</b>				
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

N/A= Not Applicable

**9. How are Medicare Advantage (MA) plans impacted by the new payment policy for 340B-acquired drugs?**

**MA Payment of contracted providers / facilities:** MAOs that contract with a facility/provider eligible for 340B drugs can negotiate the terms and conditions of payment with the provider / facility. CMS cannot interfere in the payment rates that MA organizations and providers enter into through contracts.

**MA payment of non-contract providers / facilities:** When paying a facility/provider eligible for 340B drugs, on a non-contract basis the MA plan pays the non-contract provider / facility the amount they would have received under Original Medicare payment rules less the plan allowed cost sharing collected from the MA enrollee.

**Billing**

**10. To which drugs does the 340B payment adjustment apply? How can a provider identify a drug that must be billed with modifier “JG”?**

Beginning January 1, 2018, the 340B payment adjustment applies to separately payable OPPS drugs (assigned status indicator “K”) that meet the definition of “covered outpatient drug” as defined in the section 1927(k) of the Act and that are acquired through the 340B Program or through the 340B PVP, but does not apply to vaccines

April 2, 2018

(assigned status indicator “F”, “L” or “M”) and does not apply to drugs on pass-through payment status (assigned status indicator “G”).

Providers should refer to the quarterly update of Addendum B for a listing of drugs paid under the OPSS and their assigned status indicator. The Addendum B updates are posted quarterly to the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html>.

The 340B payment reduction does not apply to OPSS separately payable drugs (assigned status indicator “K”) that are not acquired through the 340B Program. This means that if a participating 340B hospital did not purchase a 340B eligible drug at a 340B discounted price, then the hospital should not bill the drug with modifiers “JG” or “TB”.

**11. 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”) although such modifier will not result in a payment adjustment. However, modifier “JG” is not required to be reported for these packaged drugs.

**12. Are hospitals required to bill the informational modifier “TB” for pass-through drugs?**

Yes. The use of informational modifier “TB” for pass-through drugs (assigned status indicator “G”) acquired with a 340B discount is required by all hospitals except for CAHs and Maryland Waiver Hospitals.

**13. How are providers to bill using the “JG” and “TB” modifiers on claims?**

Each separately payable, non-pass through 340B-acquired drug should be billed on a separate claim line with the appropriate 340B modifier. The use of modifier “JG” will trigger a drug payment rate of ASP minus 22.5 percent. The use of modifier “TB” will have no effect on the drug payment rate.

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 vaccine (assigned status indicator “F”, “L” or “M”), or a packaged drug (assigned status indicator “N”), but could be appended if a hospital chooses.

**14. How are providers to bill for the discarded drug amount on 340B-acquired drugs? How does this affect modifiers that are already required for off-campus departments of a hospital?**

The discarded drug amount should be billed on a separate claim line with the JW

modifier and the appropriate 340B modifier. Modifier “PO” or “PN” is also required if the 340B-acquired drug is furnished in an off-campus outpatient provider-based department of a hospital, in which case three modifiers will be reported on the drug HCPCS line. For example, a 340B-acquired drug (assigned status indicator “K”) furnished in an excepted off-campus department of a hospital, would bill one claim line with the drug HCPCS code and modifiers “JG” and “PO”, and another claim line with the drug HCPCS code and modifiers “JG”, “JW”, and “PO”. As a reminder, when multiple modifiers are reported, providers should report pricing modifiers first followed by descriptive modifiers.

Please refer to the JW modifier FAQ document for more information available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf>.

**15. 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”?**

Providers are advised that reporting modifier “JG” on a claim line with an OPPTS separately payable drug HCPCS code (assigned status indicator “G” or “K”) will trigger a payment adjustment of ASP minus 22.5 percent. It is the provider’s responsibility to submit correctly coded claims. We note again that there is no circumstance under which a provider should report the “JG” modifier on a claim line with status indicator “G;” although the provider should use the informational modifier “TB” on claims for pass-through drugs.

Federal law permits Medicare to recover its erroneous payments. Medicare requires the return of any payment it erroneously paid as the primary payer. Providers are required to submit accurate claims, maintain current knowledge of Medicare billing policies, and ensure all documentation required to support the validity of the services reported on the claim is available upon request.

**16. 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. As discussed in Question 9 above, a 340B modifier is not required for a 340B-eligible drug that was not purchased under the 340B Program.

**17. My hospital is unable to upgrade its billing software by January 1, 2018 to include modifiers “JG” and “TB” and because of cash flow concerns cannot hold claims. What recourse do I have?**

April 2, 2018

Under section 1835(a) of the Act, providers have 12 months after the date of service to timely file a claim for payment. If a hospital believes that it will not be able to properly identify and bill accurately for 340B acquired drugs, it should contact its MAC to discuss whether holding claims or rebilling claims may be an option. Again, hospitals are required to be in compliance with all applicable 340B Program requirements and Medicare billing requirements.

**18. How are providers to bill 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 in accordance with the OPPS 340B payment policy. 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.