340B UPDATE FOR HOSPITALS: CMS PUBLISHES FAQS CLARIFYING USE OF MODIFIERS IN CONNECTION WITH 340B PROGRAM REIMBURSEMENT CUT ON PART B DRUGS

Date: 18 December 2017

U.S. Health Care Alert

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On December 13, 2017, the Centers for Medicare & Medicaid Services ("CMS") published subregulatory guidance to answer questions about billing for drugs acquired through the 340B Drug Pricing Program ("340B Program") (hereinafter the "FAQ"). [1] As discussed in our prior alert, the final rule updating the Medicare Hospital Outpatient Prospective Payment System ("OPPS") (hereinafter the "Final Rule") for calendar year 2018 included a reduction of Medicare Part B drug reimbursement for separately reimbursable, nonpass-through drugs purchased under the 340B Program. [2]

BACKGROUND

Prior to January 1, 2018, CMS reimbursed separately payable drugs or biologicals (referred to hereinafter as drugs) under OPPS at the drug's average sales price ("ASP") plus 6 percent. Where applicable, the reduced reimbursement rate for separately payable drugs acquired through the 340B Program, including those purchased through the Prime Vendor Program, for CY 2018 will be ASP minus 22.5 percent.

In order to identify claims for separately reimbursable drugs that are subject to the reimbursement cut, the Final Rule requires hospitals to report the modifier "JG" (Drug or biological acquired with 340B Program discount). [3] CMS excepted certain hospitals paid under the OPPS from the reimbursement cut for 340B-acquired drugs (rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals). [4] These hospitals are required to report the modifier "TB" (Drug or biological acquired with 340B Program discount, reported for informational purposes) to facilitate the collection and tracking of information on 340B drugs purchased by those excepted providers. [5] The applicable modifier must be reported on each claim line that includes a drug subject to the reporting requirement. [6]

Also excepted from application of the reimbursement cut for 340B-acquired drugs are those off-campus provider-based hospital outpatient departments that are not excepted from the site neutral payment rule (e.g., off-campus provider-based hospital outpatient departments that did not bill for services covered under the OPPS furnished prior to November 2, 2015, and those that were excepted, but subsequently undergo an impermissible relocation or change of ownership) (hereinafter "Nongrandfathered Off-Campus PBDs"). [7] CMS's rationale for excepting Nongrandfathered Off-Campus PBDs from the reimbursement cut is that since January 1, 2017, items and services furnished through Nongrandfathered Off-Campus PBDs are technically paid under the Medicare

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Physician Fee Schedule ("PFS"), not OPPS. [8] The Final Rule did not indicate that Nongrandfathered Off-Campus PBDs would be required to report any billing modifier, but did indicate that CMS intends to monitor drug utilization in these Nongrandfathered Off-Campus PBDs and would consider adopting a policy in CY 2019 to similarly reduce reimbursement for 340B-acquired drugs for such PBDs. [9]

Given the Final Rule was initially published in the Federal Register on November 14, 2017, hospitals required to use the modifiers have limited time to make modifications to their billing systems to accommodate use of the modifiers and ensure they are applied correctly. In addition, the Final Rule left a number of questions unanswered. On December 13, 2017, CMS published the FAQ clarifying the use of the modifiers and providing responses to some previously unanswered questions.

ADDITIONAL BILLING MODIFIER GUIDANCE

- Nongrandfathered Off-Campus PBDs must report modifier "TB" (Drug or biological acquired with 340B Program discount, reported for informational purposes) for 340B-acquired drugs in addition to modifier "PN" (Nonexcepted service provided at an off-campus, outpatient, provider-based department of a hospital). CMS reminds providers that pricing modifiers should come before descriptive modifiers.
- As noted in the Final Rule, since they are not reimbursed under OPPS, Critical Access Hospitals and Maryland waiver hospitals are not required to report either modifier "JG" or "TB" for 340B-acquired drugs. However, they may optionally report the "TB" modifier for pass-through drugs (status indicator ("SI") "G") and separately payable drugs (SI "K"). They may optionally report either the "TB" or "JG" modifier ONLY for packaged drugs (SI "N").
- All OPPS hospitals must report modifier "TB" for 340B-acquired drugs that are reimbursed on a pass-through basis (SI "G").
- Waste for 340B-acquired drugs should be billed on a separate claim line with the modifier "JW" and the appropriate 340B modifier ("JG" or "TB", as applicable).
- CMS confirms that all hospitals have the option of reporting either the "TB" or "JG" modifiers for packaged drugs (SI "N").
- In regards to potential billing errors related to the use of the new modifiers, CMS advises hospitals that reporting the "JG" modifier on a claim line with an OPPS separately payable drug HCPCS code will trigger the reimbursement cut, even if the modifier was used in error. Therefore, if a hospital mistakenly applies the "JG" modifier to drug with SI "G," the reimbursement cut will be applied even though these drugs are not subject to the cut.
- Finally, CMS notes that, to the extent, affected providers are unable to upgrade their billing software by January 1, 2018, to include modifiers "JG" and "TB", section 1835(a) the SSA permits providers up to 12 months after the date of service to timely file a claim for payment. In that regard, providers unable to properly identify and bill accurately for 340B-acquired drugs should contact their Medicare Administrative Contractor to discuss whether holding claims or rebilling claims may be an option.

The FAQ includes a chart that identifies the required and optional modifiers by hospital type.

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OTHER ADDITIONAL POLICY GUIDANCE

- As noted in the Final Rule, CMS reiterates that for purposes of determining whether the reimbursement cut applies, "acquired through the 340B Program means the drug was purchased at or below the 340B ceiling price from the manufacturer and includes 340B drugs purchase through the Prime Vendor Program (PVP)."
- The reimbursement cut does not apply to separately reimbursable drugs that are not acquired under the 340B Program. That is, to the extent that a 340B hospital is permitted under the 340B Program to acquire covered outpatient drugs by means other than 340B pricing, the hospitals reimbursement for such separately reimbursable drugs would be ASP plus 6%.
- CMS will utilize each hospital's Medicare hospital type in determining the applicability of the 340B reimbursement cut, regardless of how the hospital is registered in the 340B Program. That is, for hospitals that qualify under more than one covered entity type under the 340B Program, CMS will disregard the hospital's 340B covered entity type and only consider how the hospital is paid by Medicare. For example, a hospital that is classified by Medicare as a rural sole community hospital, but also meets the requirements to enroll and is enrolled in the 340B Program as a disproportionate share hospital would not be subject to the reimbursement cut for 340B-acquired drugs. In this example, the hospital would be required to report the modifier "TB". In the FAQ, CMS provides guidance on how hospitals can confirm whether they are classified as rural sole community hospitals.
- Hospital-owned retail pharmacies that bill 340B eligible claims under Part B are not subject to the reimbursement cut for 340B-acquired drugs because they are not paid under OPPS.

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[1] Medicare-FFS Program, *Billing 340B Modifiers under the Hospital Outpatient Prospective Payment System (OPPS) Frequently Asked Questions* (Dec. 13, 2017), https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Billing-340B-Modifiers-under-Hospital-OPPS.pdf (last visited Dec. 16, 2017).
[2] Department of Health and Human Services, *Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 FED. REG. 59,216* (final rule Dec. 14, 2017), https://www.gpo.gov/fdsys/pkg/FR-2017-12-14/pdf/R1-2017-23932.pdf (last accessed Dec. 18, 2017). Please note that the Final Rule was originally published on November 14, 2017 (82 Fed. Reg. 52,356), but was republished in order to correct an error that resulted in the omission of a section of the document unrelated to the issues discussed in this alert.
[3] *Id*. at 59,368.
[4] *Id*. at 59,366.
[5] *Id.*
[6] *Id.* at 59,369.
[7] *Id.* at 59,367.
[8] *Id.*
[9] That is, under OPPS drugs and biologics are reimbursed under section 1833(t)(14) of the Social Security Act (the "SSA") while those under PFS are reimbursed under section 1847A of the SSA. The reimbursement cut to

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340B-acquired drugs and biologics in the Final Rule only applies to OPPS in accordance with section 1833(t)(14)(A)(iii)(II) of the SSA. It consequently does not impact payment under PFS through section 1847A of the SSA. See Final Rule at 59,367-68; see also Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program, 82 FED. REG. 52,976. 53,028 (Nov. 15, 2017), https://www.gpo.gov/fdsys/pkg/FR-2017-11-15/pdf/2017-23953.pdf.

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