# PUBLICATION

## Medicare 340B Drug Payment Policy Survives Legal Challenge; Hospitals Say, It's Not Over

**January 16, 2018**

**A federal court has handed CMS an initial legal victory enabling drastic cuts in Medicare Part B payment to take effect for separately payable drugs and biologicals purchased by hospitals under the 340B Drug Discount Program (340B Program). In a Memorandum Opinion released December 29, 2017, U.S. District Court Judge Rudolph Contreras determined that the D.C. District Court lacked jurisdiction to adjudicate the lawsuit brought by several hospital groups and three-named hospitals because of the strict limitations under the Social Security Act for federal court jurisdiction. Under the ruling, the parties contesting CMS's authority to implement the rate cuts for 340B Program-acquired drugs and biologicals (340B Drugs) will need to present claims for Medicare reimbursement and may need to exhaust administrative remedies regarding the adjudication of those claims before the courts would have jurisdiction.**

Although Judge Contreras issued an Order dismissing the case, the hospital groups filed a Notice of Appeal on January 9, 2018. They also have vowed to continue fighting CMS's 340B drug payment policy through lobbying for legislative remedies. In the meantime, the policy is now in effect, and affected 340B hospitals must address compliance with CMS's recently released instructions for billing Medicare for 340B Drugs with dates of service on or after January 1, 2018.

### CMS's 340B Drug Payment Policy

As discussed in our previous Payment Matters article, CMS's new 340B drug payment policy provides CY 2018 hospital Outpatient Prospective Payment System (OPPS) reimbursement for 340B Drugs at Average Sales Price (ASP) minus 22.5 percent (ASP-22.5%). The policy will result in substantially less reimbursement than the prevailing rate of ASP plus six percent (ASP+6%). The rate cuts impact the vast majority of the safety-net hospitals participating in the 340B Program.

Excepted from the rate cuts are rural sole community hospitals (SCH), children's hospitals, and PPS-exempt cancer hospitals. The payment reductions do not apply to critical access hospitals, Maryland hospitals, and non-excepted off-campus hospital outpatient departments, as none of these are reimbursed under OPPS. These hospitals and departments will continue to receive ASP+6% for 340B Drugs as will other hospitals that do not participate in the 340B Program.

To implement the new payment rules, CMS is requiring the use of two new modifiers on claims for 340B Drugs: (1) "JG" modifier and (2) "TB" modifier. Hospitals subject to the rate cuts for 340B Drugs must use the JG modifier to identify separately payable drugs and biologicals purchased under the 340B Program, including those purchased through the 340B Prime Vendor Program. The TB modifier is informational in nature and will not trigger a payment reduction, but, as discussed below, CMS is mandating its use in certain circumstances.

### Court Says Jurisdiction Lacking for Judicial Review of Hospitals' Challenge

Quickly following the release of the CY 2018 OPPS final rule, the American Hospital Association, America's Essential Hospitals, the Association of American Medical Colleges, along with three-named hospitals filed a lawsuit in federal court seeking a preliminary injunction to prevent the cuts from taking effect January 1. The

court did not address the merits of the hospitals' complaint, finding instead that the hospitals' claims were not yet ripe.

Federal law permits judicial review of claims arising under the Medicare program only after the Secretary of the Department of Health & Human Services has issued a final decision on the claims. According to the court, the law requires presentment of a claim to Medicare for reimbursement and imposes a waivable requirement of exhaustion of administrative remedies. The hospital groups argued that they had presented claims through the submission of detailed comments during the notice-and-comment process for the 340B provisions of the OPPS rule. Ultimately, the court rejected that argument, concluding that the hospitals' comments did not amount to the presentment of any specific, concrete claim for reimbursement under the new 340B drug payment policy upon which the Secretary could make a final decision.

Upon making that finding, the Court granted the Secretary's motion to dismiss, denied the hospital groups motion for preliminary injunction as moot, and dismissed the case. The case is not over, however. The hospital groups intend to appeal all aspects of the court's Order and Memorandum Opinion.

### CMS's Billing Instructions for 340B-Acquired Drugs

While the hospitals' lawsuit was pending, CMS released two sets of guidance addressing when use of the 340B modifiers is mandatory, optional, or not required, and offered other important clarifications. CMS posted its first set of guidance as Billing 340B Modifiers FAQs, on December 13, 2017. It issued its second guidance via Transmittal 3941 dated December 22, 2017 as part of the January 2018 OPPS update to the Medicare Claims Processing Manual (CR 10417), along with the corresponding MLN Matters Article MM10417.

Summarized below are key highlights from CMS's sub-regulatory instructions:

***Mandatory Use of JG Modifier:*** The JG modifier is required for 340B Drugs that are separately-payable (status indicator "K") under Medicare when claimed by hospitals with a Medicare hospital-type designation of (i) DSH, (ii) Medicare-dependent hospital, (iii) rural referral center, and (iv) non-rural SCH. These hospitals will be reimbursed for 340B Drugs at ASP-22.5%.

CMS makes clear in FAQ #5 that the "Medicare hospital type designation determines applicability of the 340B drug payment adjustment, *regardless of how the hospital is enrolled in the 340B Program.*" (Emphasis added). Thus, for instance, a facility paid by Medicare under OPPS as a rural SCH would be excepted from the 340B payment policy, irrespective of whether the hospital is enrolled in the 340B Program as a DSH.

***Mandatory Use of TB modifier:*** The TB modifier is required for 340B Drugs that are:

- Separately-payable (status indicator "K") when claimed by hospitals with a Medicare hospital-type designation of (i) children's hospital; (ii) PPS-exempt cancer hospital; and (iii) rural SCH; *as well as* (iv) non-excepted off-campus provider-based departments; AND
- Pass-through drugs (status indicator "G") when claimed by (i) children's hospitals; (ii) PPS-exempt cancer hospitals; (iii) rural SCHs; (iv) non-excepted off-campus provider-based departments; *as well as* (v) DSH hospitals, (vi) Medicare-dependent hospitals, (vii) rural referral centers, and (viii) non-rural SCHs.

In FAQ #6, CMS instructs that claims submitted for 340B Drugs utilized in non-excepted, off-campus provider-based departments must be reported with the TB modifier and the "PN" modifier, which identifies "non-excepted service provided at an off-campus, outpatient, provider-based department of a hospital."

***Optional Use of TB Modifier:*** Use of the TB modifier is optional for CAHs and Maryland waiver hospitals for 340B Drugs that are pass-through (status indicator "G") and separately-payable (status indicator "K") under Medicare.

***Optional Use of TB or JG Modifier:*** Use of either the TB or JG modifier is optional for all types of 340B hospitals on claims for packaged drugs (status indicator "N"). In FAQ #10, CMS instructs that providers may, for administrative ease, report modifier "JG" on packaged drugs, though the modifier will not result in a payment reduction, nor is use of the modifier required for packaged drugs.

***Use of TB or JG Modifiers Not Required:*** The TB or JG modifiers are inapplicable to 340B-eligible drugs that are not purchased at a 340B discounted price. 340B-eligible drugs purchased at Wholesale Acquisition Cost (WAC) need not be claimed with a TB or JG modifier. Notably, in FAQ #15, CMS references 340B hospitals' obligation to know when a 340B-eligible drug is obtained under the 340B Program and to maintain documentation of drug purchases, thus signaling the potential for further claims audit activity in this area.

In addition, CMS instructs that:

- When use of a modifier is required or if optionally reported, the modifier must be included on each claim line of a 340B Drug.
- Compliance with the 340B modifier requirements is mandatory when Medicare is either the primary or secondary payer.
- Discarded drug amounts should be billed on a separate claim line with a JW modifier and the appropriate 340B modifier.

CMS also cautions that failure to properly report modifiers could result in an overpayment recoverable by Medicare.

## Baker Donelson Comments

CMS's new 340B drug payment policy has been controversial from its introduction. Even before the policy was finalized, affected 340B hospitals, CMS's own OPPS Advisory Panel and a bipartisan group of Representatives and Senators urged CMS to abandon its course over concerns that the rate cuts would strain the ability of safety net hospitals to stretch already scarce resources.

Reportedly, bipartisan interest remains in Congress for stopping the 340B reimbursement cuts, with some lawmakers in both the House and Senate pushing to do so as part of the recently-passed year-end spending legislation. That being said, a 340B legislative fix was not included in the short-term continuing resolution that lasts through January 19. Hospital advocates and some lawmakers continue to express interest in enacting legislation to avert the 340B rate cuts. One opportunity to include a legislative fix may arise as part of upcoming legislation on Medicare extenders, which may be taken up as part of the next spending measure to fund the government beyond January 19. It remains uncertain whether lawmakers will be able to reach an agreement.

The door to legal challenges of CMS's 340B drug payment policy also remains open. While the initial case will be appealed, the submission of claims for 340B Drugs could provide a basis for other lawsuits. Specifically, affected hospitals may appeal claims determinations for separately payable 340B Drugs and potentially seek access to expedited judicial review. Alternatively, it is possible that an adjudicated claim might be taken directly to federal court based on an argument that exhaustion of administrative remedies is futile and, therefore, should be waived.

In the meantime, affected 340B hospitals will need to address the complexities of upgrading their billing systems in order to use the JG and TB modifiers. Some 340B hospitals have raised concerns about their ability to timely implement the system changes necessary to accomplish that task. To the extent billing systems are not ready by January 1 (or soon thereafter), CMS has signaled that claims may need to be held or potentially rebilled, but instructed hospitals to contact their Medicare contractors in evaluating these options. Whether claims are held for some period of time, or filed and later corrected or rebilled, hospitals will need to adhere to the timely claims filing rules, which require submission of claims within 12 months after the date of service.

If you have any questions about the content of this article, please contact any member of the Baker Ober Health Law Group.