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New Year's Changes to the 340B Discount Drug Program Raise Compliance Concerns as New Billing Modifiers and Payment Reductions Take Effect

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Judge Rudolph Contreras of the U.S. District Court for the District of Columbia on December 29, 2017 dismissed a lawsuit filed by the American Hospital Association (AHA) and various hospitals and industry groups seeking declaratory judgment and a preliminary injunction blocking implementation of a dramatic cut in Medicare Part B reimbursement to certain hospitals participating in the 340B discount drug program (340B Program).[1] The dismissal of the action on jurisdictional grounds—none of the plaintiffs had yet presented a claim reimbursed at the reduced payment rate—is the latest setback for adversely impacted hospitals attempting to halt the reduced payment regime and ensured that the reductions would go into effect January 1, 2018.

The Centers for Medicare & Medicaid Services (CMS) on November 1, 2017 released the 2018 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center Payment System Final Rule (Final Rule), which finalized a controversial proposal to significantly reduce reimbursement for most drugs purchased through the 340B Program by disproportionate share hospitals (DSHs) and rural referral center hospitals (RRCs).[2]

In the Final Rule, CMS cut the applicable payment rate for separately payable, non-pass-through drugs (excluding vaccines) purchased by DSHs and RRFs through the 340B Program, including the Prime Vendor Program, by approximately 27%, from the average sales price (ASP) plus 6% to ASP minus 22.5% (collectively, the Payment Reduction).[3] For hospitals affected by the Payment Reduction, a drug with an ASP of $1,000 would be reimbursed at $775 starting January 1, 2018, down from the calendar year 2017 reimbursement rate of $1,060.

The Payment Reduction does not apply to 340B eligible entities classified as rural sole community hospitals, children's hospitals, or PPS-exempt cancer hospitals, nor does it affect critical access hospitals, which are reimbursed outside of the OPPS.

Articulating the rationale for the $1.6 billion payment cut in a press release accompanying the Final Rule, CMS Administrator Seema Verma explained that "Medicare beneficiaries would benefit from the discounts hospitals receive under the 340B Program by saving an estimated $320 million on copayments for these drugs in 2018 alone."[4] This account is disputed by affected hospitals and 340B advocacy groups, including 340B Health, which, in a release following Judge Contreras' ruling, shot back: "If these cuts remain in place, many safety net hospitals will be forced to cut back on services, close service sites, and let go clinicians and other caregivers. These payment cuts do nothing to lower drug prices, do not save Medicare a dollar, and won't reduce costs for seniors and other patients."[5]

To distinguish 340B hospitals that are subject to the Payment Reduction from those that are exempt, the Final Rule establishes two new modifiers to identify whether a drug billed under the OPPS was purchased under the 340B Program—"TB" for use by hospitals that are not subject to the Payment Reduction and "JG" for those impacted by the Payment Reduction.[6]

The Final Rule itself left many details regarding operationalization of the new modifiers unaddressed, hindering efforts by hospitals to implement billing system modifications prior to the Final Rule's effective date of January 1, 2018. However, on December 13, 2017, CMS released a Frequently Asked Questions (FAQs) memorandum, at AHA's request, to clarify the agency's new modifier policy for billing 340B-acquired drugs under the OPPS.[7]

The FAQ publication addresses a wide range of implementation issues, such as identifying drugs that must be billed with modifier "JG," the use of modifiers by non-excepted off-campus provider-based departments, the billing of waste for 340B-acquired drugs and the definition of rural sole community hospitals. Notably, the guidance clarifies that hospital-owned retail pharmacies that bill 340B-eligible claims under Part B are exempt from the Payment Reduction because they are not reimbursed under OPPS.

The FAQs confirm that *all* hospitals that bill for separately payable, non-pass-through drugs (i.e., drugs assigned status indicator "K") acquired with a 340B discount must use either the "JG" or "TB" modifier, depending on whether they are subject to the Payment Reduction. Each drug should be billed on a separate claim line with the appropriate 340B modifier, and for claims with multiple drug lines, the appropriate 340B modifier is required on each line of a 340B-acquired drug. The only hospitals excepted from these requirements are critical access hospitals and Maryland Waiver Hospitals.

The implementation of the Payment Reduction and modifiers less than six months after first proposed, two months after release of the Final Rule, and just weeks after CMS' release of sub-regulatory guidance delineating the proper use of the new claim modifiers,[8] has left hospitals scrambling to perform billing system upgrades necessary to comply with the Final Rule.

One of the most daunting obstacles confronting hospitals subject to the new modifier requirements is the timely identification of which drugs were acquired at a 340B discount to determine whether a modifier applies. Due to complex rules imposed on 340B Program participants by the Health Resources and Services Administration (HRSA), which administers the 340B Program, not all drugs purchased by a 340B eligible provider can be purchased at the 340B discounted price. Rather, drugs not eligible for a 340B discount must be acquired by 340B Program participants at Wholesale Acquisition Cost or at other price points exceeding the 340B ceiling price.[9]

Determining whether a drug prescribed at a 340B-participating hospital is considered a "Covered Outpatient Drug" eligible for 340B discount pricing requires a fact-specific inquiry into multitudinous interplaying elements, including service location, the outpatient status of the patient at the time of prescription or administration, the relationship between the hospital and the prescriber, whether the hospital maintains the patient's medical records, whether the patient is Medicaid eligible and the particular hospital's policy for defining "Covered Outpatient Drug," among other factors.

On account of these complexities, many hospitals utilize virtual inventory accumulation and/or split billing software to aid in determining whether a particular prescription is eligible for a 340B discount. These drug inventory and purchasing systems are distinct from hospitals' patient billing systems and there often exists a lag time of a few days or more before a hospital is aware of whether a particular prescription qualifies for a 340B discount. The latency inherent in 340B inventory accumulation software, coupled with the lack of integration between such software and hospital patient billing systems, presents a multifaceted challenge to operationalization of the new modifier system.

Though it is unclear whether CMS took these factors into account when devising the modifier provisions in the Final Rule, the FAQs released December 13 strongly suggest that CMS intends to enforce the modifier requirements with minimal flexibility. For example, with respect to the inadvertent reporting of a "JG" modifier (resulting in reduced reimbursement) rather than a "TB"

modifier (resulting in reimbursement at the normal OPPS rate) due to provider error, CMS exhorts that "It is a provider's responsibility to submit correctly coded claims," explaining that such a mistake would result in a lower reimbursement.[10] Accordingly, inadvertent coding of a drug with modifier "JG" (indicating it was acquired at a 340B discounted price) may result in an underpayment.

Of greater concern, failure by a provider to properly code a drug purchased at a 340B discount with the "JG" modifier could result in an overpayment, which must be returned to Medicare. In the event a provider receives "credible information" of an overpayment, overpayment disclosure obligations are triggered under the Affordable Care Act and its implementing regulations.[11] Subsequent failure to disclose and repay an overpayment within 60 days of its "identification" could subject a provider to crippling False Claims Act penalties. To this end, the FAQs affirm that: "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 . . . ."[12]

The FAQs offer little comfort to hospitals concerned about their inability to upgrade billing software by January 1, 2018 to integrate the new modifiers, stating that: "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 [Medicare Administrative Contractor] to discuss whether holding claims or rebilling claims may be an option."[13]

Judge Contreras' December 29 ruling did not reach the merits of the AHA's complaint, which asserts under the Administrative Procedure Act that the Final Rule exceeds the Department of Health and Human Services' statutory authority. AHA and other petitioners will have the opportunity to refile their lawsuit after the Payment Reduction goes into effect. In a statement following the ruling, AHA President and Chief Executive Officer Rick Pollack vowed to "continue our efforts in the courts and the Congress to reverse these significant cuts to the 340B program."[14]

On the legislative front, H.R. 4392, a bill that would reverse the Payment Reduction, was introduced by Representatives David B. McKinley (R-WV) and Mike Thompson (D-CA) on November 14, 2017 and has generated bipartisan support and 165 co-sponsors in the House. Whether Republican opposition to the Payment Reduction is sufficient to pass a bill overturning a policy promoted by CMS Administrator Seema Verma as "part of the President's priority to lower the cost of prescription drugs"[15] remains to be seen.

Though the litigation and pending legislation potentially could reverse the Payment Reduction, neither offers relief from the provisions of the Final Rule requiring utilization of the new modifiers. Moreover, it does not appear from the FAQs that CMS is inclined towards leniency regarding enforcement of the modifier requirements.

For the time being, the options available to affected providers unable to integrate the new modifiers by January 1 appear limited to working with 340B accumulation and patient billing software vendors to quickly implement the new modifiers and collaborating with legal counsel and Medicare Administrative Contractors to devise acceptable mechanisms for mitigating the consequences of delayed operationalization of the modifiers.

Continued pressure by 340B stakeholders on legislators also may incent Congress to prioritize the 340B Program in the midst of a busy legislative season.

In the wake of the Final Rule, providers subject to the Payment Reduction would be prudent to reassess whether the benefits of continued participation in the 340B Program justify the increased burdens and costs of compliance, a determination that may very well be contingent on whether or not the Payment Reduction is ultimately reversed.

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[1] *American Hosp. Ass'n v. Hargan*, No. 17-2447 (D.D.C. Dec. 29, 2017).

[2] *See* Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 52356 (Nov. 13, 2017).

[3] 82 Fed. Reg. at 52362.

[4] CMS, Press Release, *CMS Finalizes Policies that Lower Out-of-Pocket Drug Costs and Increase Access to High-Quality Care*, *available at* https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-11-01-2.html (last visited Jan. 1, 2018).

[5] Statement by 340B Health Regarding U.S. District Court on 340B Case, *available at* http://www.340bhealth.org/news/statement-by-340b-health-regarding-u.s.-district-court-on-340b-case/ (last visited Jan. 2, 2018).

[6] 82 Fed. Reg. at 52495-96, 52503-09.

[7] CMS, *Medicare-FFS Program, Billing 340B Modifiers under the Hospital Outpatient Prospective Payment System (OPPS),* Dec. 13, 2017, *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Billing-340B-Modifiers-under-Hospital-OPPS.pdf [hereinafter, Billing 340B Modifiers].

[8] *Id*.

[9] *See* 42 U.S.C. § 256b; 42 C.F.R. § 10.1 et seq.

[10] Billing 340B Modifiers, *supra* note 7, at 5-6.

[11] 42 U.S.C. 1320a-7k(d); 81 Fed. Reg. 7654, 7654-84 (Feb. 12, 2016).

[12] Billing 340B Modifiers, *supra* note 7, at 6.

[13] *Id*. at 6.

[14] AHA, Press Release, *Hospital Groups to Continue to Pursue Lawsuit to Reverse Cuts for 340B Hospitals*, *available at* https://news.aamc.org/press-releases/article/hospital-groups-appeal-340b-ruling/ (last visited Jan 2, 2018).

[15] CMS Finalizes Policies that Lower Out-of-Pocket Drug Costs and Increase Access to High-Quality Care, *supra* note 4.