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Coping With Reduced 340B Reimbursement for Safety Net Hospitals: Compliance and Budgetary Impacts

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Safety-net hospitals throughout the country are confronting compliance hurdles and budgetary concerns following the Jan. 1 effective date of a Centers for Medicare & Medicaid Services ("CMS") final rule imposing new billing modifiers and slashing payment rates for pharmaceuticals purchased through the 340B discount drug program ("340B Program"). Efforts by hospital organizations and several hospitals to halt the rule suffered a blow on Dec. 29, 2017, when a federal district court dismissed on jurisdictional grounds a lawsuit seeking to enjoin the rule.

CMS estimates that the controversial reimbursement modification contained in the 2018 Hospital Outpatient Prospective Payment System ("OPPS") and Ambulatory Surgical Center Payment System Final Rule ("Final Rule") will reduce payments to Disproportionate Share Hospitals ("DSH"), Rural Referral Centers, Medicare Dependent Hospitals, and Non-Rural Sole Community Hospitals participating in the 340B Program by $1.6 billion. Though the reduction is applicable only to affected providers in CY 2018, nearly all 340B-participating hospitals reimbursed under the OPPS are subject to the new 340B billing modifier regime imposed by the Final Rule.

The Final Rule reduces the applicable payment rate for separately payable, nonpass-through drugs (excluding vaccines) purchased by affected providers through the 340B Program, including the Prime Vendor Program, by approximately 27 percent, from the average sales price ("ASP") plus 6 percent to ASP minus 22.5 percent (the "Payment Reduction"). For

hospitals affected by the Payment Reduction, a drug with an ASP of $1,000 would be reimbursed at $775 starting Jan. 1, 2018, down from the CY 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, which are expressly exempted in the Final Rule, nor does it extend to Critical Access Hospitals, which are reimbursed outside of the OPPS. Notably, nonexcepted off-campus hospital outpatient departments paid under the Medicare Physician Fee Schedule rather than the OPPS are not impacted by the Payment Reduction. Likewise, hospital-owned retail pharmacies that bill 340B eligible claims are not subject to the Payment Reduction because they are not reimbursed under OPPS.

CMS Administrator Seema Verma has lauded the Payment Reduction as a boon to Medicare beneficiaries. By capping the reimbursement rates to affected 340B hospitals for nonpass-through drugs acquired under a 340B discount, she explained in a press release, "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."

Though this statement may ring true if one focuses solely on drug copayments, the Final Rule implements the Payment Reduction in a budget neutral manner. Thus, every dollar in savings from the Payment Reduction will, as expressed in the Final Rule, result in a corresponding "increase [in] payment rates for other non-drug items and services paid under the OPPS by an offsetting aggregate amount . . . [of] approximately 3.2 percent in CY 2018." Just as the decreased 340B reimbursement rate purportedly will lower Medicare drug copayments for affected provider patients (CMS's estimate does not account for the waiver of copayments by affected providers due to the financial needs of economically distressed patients, a population which safety-net hospitals disproportionately serve), the escalated reimbursement rate for non-drug items and services will increase beneficiary copayment liabilities. These increased copayments for non-drug items and services will affect Medicare beneficiaries receiving services at all OPPS hospitals, not just affected provider patients.

Accordingly, any savings in the form of reduced out-of-pocket drug copayments for the relatively narrow set of Medicare beneficiaries that obtain 340B-acquired prescriptions from hospitals affected by the Payment Reduction will be offset by increased out-of-pocket costs to beneficiaries at all OPPS hospitals, attributable to the 3.2 percent payment increase for non-drug items and services.

Though a reasoned policy justification for the redistribution of Medicare funds away from safety-net hospitals to the benefit of all hospitals reimbursed under OPPS may exist, none is articulated in the Final Rule. In fact, CMS declined to substantively respond in the Final Rule to commenters noting that "CMS's proposal to redistribute the savings that result from the 340B reduction would increase beneficiary copayments on non-drug services" and that "most patients would not directly receive the benefit of the 340B copayment reduction even if reduced payments for 340B drugs lower coinsurance amounts for these drugs."

Likewise, CMS offers no compelling rebuttal in the Final Rule to commenters' observations that "the proposal will likely increase costs for uninsured patients because 340B hospitals provide a disproportionate amount of care to that population

and participating 340B hospitals may no longer be able to provide 'discounts to low-income patients' or other uncompensated care."

It is on these very grounds, among others, that the American Hospital Association ("AHA") and other industry plaintiffs instituted a lawsuit on Nov. 13, 2017, seeking to enjoin the Payment Reduction. In its Complaint, the AHA argued that the Payment Reduction "thoroughly undermine[s] the 340B Program by depriving eligible hospitals of critical resources Congress intended to provide these hospitals through the 340B discounts. Elimination of these resources will, in turn, threaten the ability of covered entities to provide essential health-care services and programs to their communities, including underserved populations within these communities. This is flatly inconsistent with the intent of the 340B Program, which was designed to help covered entities stretch scarce federal resources to reach more patients."

The AHA lawsuit ultimately was dismissed on jurisdictional grounds – as none of the plaintiffs had yet presented a claim reimbursed at the reduced payment rate – but the petitioners have vowed to continue to pursue the lawsuit and seek a ruling on the merits.

A bipartisan contingent in Congress also has come out in support of H.R. 4392, a bill that would reverse the Payment Reduction. The legislation was introduced in November by Representatives David B. McKinley (R-W.Va.) and Mike Thompson (D-Calif.) and has generated the support of over 170 co-sponsors in the House of Representatives.

Whether legal or legislative action will result in elimination of the Payment Reduction remains to be seen. However, neither H.R. 4392 nor the recently dismissed AHA lawsuit targets the modifier requirement imposed by the Final Rule, suggesting that the modifier requirement will persist irrespective of the fate of the Payment Reduction.

In light of the Final Rule, prudent hospital administrators should undertake an accounting of the potential budgetary impact of the Payment Reduction to quantify the residual financial benefit, if any, from continued 340B Program participation.

Moreover, all 340B-participating hospitals (with the exception of Critical Access Hospitals and Maryland waiver hospitals) should operationalize the new 340B billing modifiers without delay.

The new modifier requirements and associated compliance considerations are addressed in the following section. The remainder of this article will explore the various costs associated with 340B Program participation to impart a framework for computing the impact of the Payment Reduction on a hospital's budget.

340B Modifier Compliance

To enable CMS to identify which 340B hospital claims are subject to the Payment Reduction and track 340B-acquired drug claims of all 340B Program participants, the Final Rule establishes two new billing modifiers for 340B-acquired drug claims. The modifier "JG" is mandatory for affected providers and "TB" is required for the remaining classes of 340B participating hospitals and certain provider-based hospital outpatient departments.

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 Jan. 1. However, on Dec. 13, 2017, CMS released a Frequently Asked Questions ("FAQ") memorandum to clarify CMS's new modifier policy for billing 340B-acquired drugs under the OPPS.

The FAQs confirm that all hospitals (with the exception of critical access and Maryland waiver 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, and that each drug should be billed on a separate claim line with the appropriate 340B modifier. For claims with multiple drug lines, the appropriate 340B modifier is required on each line of a 340B-acquired drug.

The implementation of the Payment Reduction and modifiers less than six months after issuance of the 2018 OPPS Proposed Rule, two months after release of the Final Rule (which inverted the modifier requirement set forth in the Proposed Rule), and weeks after CMS' release of sub-regulatory guidance delineating the proper use of the new claim modifiers, provided scant lead time for hospitals to perform billing system upgrades necessary to implement the modifiers.

Timely identification of drugs acquired at a 340B discount is a prerequisite to compliant billing under the new modifier requirement but presents a significant hurdle to most 340B hospitals. Due to complex rules imposed on 340B Program participants by the Health Resources and Services Administration ("HRSA") (HRSA, not CMS, administers the 340B Program), not all drugs purchased by a 340B eligible provider can be purchased at the 340B discounted price. Moreover, for 340B-participating entities subject to the prohibition on drugs purchased through group purchasing arrangements, including DSHs, medications ineligible for a 340B discount must be acquired at Wholesale Acquisition Cost or through the 340B Prime Vendor Program, necessitating utilization of multiple wholesaler accounts and split billing software.

As a fundamental matter, 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 various 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 with respect to 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 and to avoid duplicate discounts with respect to Medicaid patients. These virtual drug inventory 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.

The FAQs released Dec. 13 indicate that CMS intends to enforce the modifier requirements immediately 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. 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, the application of the modifier requirement on 340B-acquired drugs rather than on drugs not purchased with a 340B discount (as was initially proposed by CMS) introduces an increased risk of overpayment and attendant compliance consequences. Failure by a provider to properly code a drug purchased at a 340B discount with the "JG" modifier could result in an overpayment by 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. 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...".

The FAQs offer little comfort to hospitals facing obstacles to operationalization of 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 ("MAC")] to discuss whether holding claims or rebilling claims may be an option."

Representatives for MACs contacted the first week of January appeared generally unaware of concerns surrounding the new 340B modifiers and of the guidance contained in the FAQs. Following internal research efforts, one MAC representative suggested that providers could avoid billing delays and interruption in cash flow by performing post-claim billing adjustments within one year of the service date. This time-intensive method would require a coder to adjust claims on a claim-by-claim basis once a hospital identifies a prescription as 340B-acquired.

Any provider facing hardships complying with the new modifiers should consult with their MAC and with counsel to determine whether the rebilling or holding of claims is a viable and compliant option.

Assessing Budgetary Impacts of the Payment Reduction

Irrespective of the future prospects for the Payment Reduction, the Final Rule went into effect Jan. 1 and hospital administrators would be wise to perform a thorough analysis to quantify the entity's potential losses. Conducting such an assessment will enable an affected entity to determine the amount of a 340B revenue stream following the Payment Reduction and whether it will be sufficient to justify the continued incurrence of administrative expenditures necessary to remain compliant with 340B Program requirements and, if applicable, the surrender of group purchase organization discounts on 340B-ineligible outpatient drugs. Armed with estimates of reduced net 340B revenue, affected entities will

possess the data necessary to make tough decisions regarding the discontinuation of programs funded with 340B revenue, or whether to exit the 340B Program altogether.

In the Final Rule, CMS downplayed the adverse impact of the Payment Reduction on affected providers' budgets and the extent to which it would, as asserted by commenters, greatly "'undermine 340B hospitals' ability to continue programs designed to improve access to services – the very goal of the 340B Program.'" CMS disputed claims that the Payment Reduction would "eviscerate" or "gut" the 340B Program. Relying on reports that "show a wide range of discounts that are afforded to 340B hospitals, with some reports finding discounts of up to 50 percent," CMS concluded that "we believe ASP minus 22.5 percent is a conservative estimate of the discount for 340B acquired drugs and that even with the reduced payment, hospitals will continue to receive savings that can be directed at programs and services to carry out the intent of the 340B Program."

CMS does not contest in the Final Rule that 340B discounts vary greatly by drug and are confidential and thus not susceptible to accurate estimates. It even conceded that the reports upon which it relied in formulating the Payment Reduction "note[d] limitations in estimating 340B-purchased drugs' acquisition costs [due to] the inability to identify which drugs were purchased through the 340B Program within Medicare claims data …." In addition to the foregoing shortcomings, CMS' conjecture that affected providers would continue to achieve sufficient savings after imposition of the Payment Reduction neglects to account for the extent to which these savings are offset by costs incurred to comply with complex 340B Program requirements imposed under the 340B statute and policies adopted by HRSA. As acknowledged by CMS in the Final Rule, HRSA administers the 340B Program and "340B Program policies are . . . not addressed" in the Final Rule. As a result, it is unsurprising that CMS failed to consider the true cumulative cost of 340B compliance measures, which will serve to deplete, and may completely offset, any residual differential between 340B discount drug costs and the reduced OPPS reimbursements.

As detailed above, determining whether a drug prescribed at a 340B-participating hospital is eligible for 340B discount pricing demands a multi-factor case-by-case determination requiring timely coordination between hospital departments and distinct record-keeping systems.

The 340B statute also prohibits certain 340B-participating hospitals, in particular, DSHs, from purchasing Covered Outpatient Drugs that are ineligible for 340B discounts through group purchasing organizations or a "group purchasing arrangement," which encompasses any discount negotiated through an integrated delivery network, an accountable care organization or a parent health system (the "GPO Prohibition"). Instead, entities subject to the GPO Prohibition must purchase all 340B-ineligible Covered Outpatient Drugs at elevated WAC prices or through the Prime Vendor Program, foregoing sizable GPO discounts. These offsetting losses are wholly unaccounted for in the Final Rule.

340B-participating hospitals incur significant expenditures on inventory software and vendors to ensure 340B-discounted drugs are allocated only to eligible patients and to satisfy 340B Program requirements such as the GPO Prohibition and the ban on duplicate discounts. 340B compliance programs also include costs of annual audits conducted by third party consultants. All of the foregoing costs, which serve no purpose other than facilitating compliance with 340B Program

requirements, further diminish any 340B savings realized from the differential between a drug's 340B discount price and OPPS reimbursement.

Additionally, because 340B Program compliance requires coordination between various departments throughout a hospital, including, among others, pharmacy, IT, medical records, billing and human resources, most 340B hospitals employ at least one full-time 340B manager to facilitate the necessary intra-organizational collaboration and to address various other 340B compliance issues, such as registration requirements.

System upgrades and increased administrative burdens associated with implementing the modifier system imposed by the Final Rule also will likely require additional expenditures by 340B hospitals.

CMS' decision not to impose a payment reduction on prescriptions originating from 340B-registered off-campus hospital outpatient departments not excepted from the site-neutral payment provision of the Bipartisan Budget Act of 2015 (" nonexcepted HOPDs") is perhaps the only nugget of positive news for affected providers in the Final Rule. Reasoning that nonexcepted HOPDs are reimbursed under the Medicare Physician Fee Schedule rather than OPPS, CMS declined to alter payment for 340B-acquired drugs originating from nonexcepted HOPDs, which generally are reimbursed at ASP plus 6 percent. This payment disparity creates a potential opportunity for affected hospitals to adjust the site of care for certain outpatient services in order to capture the higher reimbursement rate for 340B-acquired drugs available to non-excepted HOPDs.

CMS addressed this potentiality, anticipated by commenters that predicted the Final Rule would "create financial incentives for hospitals to shift or reallocate services" by stating that CMS will "continue to monitor the billing patterns of claims submitted by nonexcepted [HOPDs] as we continue to pursue future rulemaking on the issues of clinical service line expansion or volume increases…." To this end, CMS' Dec. 13 FAQs require non-excepted HOPDs to report the modifier "TB" for 340B-acquired drugs, in addition to modifier "PN." Hospitals considering relocation of outpatient services are on notice that this exception to the Payment Reduction may be short-lived and, in any event, should evaluate the extent to which any increased 340B revenue would be offset by the loss of facility fees.

To obtain a global understanding of the financial impact of the Payment Reduction, affected providers should consider not only the labor, vendor and technology costs highlighted above but also state-specific Medicaid billing rules and reimbursement rates for 340B-acquired drugs, Medicare and Medicaid MCO payment rates for 340B-acquired prescriptions, the identity and quantity of drugs purchased by the hospital at a 340B discount (which varies by drug and fluctuates periodically), whether 340B-acquired drugs are prescribed or administered at nonexcepted HOPDs, and, for DSHs subject to the GPO prohibition, the differential between potential GPO savings and WAC/PVP spend on Covered Outpatient Drugs that are 340B ineligible.

Conclusion

This article has not attempted to offer a comprehensive account of all factors affecting 340B savings but, rather, is intended to provide a useful roadmap for hospitals undertaking an analysis of the extent to which the Payment Reduction will reduce revenue and impact operations. Hospitals seeking to perform a global accounting of 340B outlays and revenue realization are well-advised to involve the various 340B stakeholders throughout the organization and counsel familiar with 340B Program rules.