340B UPDATE: CMS FINALIZES 340B PROGRAM REIMBURSEMENT CUT ON PART B DRUGS

Date: 6 November 2017

U.S. Health Care Alert

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On November 1, 2017, the Centers for Medicare and Medicaid Services ("CMS") issued a final rule updating the Medicare hospital Outpatient Prospective Payment System ("OPPS") for the calendar year 2018.[1] As part of this update, CMS finalized its proposal to reduce Medicare Part B drug reimbursement for drugs purchased under the 340B Drug Pricing Program ("340B Program") to the drug's average sales price ("ASP") minus 22.5%; a change from the current reimbursement rate of ASP plus 6%. This reduction, which drew criticism from 340B Program stakeholders and Congress when CMS proposed it earlier this year, is expected to limit the financial benefit of the 340B Program to safety net providers across the country and may have ripple effects on payor reimbursement policies outside of Medicare.

BACKGROUND

As discussed in our prior alert, CMS proposed in July 2017 as part of its calendar year 2018 update to the OPPS to apply a discount of 22.5% off of ASP for non-pass-through, separately payable drugs purchased under the 340B Program, compared to the current reimbursement rate of ASP plus 6%.[2] CMS also proposed to implement the reimbursement cut through the use of a new claims modifier for hospitals to use with separately payable drugs under the OPPS that were not acquired under the 340B Program.[3] Further, in order to comply with budget neutrality rules under the OPPS, CMS proposed to offset the decrease in 340B Program payments by increasing non-drug payments under the OPPS, thereby redistributing the funds saved from 340B Program payments to both 340B Program and non-340B Program hospitals.[4] Discussing the proposal, CMS explained that its goal was to "make Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs while recognizing the intent of the 340B program to allow covered entities, including eligible hospitals, to stretch scarce resources while continuing to provide access to care."[5]

The proposal generated significant criticism from 340B Program stakeholders including safety net facilities and patient advocacy groups, which generally opposed the proposal. For example, CMS received comments from hospital organizations questioning its authority to implement the new policy, challenging the substance of the proposal, and raising concerns about the administrative process through which CMS sought to implement the change.[6] Additionally, a majority of the members of the House and Senate signed on to separate letters to CMS opposing the cut and arguing that CMS's proposal to redistribute Medicare's savings on 340B Program drugs to all OPPS hospitals is inconsistent with Congress' intent for the 340B Program to benefit specific categories of covered entities.[7]

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THE FINAL RULE

Notwithstanding the above criticism and congressional feedback, CMS is finalizing the proposal to reduce Part B reimbursement for 340B Program drugs under the OPPS from ASP plus 6% to ASP minus 22.5% effective January 1, 2018. CMS justified the decision by noting that the new policy will "allow the Medicare program and Medicare beneficiaries to pay less for drugs"[8] and that the previous payment rate of ASP plus 6% did not recognize the "significantly lower acquisition costs of such drugs incurred by a 340B participating hospital."[9] In this regard, CMS relied on supportive commenters who agreed that ASP minus 22.5% is the most appropriate reimbursement rate for 340B Program drugs because it allows hospitals to "retain a profit on those drugs for use in care of low-income and uninsured patients," without creating an incentive for the use of overpriced drugs.[10] Based on its own analysis, CMS believes that the new payment rate is actually a lower bound estimate.[11]

Responding to critics who commented that the reimbursement cut would "effectively eviscerate the 340B Program" and will "greatly undermine 340B hospitals' ability to continue programs designed to improve access to services—the very goal of the 340B Program,"[12] CMS argued that the change will not punitively target safety-net hospitals because 340B Program discounts can be as much as 50% below ASP (or greater through the Prime Vendor Program).[13] CMS also rejected arguments put forth by commenters who questioned CMS's statutory authority to implement the new policy, stating that specific language in the Social Security Act that allows the Secretary to "calculate and adjust" drug payments "as necessary" gives the Secretary broad discretion to adjust payments for drugs, including when certain drugs are acquired at a significant discount.[14] In further defending the proposal against claims that it will undermine the 340B Program, CMS emphasized that it decided to exempt certain categories of hospitals from the new alternative payment methodology. In the Final Rule, CMS specifically exempts rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals.[15]

CHANGES FROM THE PROPOSED RULE

Although the reimbursement cut was finalized as initially proposed, the Final Rule does make some significant changes in how providers must identify these claims. Most significantly, in the proposed rule, providers would have been required to use an OPPS claims modifier to identify when drugs were not purchased under the 340B Program. In the Final Rule, however, CMS reversed course and is now requiring that covered entities include a claims modifier "JG" (drug or biological acquired with 340B Drug Pricing Program Discount) for drugs that are acquired under the 340B Program. This modifier must appear on the same claim line as the drug's HCPCS code. CMS argues that this approach will pose less of an administrative burden, will allow better tracking of the Program overall, and will better align CMS's payment policies with existing modifier requirements imposed by various Medicaid programs.[16] Similarly, even though rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals are exempt from the reimbursement cut (as noted above), those hospitals are required to report an informational claims modifier "TB" for tracking and monitoring purposes.[17]

IMPACT OF THE FINAL RULE

The Final Rule generated an immediate reaction from hospital organizations, with the American Hospital Association, Association of American Medical Colleges, and America's Essential Hospitals announcing that they

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intend to pursue litigation against CMS challenging the 340B Program reimbursement cut.[18] As noted above, many commenters questioned whether CMS has the statutory authority to selectively target 340B Program covered entities for an alternative payment methodology.

There is also concern that CMS's new policy will accelerate a trend that has seen commercial payors and PBMs pursue two-tier payor reimbursement policies that pay 340B Program covered entities less than non-340B Program covered entities. With CMS pursuing a two-tier reimbursement approach in the Final Rule, other payors may more aggressively pursue similar policies, to the detriment of 340B Program covered entities and their patients notwithstanding that the Health Resources Services Administration has historically viewed such two-tier reimbursement models as inconsistent with congressional intent that the margin on 340B Program drugs should accrue to the benefit of safety net providers.[19]

More broadly, the Final Rule suggests that the Trump administration may move forward with other proposals aimed at cutting back on the 340B Program in the face of opposition from hospitals and Congress. For example, as discussed in prior alerts, the Trump administration is considering such ideas as cutting back on contract pharmacy arrangements and new legislation to limit the ways in which covered entities are permitted to make use of 340B Program discounts. As a result, it will be critical to monitor developments from the administration and Congress in the coming months to ensure that key decision makers receive meaningful input on these proposals from 340B Program stakeholders.

NEXT STEPS FOR PROVIDERS

340B Program hospitals will need to immediately begin preparing for implement the systems needed to identify and bill 340B Program drugs with the "JG" modifier (or "TB" modifier if exempt from the Final Rule). Additionally, covered entities will want to closely monitor litigation brought by stakeholder representative entities and may wish to participate in a more active role in that litigation and/or pursue simultaneous litigation. Finally, covered entities may wish to continue to pursue a congressional fix for the reimbursement cut through lobbying efforts, given the significant congressional support that opponents of the proposed rule were able to generate.

K&L Gates' Health Care practice and Public Policy and Law practice can assist providers in each of these areas. K&L Gates regularly advises clients on 340B Program implementation and compliance matters, engages in high stakes litigation with payors and federal agencies, and facilitates stakeholder engagement with Congress.

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[1] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-23932.pdf (scheduled for publication Nov. 13, 2017) (hereinafter "Final Rule").

[2] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Systems, 82 Fed. Reg. 33,558 (July 20, 20 17), https://www.gpo.gov/fdsys/pkg/FR-2017-07-20/pdf/2017-14883.pdf.

[3] *Id.* at 33,633.

[4] *Id.* at 33,712.

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[5] *Id.* at 33,633.

[6] *See generally* Final Rule at 554-613 (discussion of comments received on the proposed rule).

[7] *See* Letter to Acting Secretary Don J. Wright and CMS Administrator Seema Verma from Members of the United States Senate, Oct. 6, 2017, http://www.aha.org/advocacy-issues/letter/2017/171006-senate-hhs-cms-final-340b.pdf (signed by 57 members of the Senate); *see also* Letter to CMS Administrator Seema Verma from Members of the United States House of Representatives, Sept. 27, 2017, https://mikethompson.house.gov/sites/mikethompson.house.gov/files/340B%20Letter%20FINAL%20Signed.pdf (signed by 228 members of the House).

[8] Final Rule at 548.

[9] *Id.* at 553.

[10] *Id.* at 557.

[11] *Id.* at 561.

[12] *Id.* at 562.

[13] *Id.* at 562.

[14] *Id.* at 566-68.

[15] *Id.* at 594-95.

[16] *Id.* at 604-08.

[17] *Id.* at 608.

[18] *See* Press Release, American Hospital Association, Statement on Final CY 2018 OPPS Rule, Nov. 1, 2017, http://www.aha.org/presscenter/pressrel/2017/110117-pr-opps.shtml.

[19] Previous 340B Program guidance from HRSA's prime vendor, Apexus, explicitly advised covered entities that they are not required to accept 340B Program price discrimination by Medicaid managed care organizations ("MCOs") and directed covered entities to report MCO 340B Program price discrimination to HRSA. This guidance currently states, "If your entity receives a discriminatory contract, you do not have to agree to the terms." Apexus, 340B & Medicaid, https://docs.340bpvp.com/documents/public/resourcecenter/340B_Medicaid.pdf (accessed on Aug. 9, 2017).

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