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ISSUE ALERTS

AND THE HITS KEEP COMING: CMS PROPOSES TO CUT REIMBURSEMENT RATES FOR 340B DRUGS AND NON-EXCEPTED PROVIDER-BASED DEPARTMENT SERVICES

FOULSTON SIEFKIN HEALTH CARE ISSUE ALERT

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CMS proposed two new blows to hospital reimbursement this past week with the release of its 2018 Outpatient Prospective Payment System ("OPPS") proposed rule and the 2018 Medicare Physician Fee Schedule ("MPFS") proposed rule. CMS intends to significantly cut the reimbursement rates for 340B drugs and for non-excepted, provider-based department ("PBD") services.

340B Drug Discount Program

The 340B program allows qualifying hospitals to purchase covered outpatient drugs at discounted prices from drug manufacturers. Hospitals in the 340B program receive the same reimbursement as other, non-340B hospitals, but that may soon change. In its 2018 OPPS proposed rule, published in the Federal Register on Thursday, July 20, 2017, CMS proposed to reduce the reimbursement for 340B drugs by more than 25% of the current rate.

The Health Resources and Services Administration ("HRSA"), which is the HHS department responsible for the 340B program, establishes the "ceiling price" that manufacturers may charge for each 340B drug. The ceiling price depends on the drug's average manufacturer price, whether the drug is a brand or generic drug, and whether a generic drug is available. The Medicare Payment Advisory Commission ("MedPAC") and the Office of Inspector General for HHS estimate that 340B hospitals receive an average discount of at least 22.5% to 33.6% of the average sales price ("ASP") for 340B drugs.

Medicare currently pays all hospitals (other than critical access hospitals, which are paid 101% of reasonable costs) for separately payable drugs the ASP plus 6%, regardless of whether the drugs are purchased through the 340B

program. Medicare beneficiaries are responsible for their copayment of 20% of the Medicare rate, again regardless of whether the drugs are purchased at a 340B discount.

Though Congress did not specify how 340B providers must use their 340B discounts, CMS noted that the statutory intent of the 340B program is to maximize scarce Federal resources to reach more eligible patients and provide more comprehensive care. Notably, hospitals must have a minimum disproportionate share hospital ("DSH") percentage to participate in the 340B program, so they already treat a disproportionate number of low-income patients. Those hospitals presumably use their 340B discounts to continue and expand treatment of low-income patients.

Nevertheless, CMS apparently believes that the discounts should be passed through to the Medicare program and Medicare beneficiaries. To that end, CMS proposes to reduce the Medicare payment for 340B drugs to ASP minus 22.5%. It also intends to add a modifier to drugs billed under the OPPS to identify whether the drugs were purchased under the 340B drug discount program. CMS believes the new reimbursement rate will more appropriately reflect the resources and acquisition costs that 340B hospitals incur. The rate will also allow the Medicare program and Medicare beneficiaries to share in the savings realized by 340B hospitals. CMS seeks comments regarding whether it should apply a different reimbursement rate for 340B drugs and whether the new 340B drug rate should be phased in over a number of years.

Non-Excepted Provider-Based Departments

In November 2016, we highlighted CMS' interpretation of Section 603 of the Bipartisan Budget Act, which prohibits provider-based billing at new off-campus outpatient departments created after November 1, 2015. Items and services furnished at a non-excepted PBDs are reimbursed under the applicable, non-OPPS payment system. CMS clarified that the MPFS is the "applicable payment system" for most items and services furnished in a non-excepted PBD. CMS also adopted new payment policies for those items and services furnished in non-excepted PBDs.

CMS believes its payment policies should equalize payment rates between non-excepted PBDs and physician offices to the greatest extent possible, while allowing those non-excepted PBDs to bill in a straight-forward way for services they furnish. Thus, for the technical component of items and services furnished in a non-excepted PBD in 2017, CMS paid under the MPFS a rate of 50% of the OPPS payment rate for the same items and services. CMS refers to this adjustment as the "PFS Relativity Adjuster." For 2018, CMS proposes to adopt a PFS Relativity Adjuster of 25%, meaning CMS will pay for items and services furnished in a non-excepted PBD at the rate of 25% of the OPPS rate for the same items and services. In short, after a 50% cut in rates for 2017, non-excepted PBDs may have their rates halved again in 2018.

Comments regarding the proposed rules are due September 11, 2017. For more information regarding the proposed 340B drug rates, see https://www.federalregister.gov/documents/2017/07/20/2017-14883/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment, and 42 C.F.R. 10.1 et seq. For more information regarding the proposed cuts to non-excepted PBD rates, see https://www.federalregister.gov/documents/2017/07/21/2017-14639/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions.

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