Newly-Announced 340B Payment Rule Presents Financial & Operational Challenges to All Covered Entities

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In its 2018 Outpatient Prospective Payment System final rule (Final Rule) issued Nov. 1, Centers for Medicare and Medicaid Services (CMS) implemented a significant Medicare Part B payment reduction for separately payable, non-pass-through drugs provided in the hospital outpatient setting. CMS also finalized several new modifiers that will present significant operational challenges, given a very short turnaround time to implement.

It is critical that all covered entities take action now to combat implementation of the 340B provisions in the Final Rule and to develop an action plan to implement the use of CMS’s new modifiers.

Find the Final Rule here. Read Polsinelli's analysis of CMS’s initial proposal here.

Below is a high-level analysis of some key concepts in the Final Rule:

- In 2018, CMS will cut Part B reimbursement for certain 340B drugs from ASP plus 6% to ASP minus 22.5% – the reduction applies to separately payable, non-pass-through drugs with status indicator “K”. CMS selected the reimbursement rate of ASP – 22.5% based on previous analysis by MedPAC. Interestingly, even MedPAC commented on the proposed rule, reiterating its recommendation to set the reimbursement at ASP – 4% and not ASP – 22.5%.

- The scope of the reduction is limited to disproportionate share and rural referral center hospitals – sole community, children’s and cancer hospitals are exempt, but they still must use the modifiers discussed below. The Final Rule does not apply to critical access hospitals (CAHs).

- Non-exempt provider-based sites under Section 603 of the Bipartisan Budget Act are exempt from CMS’s Part B drug reimbursement reductions and will continue to be paid at ASP plus 6% - CMS indicated that they will revisit this policy in CY 2018.

- The proposal is budget neutral – CMS will increase the non-drug OPPS conversion factor for all hospitals in 2018 by 3.2 %. CMS believes the overall OPPS payment increase in 2018 will be 1.4% (1.3% urban; 2.5% rural). Effectively, 340B entities will face substantial decreases in drug reimbursement, and these dollars will be allocated to all hospitals (for-profit and non-profit).

- All 340B hospitals must implement OPPS claim modifiers by 1/1/18 – Non-exempt hospitals must report modifier “JG” on all OPPS claims for 340B-acquired drugs; exempt hospitals must report modifier “TB” for all 340B-acquired drugs (excluding CAHs).

- The Final Rule included an unusually detailed discussion of CMS’s statutory authority to cut the drug payment rate – Commenters argued that CMS lacked the legal ability to enact its proposal on a number of grounds, each of which CMS rejected. These comments may provide a useful preview of legal arguments that will be made in challenges to the rulemaking. Polsinelli presented a number
of these legal arguments in comments to CMS’s original proposal. As of today, several parties have publicly threatened litigation to enjoin the 340B components of the Final Rule.

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