HALL RENDER
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MEDICARE'S 340B PAYMENT CUT: WHAT DOES IT MEAN FOR ALL HOSPITALS?

On November 1, the Centers for Medicare & Medicaid Services ("CMS") surprisingly finalized a proposal to reduce reimbursement by almost 27 percent for separately payable drugs purchased at reduced prices under the 340B drug discount program ("340B Program"). Currently, all 340B-participating hospitals ("Covered Entities") except for critical access hospitals ("CAHs") receive Medicare OPPS payments of 6 percent over a drug's Average Sales Price ("ASP"), which is commonly referred to as "ASP + 6 percent" pricing. Once effective, Medicare payment for separately payable "non-pass through" drugs (generally those costing more than $120) in the hospital setting will be at ASP – 22.5 percent.

Published solely as sub-regulatory guidance without regulations in the 2018 hospital Outpatient Prospective Payment System ("OPPS") final rule ("Final Rule"), this reimbursement reduction will be fully effective on January 1, 2018, less than six months after it was first proposed and less than two months after being finalized. This implementation will occur in spite of what appeared to be relatively widespread opposition on the part of various hospital stakeholders as well as meaningful portions of both Congress and the Senate.

This OPPS payment cut represents a significant change for hospitals enrolled in the 340B Program as a disproportionate share hospital ("DSH"), a rural referral center ("RRC") or an urban sole community hospital ("SCH"). The reduction does not impact Medicare OPPS drug reimbursement for: i) certain Medicare provider types;[1] or ii) non-excepted off-campus provider based departments established after November 2, 2015 that are paid under the Medicare Physician Fee Schedule.

CMS notes that the savings realized from the payment reduction will be applied in a "budget neutral" manner by using the $1.6 billion projected savings to increase the OPPS conversion factor for all hospital outpatient services by 3.2 percent. This approach will result in the 340B savings being indirectly used to support both drug and non-drug items and services provided by 340B and non-OPPS hospitals alike, including those provided by for-profit hospitals.

In explaining its rationale for the 340B payment reduction, CMS expressed concerns that present payments for 340B Program drugs "are well in excess" of overhead and acquisition costs, have resulted in overutilization of hospital-based services and are not correlated to an increase in charity care.

IMPACT ASSESSMENT

Although various national affinity groups have discussed legal challenges to this proposal based on statutory construction arguments, all hospital 340B Covered Entities excluding CAHs need to carefully assess and plan for the impact of this reimbursement cut. As part of the budget planning process, hospital finance team members will need to estimate the impact of non-pass through status drugs (Status indicator 'K') being paid at ASP – 22.5 percent rather than the current ASP + 6 percent.

CMS states in the Final Rule that this 27 percent payment reduction for separately payable Medicare 340B drugs still provides payment that is in excess of 340B Program savings. Covered Entities will need to: i) validate that this statement is accurate; and ii) confirm the overall budget impact irrespective of the amount by which new Medicare OPPS drug payment might exceed 340B drug costs.

In carrying out this analysis, affected 340B Covered Entities should utilize the list of the drugs by HCPCS code that CMS included in the Final Rule as an addendum that will receive separate payments under Medicare Part B in CY 2018. Drugs paid under HCPCS codes with a status indicator of "K" will be affected by the proposed rule (non-pass-through drugs and non-implantable biologicals, including therapeutic radiopharmaceuticals). 340B Covered Entities should also note that this change does not apply to managed care plans (Medicare or Medicaid), private payors or Medicaid fee-for-service. Of course, a now-effective federal requirement requires 340B acquisition cost billing in all states for Medicaid fee-for-service.

PRACTICAL TAKEAWAYS

The steps CMS took in the Final Rule continue a trend of CMS, industry and even Congressional scrutiny of the 340B Program. As mentioned earlier this year, a member of Congress proposed a bill altering the 340B Program, a congressional subcommittee held hearings regarding 340B Program oversight and a draft executive order proposed rescinding or revising 340B-related rules. As such, 340B Covered Entities

should consider more actively documenting how they use 340B Program savings to support their nonprofit mission, including charity care and other safety net activities.

With respect to detailed implementation, 340B Covered Entities will need to ensure that appropriate billing modifiers are implemented in order to be able to submit claims for drug payment.[2] Specifically, these modifiers will identify whether a drug billed under the OPPS was purchased through the 340B Program at a hospital subject to the payment reduction or not.

Despite the looming uncertainty in the 340B Program, participating hospitals have options to mitigate the impact of the Final Rule. These options include assessing alternative 340B Covered Entity type enrollment and GPO purchase optimization (if and where permitted), among other options. In all cases, 340B Program stakeholders should carefully consider the impact of all Medicare, Medicaid and private payor reimbursement approaches in the 340B Program context before moving forward with any strategic initiatives given the climate of oversight.

Going forward, stakeholders should monitor future actions by the executive branch, CMS, Congress and the Health Resources and Services Administration. 340B stakeholders should also contact their federal representatives to ensure the true impact of the Final Rule is understood.

Finally, Hall Render is evaluating options for establishing a Medicare group appeal challenging the validity of the Final Rule's 340B payment reduction as inconsistent with statutory authority and Congressional intent. Legal challenges to Medicare payment changes of this sort are always a long uphill battle. However, we recommend that Covered Entities explore their options for preserving their appeal rights while pursing potential remedies at the policy and legislative levels.

If you have any questions or would like additional information about this topic, please contact:

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[1] Not subject to the payment reduction are: i) critical access hospitals; ii) rural sole community hospitals; iii) children's hospitals; or iv) PPS-exempt freestanding cancer hospitals.

[2] JG modifier for 340B drugs; JG or TB modifier for status 'N' drugs; or TB modifier for rural SCH, children's or PPS cancer hospital claims (informational only).