MEDICARE 340B PAYMENT CUTS GO LIVE AS OF JANUARY 1. WHAT'S NEXT?

As we noted in a previous article, significant Medicare payment cuts for certain 340B-participating hospitals[1] ("Covered Entities") **went into effect as of January 1, 2018** after a federal district court judge declined to take action to prevent implementation of certain 2018 Outpatient Prospective Payment System ("OPPS") final rule ("Final Rule") provisions. These changes represent a dramatic (nearly 27 percent) reduction in reimbursement for separately payable drugs purchased at reduced prices under the 340B drug discount program ("340B Program").

Given the significance of these cuts, we discuss here key implementation requirements and potential next steps, including subsequent litigation on the merits and legislative action. In the short term, Covered Entities need to ensure that their 340B Program software and payment systems are actively adding billing modifiers required by the Final Rule (as discussed in detail herein). If Covered Entities are unable to do so, or if the implementation will occur on bills submitted after January 1, they will need to consider potential corrective action.

DETAILED DISCUSSION

While the judge ultimately declined to halt the OPPS payment cuts since no remittances have been affected and therefore no harm yet realized, there will almost certainly be subsequent litigation aimed at invalidating the OPPS 340B payment cuts. Nonetheless, for the foreseeable future, affected Covered Entities must comply with the Centers for Medicare & Medicaid Services' ("CMS's") billing requirements for drugs purchased at 340B Program prices.

The most significant related billing requirement involves the submission of claim modifiers that will identify whether a drug billed under the OPPS was purchased through the 340B Program by an affected Covered Entity. Covered Entities that are not exempt from OPPS 340B adjustment must now report modifier "JG" (drug or biological acquired with 340B Drug Pricing Program Discount) for these drugs. This modifier will trigger the 27 percent payment reduction. Meanwhile, Covered Entities that are exempt from the OPPS 340B adjustment (such as rural sole community hospitals) must use the informational modifier "TB" (drug or biological acquired with 340B Drug Pricing Program Discount, reported for informational purposes) to identify all drugs purchased at 340B Program prices.

Notably, even though technically paid under the Physician Fee Schedule, all non-excepted off-campus provider-based departments of hospitals (established after November 2, 2015) are required to report modifier "TB" for 340B-acquired drugs *in addition to* modifier "PN" (non-excepted service provided at an off-campus, outpatient, provider-based department of a hospital).

While some Covered Entities have been able to implement processes to include the newly required modifiers by the January 1, 2018 effective date, other Covered Entities have struggled to revamp their systems to include these new modifiers. Unfortunately, CMS has offered little consolation to Covered Entities lagging behind in implementation. Instead, it has merely advised such Covered Entities to withhold the submission of claims until the requisite modifiers are included.

PRACTICAL TAKEAWAYS

Given the novelty of these modifiers, and the potential for overpayments if appropriate modifiers are not included, all Covered Entities should work to ensure that they are properly submitting all claims for drugs purchased at 340B Program prices as of January 1, 2018. Covered Entities that operate non-excepted off-campus provider-based departments of hospitals established after November 2, 2015 will also want to carefully consider special processes for such departments to ensure that claims from these departments include both of the required modifiers (PN and TB).

Covered Entities that are currently unable to comply with these requirements must implement a solution quickly, including coordinating communications with the responsible FI/MAC. These communications should be carefully coordinated with the organization's Compliance, Legal and Finance resources.

As stated in our previous articles, Hall Render continues to evaluate 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. Again, as legal challenges of this nature are always an uphill battle, we recommend that Covered Entities explore their options for preserving their appeal rights while

pursuing potential remedies at the policy and legislative level.

Finally, as bipartisan legislation to nullify the payment cuts is currently circulating around Capitol Hill, there is no time like the present to make your voices heard about the potential detrimental impact of these payment cuts.

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

- Todd Nova at (414) 721-0464 or tnova@hallrender.com;
- Richard Davis at (414) 721-0459 or rdavis@hallrender.com; or
- Your regular Hall Render attorney.

[1] These hospitals include disproportionate share hospitals, rural referral centers and urban sole community hospitals. Critical access hospitals are reimbursed on the basis of reasonable cost and are therefore unaffected by the OPPS Medicare payment cuts. The payment cuts also do not apply to rural sole community hospitals, children's hospitals, PPS-exempt freestanding cancer hospitals or non-excepted off-campus provider based departments established after November 2, 2015 that are paid under the Medicare Physician Fee Schedule. Modifier reporting, however, is still required in certain situations.