

CMS CONTINUES 340B PAYMENT CUTS IN 2020 OPPS PROPOSED RULE YET ACKNOWLEDGES POTENTIAL FOR FUTURE REVERSAL

This week, CMS released the 2020 Medicare Hospital Outpatient Prospective Payment System (“OPPS”) and Ambulatory Surgical Center Payment System Proposed Rule (“Proposed Rule”). Among a host of other items, CMS announced its intent to continue paying Average Sales Price (“ASP”) minus 22.5 percent for most drugs acquired under the 340B drug discount program (“340B Program”) in spite of a Federal District Court ruling that CMS does not have the authority to do so. CMS reiterated that reduced reimbursement would again apply to 340B Program drugs furnished in off-campus provider-based departments paid under the Physician Fee Schedule. However, CMS also acknowledges that these payment cuts may be invalidated by federal courts and that retroactive repayment could be made to affected 340B Program covered entities. As such, covered entities should work with their finance and legal teams to protect their appeal rights for 2018, 2019 and possibly 2020.

The Proposed Rule addresses the decision by the U.S. District Court for the District of Columbia in *American Hospital Association v. Azar*, the ongoing litigation over the CY 2018 and 2019 OPPS 340B Program payment policies. There, the Court determined that CMS violated its statutory authority by reducing reimbursement for 340B Program drugs by nearly 30 percent and directed CMS to take a first pass at designing a remedy for an admittedly complex problem.

In spite of its loss before the Court, we suggested in our prior [article](#) that CMS may try persuading an appellate court of the merits of the CY 2018 and 2019 reimbursement reductions. This is indeed the approach CMS announced it will take, noting in the Proposed Rule that CMS requested on July 10, 2019 that the Court enter a final judgment so it could file an immediate appeal. The Court granted CMS’s request, and we expect CMS to file an appeal in the near future. However, in the interim, CMS announced through the Proposed Rule that it seeks comments regarding potential corrective action in the event that it loses on appeal.

These corrective action options include implementing a reimbursement rate of ASP plus 3 percent for 340B Program drugs rather than ASP minus 22.5 percent, ostensibly since this is closer to the current ASP plus 6 percent rate payable to non-340B Program covered entities. Setting aside the fact that the Court already found that CMS lacks statutory authority to implement rate cuts absent clear data, CMS stated this increased rate could apply both prospectively and retroactively as a remedy for the CY 2018 and 2019 OPPS reductions. Separately, CMS also seeks input on structuring a remedy for the CY 2018 and 2019 OPPS payment cuts, suggesting budget neutral, equitable mechanisms that may be retrospective (each claim) or prospective (upward adjustment to claims in future to account for prior underpayments). In light of these events, 340B Program covered entities should continue working with legal counsel to maintain their appeal rights and recoupment rights by, at minimum, maintaining an accurate accounting of the impact of the payment cuts.

Covered entities, contract pharmacies and other stakeholders should expect more developments in this arena. Covered entities and other interested parties may submit comments [electronically](#) or by regular or express mail using the addresses provided in the Proposed Rule. All comments must be received no later than **5 PM on September 27, 2019** and should reference file code CMS-1717-P. Additionally, covered entities should work with their legal counsel to affirmatively preserve their appeal rights and collaborate with their advocacy teams to support their position.

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

- **Todd A. Nova** at (414) 721-0464 or tnova@hallrender.com;
- **Kristen H. Chang** at (414) 721-0923 or kchang@hallrender.com;
- **Abigail L. Kaericher** at (202) 780-2989 or akaericher@hallrender.com; or
- Your regular Hall Render attorney.

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