

340B UPDATE: CMS ADDRESSES ONGOING LITIGATION AND REIMBURSEMENT CHANGES FOR 340B DRUGS IN CY 2020 OPPS PROPOSED RULE

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On July 29, 2019, the Centers for Medicare & Medicaid Services ("CMS") released its annual proposed rule announcing potential changes to the Medicare Outpatient Prospective Payment System ("OPPS") for upcoming Calendar Year ("CY") 2020 ("Proposed Rule"). [1] In addition to proposing certain payment rates for the upcoming year, CMS used the Proposed Rule to comment on the ongoing litigation relating to the reimbursement cuts under the OPPS in CY 2018 and CY 2019 for drugs purchased under the 340B Drug Discount Program ("340B Program" or "340B"). While CMS continues to maintain that its reduced reimbursement rate for 340B drugs of average sales price ("ASP") minus 22.5 percent is appropriate, it solicits comments from stakeholders on appropriate payment rates in future years and how to structure a remedy if, on appeal, the federal courts uphold the lower court ruling that reimbursement cuts from prior years are in fact unlawful.

BACKGROUND

As discussed in our prior alert, the American Hospital Association and other hospital groups brought a federal suit against Secretary Alexander Azar challenging CMS' decision for CY 2018 to reduce reimbursement of certain 340B Program drugs provided by hospitals paid under the OPPS from ASP plus 6 percent to ASP minus 22.5 percent, primarily on the grounds that CMS lacked authority to implement the cuts under the existing statutory framework. In late 2018, the U.S. District Court for the District of Columbia ("District Court") agreed with the plaintiffs, concluding that the cuts "fundamentally altered the statutory scheme" established by Congress and therefore exceeded CMS's authority. However, the District Court did not propose a remedy or vacate the prior rules implementing the cuts moving forward. [2] The District Court later determined that CMS is best positioned to devise a plan to correct the issue, particularly given the complexity that a solution for CY 2018 and CY 2019 would require under the OPPS budget neutrality requirements, [3] as changing payment for 340B Program drugs ex post facto would affect payment for other non-drug items and services provided over this time. [4] Most recently, while the matter of remedies is still outstanding, the District Court entered a final judgment to afford the parties an opportunity for expedited review on appeal. [5] As expected, CMS has filed a notice of appeal, contending its rates were lawful.

CY 2020 PROPOSED RULE

Although the Proposed Rule acknowledges the ongoing litigation and the District Court decision, CMS maintains

its position that it has the requisite authority to implement the cuts and proposes to continue paying ASP minus 22.5 percent for 340B drugs under the OPPTS, as well as for 340B drugs furnished in nonexcepted off-campus provider-based outpatient departments that are paid under the Physician Fee Schedule. [6] However, in the event the District Court's decision is upheld on appeal, CMS solicits comments from stakeholders both on the appropriate remedy and appropriate payment rates moving forward.

With regard to the remedy, CMS is soliciting comments on such issues as whether a remedy should be retrospective in nature (i.e., additional payments to 340B entities demonstrating harm on a claim-by-claim basis) or whether it may be prospective (i.e., an upward adjustment to future claims to account for underpayments in prior years). [7] CMS also notes that any changes to the OPPTS must be budget neutral. In this regard, CMS notes that the effect of the CY 2018 policy change raised reimbursement on other items and services by about \$1.7 billion across about 3,900 facilities. [8] Finally, CMS notes that a remedy will need to take beneficiary cost-sharing into effect. CMS speculates that potentially millions of Medicare beneficiaries will be affected by a remedy, as beneficiaries have a statutory obligation to pay a cost-sharing amount for certain items and services received, typically at about 20 percent of the total Medicare payment rate. [9]

CMS anticipates that it would propose a specific remedy for CY 2018 and CY 2019, as well as retrospective changes to the CY 2020 rates, in the CY 2021 proposed rule. [10] However, in order to propose and finalize a remedy and make appropriate budget neutrality adjustments on this timeline, the D.C. Court of Appeals will need to render a final decision "likely by March 1, 2020." [11] Additionally, CMS suggests a rate of ASP plus 3 percent as a potentially appropriate remedial payment for 340B drugs, both for CY 2020 and for purposes of determining the remedy for CY 2018 and CY 2019. [12] CMS believes this rate would result in payment that is well above the actual costs hospitals would incur in purchasing 340B drugs and is intended to be "at the upper end" of the appropriate payment adjustments discussed in the District Court's December 27, 2018 opinion. [13] CMS also notes that the adoption of this rate would require a budget neutrality adjustment to the OPPTS conversion factor to account for the payment differential, ultimately resulting in a reduction of approximately \$1.4 billion in payment for non-drug items and services for CY 2020. [14]

NEXT STEPS

Providers receiving reimbursement for 340B Program drugs under the OPPTS should consider whether to submit comments to CMS on a preferred remedy and reimbursement rates if the federal courts uphold the District Court's decision. Comments are due no later than 5 p.m. September 27, 2019. K&L Gates' health care practice and public policy and law practice regularly advise clients on 340B Program implementation and compliance matters and facilitate stakeholder engagement with Congress and the administration, including through the development and submission of public comments.

NOTES:

[1] Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the

Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals-Within-Hospitals (to be published Aug. 9, 2019), *available at* <https://s3.amazonaws.com/public-inspection.federalregister.gov/2019-16107.pdf> (hereinafter "Proposed Rule").

[2] Memorandum Opinion Denying Defendants' Motion to Dismiss; Granting Plaintiffs' Motion for a Permanent Injunction; Denying as Moot Plaintiffs' Motion for a Preliminary Injunction, *Am. Hosp. Ass'n v. Azar*, No. 18-2084, 28 (Dist. D.C. Dec. 27, 2018).

[3] While not incorporated in the original opinion, the District Court incorporated the extension of the reimbursement cuts for CY 2019 in a subsequent order. Memorandum Opinion Granting In Part Plaintiffs' Motion For a Permanent Injunction; Remanding the 2018 and 2019 OPPS Rules to HHS, *Am. Hosp. Ass'n v. Azar*, No. 18-2084 (Dist. D.C. May 6, 2019).

[4] See Memorandum Opinion Granting in Part Plaintiffs' Motion for a Permanent Injunction; Remanding the 2018 and 2019 OPPS Rules to HHS, *Am. Hosp. Ass'n v. Azar*, No. 18-2084 (Dist. D.C. May 6, 2019).

[5] Memorandum Opinion Granting Defendants' Motion for Entry of Final Judgment; Denying as Moot Plaintiffs' Motion for a Firm Date, *Am. Hosp. Ass'n v. Azar*, No. 18-2084 (Dist. D.C. July 10, 2019).

[6] Proposed Rule at 345.

[7] *Id.* at 347.

[8] *Id.* at 344.

[9] *Id.* at 344.

[10] *Id.* at 345.

[11] *Id.* at 348.

[12] *Id.* at 346.

[13] *Id.*

[14] *Id.* at 727.

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