

340B UPDATE: CMS MAINTAINS PAYMENT REDUCTIONS FOR 340B DRUGS IN CY 2020 OPPS FINAL RULE

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U.S. Health Care Alert

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On November 1, 2019, the Centers for Medicare & Medicaid Services (“CMS”) issued the Medicare Outpatient Prospective Payment System (“OPPS”) final rule for upcoming Calendar Year (“CY”) 2020 (“Final Rule”). [1] Importantly, as part of the Final Rule, CMS finalized a proposal to continue to pay an adjusted amount of average sales price (“ASP”) minus 22.5 percent for 340B drugs under the OPPS, as well as for 340B drugs furnished in non-excepted off-campus provider-based outpatient departments that are paid under the Physician Fee Schedule (“PFS”). In addition to commenting on the ongoing litigation concerning the agency’s reduced payment rate for 340B drugs, CMS addressed stakeholder feedback on appropriate payment rates for future years and how to structure a potential remedy if, on appeal, the district court’s ruling that the payment reductions for 340B drugs from prior years are unlawful is upheld.

BACKGROUND

As discussed in our prior alerts [here](#) and [here](#), the American Hospital Association, along with other hospital groups, sued the Secretary of the U.S. Department of Health and Human Services challenging the adjustment to payment rates for 340B drugs from ASP plus 6 percent to ASP minus 22.5 percent for CY 2018. In *American Hospital Ass’n v. Azar*, the U.S. District Court for the District of Columbia ruled that the Secretary exceeded his authority to adjust the payment rates under the existing statutory framework. [2] The district court reasoned, in part, that the Secretary had not collected the necessary data to set payment rates based on acquisition costs. [3] CMS disagreed with the district court’s judgment and has since appealed the ruling.

Notwithstanding the ongoing litigation concerning the agency’s reduced payment rate for 340B drugs, CMS proposed for CY 2020 to continue its reduced payment rate for 340B drugs of ASP minus 22.5 percent. [4] In the event that the district court’s ruling is upheld on appeal, CMS also solicited comments on a potential remedy for CYs 2018 and 2019. Additionally, as reported in our prior alert [here](#), CMS recently announced its intent to conduct a 340B hospital survey to collect drug acquisition cost data for CYs 2018 and 2019. [5] CMS has indicated that such survey data may be used to devise an appropriate remedy, as well as to set future payment rates.

As part of CMS’s proposed survey, hospitals that participated in the 340B Drug Pricing Program (“340B Program”) in the last quarter of CY 2018 and/or first quarter of 2019 would supply their average acquisition cost for each specified covered outpatient drug purchased during this time, which could be the 340B ceiling price, a sub-ceiling price, or another amount depending on the discounts the hospital received. [6] If the acquisition price for a drug is

not available, CMS intends to use the ceiling price for that drug as a proxy for the hospital's acquisition cost. [7] Completed surveys would need to be submitted to corresponding Medicare Administrative Contractors by March 16, 2020. [8]

CY 2020 OPPS FINAL RULE

Payment Rate for 340B Drugs in CY 2020

As part of the Final Rule, CMS finalized its proposal to continue to pay ASP minus 22.5 percent for 340B drugs under the OPPS, as well as for 340B drugs furnished in non-excepted off-campus provider-based outpatient departments that are paid under the PFS. CMS indicated that ASP minus 22.5 percent is a reasonable payment amount and declined to pay the statutory default payment of ASP plus 6 percent or an alternative payment of ASP plus 3 percent. [9]

CMS further indicated that it anticipates the survey data it is proposing to collect for CYs 2018 and 2019 will confirm that the ASP minus 22.5 percent formula “overcompensates” 340B hospitals. [10] The agency noted that, despite having data regarding their drug acquisition costs, no hospital had disputed in comments that the ASP minus 22.5 percent formula was a conservative adjustment that represented the minimum discount that hospitals receive for drugs acquired through the 340B Program. [11] CMS also disagreed with commenters who argued that the payment reduction has had a negative impact on Medicare patients, noting that patients receiving 340B drugs for which Medicare paid ASP minus 22.5 percent have lower cost sharing than if they had received 340B drugs for which Medicare paid ASP plus 6 percent. [12]

Potential Remedy for CYs 2018 and 2019

In the Final Rule, CMS acknowledged that the agency may use the survey data it is proposing to collect for CYs 2018 and 2019 to develop a remedy in the event that the district court's ruling is upheld. [13] CMS noted that relying on such data could avoid the complexities associated with devising an appropriate remedy. [14] In this regard, CMS appears to be intending to use the survey data not only to justify and promulgate a new future looking reimbursement cut, but potentially also to justify that notwithstanding the district court's decision, no remedy is owed to 340B hospitals for CYs 2018 and 2019.

In the event that the agency decides not to rely on the survey data to develop a remedy, CMS is considering stakeholder feedback on the appropriate remedy. In particular, CMS is considering stakeholder feedback on whether the remedy should be retrospective (i.e., additional payments on a claim-by-claim basis) or prospective (i.e., an upward adjustment to future claims), the best way to maintain budget neutrality under either approach, and the potential impact of a remedy on Medicare beneficiaries. CMS indicated that it anticipates posting the specific remedy for CYs 2018 and 2019 in the CY 2021 OPPS rulemaking. [15]

With regard to the remedy structure, CMS noted that many commenters had supported a retrospective approach under which the agency would repay the difference between ASP plus 6 percent and ASP minus 22.5 percent plus interest for all claims for 340B drugs for CYs 2018 and 2019. [16] CMS also noted that some commenters acknowledged how complex a retrospective approach would be and supported instead a prospective remedy. By way of example, the agency noted that one commenter had suggested applying an increase factor of 26.89,

which would approximate ASP plus 6 percent. [17] Other commenters suggested staggered methods of payment. [18] CMS noted that some requested an opportunity for public comment. [19]

Additionally, with regard to budget neutrality, CMS indicated that some commenters had argued that budget neutrality was not necessary in light of precedent involving underpayments, while others argued that the OPPS statute does not authorize the agency to revisit budget neutrality if its estimates for a prior year are incorrect. [20] CMS noted that some commenters had supported a payment rate reduction for non-drug items and services to maintain neutrality. [21]

CMS had speculated that potentially millions of Medicare beneficiaries would be affected by a remedy because they 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. CMS noted that many commenters believe that beneficiaries should not have to pay any additional payments. [22] The agency did not make further comments on beneficiary copay adjustments.

NEXT STEPS

The U.S. Court of Appeals for the District of Columbia is scheduled to hear oral arguments in the ongoing litigation concerning the payment reductions for 340B drugs on November 8, 2019. In the meantime, stakeholders receiving reimbursement for 340B drugs under the OPPS should review the Final Rule and continue to engage with CMS regarding preferred remedies for CYs 2018 and 2019 in the event that the district court's ruling is upheld. Stakeholders should also consider commenting on CMS's intent to conduct a survey to collect 340B drug acquisition cost data for CYs 2018 and 2019. Comments on the proposed survey are due by November 29, 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 CMS, including through the development and submission of public comments.

NOTES:

[1] Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Revisions of Organ Procurement Organizations Conditions of Coverage; Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Changes to Grandfathered Children's Hospitals-Within-Hospitals; Notice of Closure of Two Teaching Hospitals and Opportunity to Apply for Available Slots (to be published Nov. 12, 2019), <https://s3.amazonaws.com/public-inspection.federalregister.gov/2019-24138.pdf> (hereinafter "Final Rule").

[2] See *Am. Hosp. Ass'n v. Azar*, 348 F. Supp. 3d 62, 82–83 (D.D.C. 2018), appeal pending, Nos. 19–5048 & 19–5198 (D.C. Cir.).

[3] *Id.* at 82.

[4] See 84 Fed. Reg. 39398, 39500 (Aug. 9, 2019).

[5] See 84 Fed. Reg. 51590 (Sept. 30, 2019).

[6] See Hospital Survey for Specified Covered Outpatient Drugs, Supporting Statement A, CTRS. FOR MEDICARE & MEDICAID SERVICES (Sept. 26, 2019), <https://www.cms.gov/Regulations-and->

[Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html](https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html).

[7] *Id.*

[8] See Hospital Survey for Specified Covered Outpatient Drugs, Centers for Medicare and Medicaid Services Average Sales Price Survey, CTRS. FOR MEDICARE & MEDICAID SERVICES (Sept. 26, 2019), <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

[9] Final Rule at 553-58.

[10] *Id.* at 549.

[11] *Id.*

[12] *Id.* at 554.

[13] *Id.* at 562.

[14] *Id.*

[15] *Id.*

[16] *Id.*

[17] *Id.* at 563.

[18] *Id.* at 564.

[19] *Id.* at 563-64.

[20] *Id.* at 565.

[21] *Id.* at 566.

[22] *Id.*

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