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ALERT • Health Care

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Supreme Court Overturns Reduction in Reimbursement for Outpatient Drugs Purchased by Hospitals Under 340B Program

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On June 15, 2022, a unanimous United States Supreme Court decided in favor of the American Hospital Association ("AHA") in its challenge to the 2018 and 2019 final rules of the United States Department of Health and Human Services ("HHS") reducing the amount of reimbursement for outpatient prescription drugs provided by hospitals participating in the 340B Drug Pricing Program ("340B Program").[1] The Court held that HHS's rules reducing reimbursement for drugs purchased through the 340B program were inconsistent with the Medicare Act. This alert summarizes the key portions of the Court's decision and discusses the implications of the decision. In short, while the decision clearly found unlawful the agency's changes to Medicare reimbursement rates relating to 340B drugs that it made without undertaking the requisite survey of drug acquisition costs, it remains to be seen how and when the agency will take action to implement the decision, and whether the agency might still try to effectuate the same rate changes.

Background

Under the Medicare statute, HHS must annually determine Medicare rates under the outpatient prospective payment system ("OPPS"), including for "covered outpatient drug[s]."[2] As explained by the Court, the statute provides two options to set rates for covered outpatient drugs. The first option provides that the payment furnished be equal to the average acquisition cost for the drug for the given year (which, at the option of the Secretary of HHS *may vary by hospital group*) as determined by the Secretary taking into account survey data on hospitals' actual acquisition costs.[3] The second option provides that, if such hospital acquisition cost data are not available, the payment must be equal to the average price for the drug in the given year, "as calculated and adjusted by the Secretary as necessary."[4] Notably, the statutory language of this second option, unlike the first, does not permit payment rates to vary by hospital group. From 2006, when these reimbursement rate options took effect, to 2018, HHS exclusively utilized the second option; that is, the agency did not conduct a survey of acquisition costs and did not vary the reimbursement rates by hospital group. During this period, HHS defined average acquisition cost as the average sales price ("ASP") of each drug – as reported by pharmaceutical manufacturers under Medicare Part B rules – plus 6 percent (or, in the case of newly launched drugs, a benchmark based on wholesale acquisition cost ("WAC") until there is sufficient data for a manufacturer to compute ASP).

Congress enacted the 340B Program in 1992 to allow participating hospitals and other health care providers (collectively "covered entities") to "stretch scarce federal resources as far as possible"[5] and obtain mandatory pharmaceutical manufacturer discounts on covered outpatient drugs. Covered entities eligible to participate in the 340B Program may purchase covered outpatient drugs from manufacturers at or below ceiling prices.[6] Acute care hospitals that meet certain thresholds of Medicare disproportionate share adjustment percentages qualify as covered entities under the 340B Program and therefore are eligible to purchase certain covered outpatient drugs at 340B discounts.[7] Historically, HHS reimbursed all hospitals for covered outpatient drugs at ASP plus 6 percent (or a WAC-based rate for a short period post-launch), regardless of whether they purchased the drugs at 340B Program discounts.

In 2017, however, HHS abandoned this approach when it released the required annual rulemaking for payments under the outpatient prospective payment system ("OPPS") applicable for 2018. For calendar year 2018, HHS set the reimbursement rate for prescription drugs that hospitals purchased through the 340B Program at ASP *minus* 22.5 percent, as opposed to the historical rate of ASP *plus* 6 percent.[8] As part of the final rule, HHS also required hospitals to use the modifier "JG" on their claims submissions to Medicare to identify drugs purchased through the 340B Program.[9] Drugs not purchased through the 340B Program, as well as drugs eligible for pass-through payments, continued to be

reimbursed at the rate of ASP plus 6 percent with their traditional modifiers on the claims for payment.[10] HHS made the reduction to reimbursement rates for 340B-procured drugs in a budget neutral manner by redistributing the amount of reduced drug payments for 340B hospitals to all OPPS hospitals through an across-the-board upward 3.2% increase to the conversion factor of the outpatient prospective payment rate.[11] In its final rule, HHS stated that the source of its percentage reduction in reimbursement for 340B drugs was the Medicare Payment Advisory Commission ("MedPAC"), which had estimated that, on average, hospitals in the 340B Program receive a minimum discount of 22.5 percent off of the ASP.[12] HHS continued to employ the same reimbursement rate methodology as it had for CY 2018 through CY 2022.[13] Crucially for the case at hand, HHS did not conduct a survey of acquisition costs prior to implementing its reduced reimbursement rates based on the MedPAC estimate. Despite the statutory language requiring a survey when the reimbursement rate is not based on average price, the agency asserted it had the authority to implement these reimbursement reductions under a portion of the Part D statute that provides that HHS may "adjus[t]" the average price "as necessary for purposes of" the statutory provision.[14]

In November 2017, plaintiffs AHA, two other hospital associations, and three non-profit hospitals brought an action against HHS in the United States District Court for the District of Columbia challenging the final rule. The plaintiffs contended that HHS acted contrary to law, exceeded its statutory authority under the Medicare statute, and engaged in arbitrary and capricious agency action in making the reimbursement reductions. HHS, on the other hand, argued that the Medicare statute broadly afforded the agency the ability to make rate adjustments "as necessary." The District Court for the District of Columbia held in favor of the plaintiffs, holding that if HHS has not performed a survey of acquisition costs, then reimbursement must be the average sale price.[15] The Court found that the HHS's reduction in payment for 340B hospitals "fundamentally rework[ed] the statutory scheme" and was therefore invalid. HHS then appealed the matter to the United States Court of Appeals for the District of Columbia Circuit.[16] The Court of Appeals reversed the judgment of the District Court by a split 2-1 decision, with the majority finding that HHS's interpretation of the Medicare statute was entitled to deference and was a reasonable interpretation of the statute that allows HHS to make "adjustments" to the calculation of the average sales price under option two of the statute. The dissent concluded that this across-the-board reduction for 340B hospitals was more than an "adjustment" and actually an unlawful variation of reimbursement by hospital group, which by statute can only be achieved using acquisition cost data. The majority therefore held that the reduction in reimbursement rates for 340B drugs purchased by hospitals was allowable and the hospitals appealed to the Supreme Court.

Supreme Court's Ruling and Reasoning

On June 15, 2022, the Supreme Court issued its opinion overturning the Court of Appeals decision and siding with the District Court. In a unanimous decision authored by Justice Kavanaugh, the Court determined that, absent a survey of hospitals' acquisition costs, the Medicare statute is clear that HHS may not vary the reimbursement rates for drugs only for 340B hospitals.[17]

The Court explained that the Medicare statute authorizes HHS to set reimbursement rates for covered outpatient drugs provided by hospitals and explains how HHS must do so through one of the two options described above.[18] The Court stated that, if the agency does not conduct the requisite survey of acquisition data, it has no choice but to proceed under the second statutory option and utilize the average price for the drug in the given year and not vary rates by hospital group.[19] The Court explained that, while HHS has the authority to adjust the average price, this discretion is distinct from the ability to set different rates for different groups of hospitals.[20] The Court succinctly summarized its holding as follows: "In short, the statute allows HHS to set reimbursement rates based on average price and affords the agency discretion to 'adjust' the price up or down. But unless HHS conducts a survey of hospitals' acquisition costs, HHS may not vary the reimbursement rates by hospital group."[21]

The Court opined that when Congress enacted this statute, it was aware that hospitals participating in the 340B Program obtained upfront discounts on covered outpatient drugs and yet did not distinguish between 340B and non-340B hospitals for reimbursement rate setting purposes.

The Court left open the possibility of HHS varying payment rates for covered outpatient drugs by category of hospitals but clarified that the agency must first conduct a survey of acquisition costs to determine whether and how much the survey data justify varying reimbursement rates by hospital group.[22] In the factual background of the decision, the Court further highlighted that HHS attempted to conduct such a survey in 2020 after this litigation had commenced, but that agency counsel admitted at oral arguments that HHS had not previously undertaken such efforts because it considered the acquisition cost surveys "very burdensome" on the agency and hospitals, and did not "produce results that are all that accurate."[23]

Looking Ahead

While the Supreme Court ruled that HHS's reductions to payment rates for 340B drugs for CYs 2018 and 2019 were unlawful, it could be some time before we know how and when the agency intends to modify OPPS payment rates for those drugs, or the offsetting increase in OPPS rates more generally, for past and future years.

The Supreme Court remanded the case to Court of Appeals,[24] which will in turn remand the case to the District Court to again determine the proper remedy for the finding that the rules were unlawful. Importantly, when the District Court initially held the reduction violated the statute, that court concluded that the appropriate remedy for that violation was remand to the agency without specific instructions on how to implement its decision, citing the complex OPPS system and the offsetting increase to the OPPS conversion factor made to offset the reduction in 340B reimbursement.[25] In addressing the rate reductions in the most recent OPPS rulemaking for CY 2022, the agency indicated that, prior to its success on appeal at the D.C. Circuit, it had been exploring potential remedies for these years.[26] The agency suggested that survey data may be utilized for years going forward, and the data "also may be used to devise a remedy for prior years," which could "avoid the complexities referenced in the district court's opinion."[27] Notably, the Supreme Court decision confirms that HHS could down the road vary the reimbursement rates for different categories of hospitals in the future if the agency were to perform the survey of acquisition costs required by the statute and demonstrate that any proposed reduction in reimbursement is supported by the survey results.[28] Consequently, the outcome of this litigation may not be a straightforward reversal of the prior OPPS rate changes relating to 340B drugs.

Nor would any resolution of the matter necessarily occur quickly. Often the agency has not acted immediately after an adverse court decision, and has instead taken months to years to address the issue through rulemaking or other agency publications. HHS could also take the position that only those hospitals that adequately preserved their appeal rights are entitled to relief as to the 2018-2022 years for which the agency made the OPPS reimbursement changes at issue. HHS has often only granted relief to entities that have appealed.[29] For this reason, we encourage all impacted entities to monitor these developments and take the necessary steps to preserve their rights as appropriate.

It is possible that HHS could address the effect of Supreme Court's decision in the upcoming CY 2023 OPPS rulemaking. While it can vary, the agency traditionally issues the proposed OPPS rule for the next calendar year in late July to early August, and the final rule in November. HHS submitted the CY 2023 proposed OPPS rule to the Office of Management and Budget for review on May 4, 2022. While that version of the proposed rule could not have addressed the Supreme Court's decision, it is possible the agency could elect to amend the proposed rule in the coming weeks, or decide to proceed differently. Comments on any proposed rule relating to the decision could be advisable.

If you have any questions related to this decision, please feel free to contact your usual Ropes & Gray advisor or one of the authors listed below.

1. *See Am. Hosp. Ass'n v. Becerra*, No. 20-1114, 2022 WL 2135490 (U.S. June 15, 2022).
2. 42 U.S.C. § 1396r-8(k)(2).
3. *Id.* § 1395*l*(t)(14)(A)(iii)(I).
4. *Id.*§ 1395*l*(t)(14)(A)(iii)(II).
5. *340B Drug Pricing Program*, HRSA (Mar. 2022), https://www.hrsa.gov/opa/index.html.
6. *See* 42 U.S.C. § 256b.
7. *See id.*§ 256b(a)(4).
8. *See* 82 Fed. Reg. 52,356, 52,509 (Nov. 13, 2017); *see also* 83 Fed. Reg. 58,818, 58,980 (Nov. 21, 2018) (agency clarifying that 340B payment reduction applies to drugs that do not have an ASP and instead receive WAC pricing).
9. 82 Fed. Reg. at 52,509.
10. *Id*.
11. *Id*. at 52,509-10.
12. *See* 82 Fed. Reg. at 52,494.
13. *See* 83 Fed. Reg. 58,818 (Nov. 21, 2018); *see also* 84 Fed. Reg. 61,142 (Nov. 12, 2019); *see also* 85 Fed. Reg. 85,866 (Dec. 29, 2020); *see also* 86 Fed. Reg. 63,458 (Nov. 16, 2021).
14. *See* 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II); 82 Fed. Reg. at, 52,499.
15. *See Am. Hosp. Ass'n v. Azar*, 348 F. Supp. 3d 62, 81-82 (D.D.C. 2018), *rev'd*, 967 F.3d 818 (D.C. Cir. 2020), *cert. granted sub nom. Am. Hosp. Ass'n v. Becerra*, 141 S. Ct. 2883 (2021), *rev'd and remanded sub nom. Am. Hosp. Ass'n v. Becerra*, No. 20-1114, 2022 WL 2135490 (U.S. June 15, 2022)
16. *See Am. Hosp. Ass'n*, 967 F.3d 818.
17. The Court also agreed with both lower courts in rejecting HHS's argument that the Medicare statute precludes judicial review of the 2018 and 2019 reimbursement rates. The Court found no language in the Medicare statute precluding its review, found that the statute's detailed reimbursement rate methodology did not suggest that it was Congress's intent to provide HHS with unreviewable discretion, and that HHS's requirement to maintain budget neutrality was not sufficient to override judicial review of its actions. *See Am. Hosp. Ass'n*, No. 20-1114, 2022 WL 2135490, at *5.
18. *See id.* at *2.
19. *Id*.
20. *Id*. at *6.
21. *Id.* at *7.
22. *See id.*
23. *Id.* at *3.
24. *See id*. at 8.
25. Mem. Op., *Am. Hosp. Ass'n v. Azar*, No. 18-cv-2084, 2019 WL 3037306 (D.D.C. May 6, 2019).
26. *See* 86 Fed. Reg. 63,458, 63,646 (Nov. 16, 2021).
27. *Id.*
28. *Id.* at *7.
29. *See, e.g.*, 86 Fed. Reg. 73,416, 73,467-68 (Dec. 27, 2021); CMS Ruling 1498-R (Apr. 28, 2010), https://www.cms.gov/regulations-and-guidance/guidance/rulings/downloads/cms1498r.pdf.