American Hospital Association et al. v. Becerra et al.: Supreme Court Rejects CMS Policy to Adjust Medicare Part B Payments for 340B Drugs

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Key Takeaways:

- The Supreme Court unanimously held that HHS's 2018 and 2019 policy to reduce Medicare Part B payments to hospitals for outpatient drugs acquired under the 340B program is invalid.
- HHS cannot vary payment rates between hospitals or hospital groups for separately payable outpatient drugs absent a survey of hospital acquisition costs.
- Because the Court concluded that the statute unambiguously foreclosed HHS's payment policy, the Court did not address the scope of *Chevron* deference.
- The Supreme Court remanded the case for further proceedings with respect to remedies, an issue that is complicated by the fact that Medicare outpatient payments must be applied in a budget neutral manner.

Earlier this week, the Supreme Court released its opinion in *American Hospital Association et al. v. Becerra et al.*, a case that involves the proper method for the Medicare program to reimburse hospitals for outpatient drugs that the hospitals acquire under the 340B program. In a unanimous decision by Justice Kavanaugh, the Supreme Court concluded that the Department of Health and Human Services (HHS) must, in the absence of conducting a survey to determine the acquisition costs of outpatient drugs, reimburse all hospitals for outpatient drugs under a methodology that the agency has maintained in effect since 2006: at the average sales price (ASP) of the drug, plus 6%. In deciding the case, the Supreme Court reversed a decision of the U.S. Court of Appeals for the D.C. Circuit that had affirmed the policy. The Court remanded the case to the D.C. Circuit, which will likely further remand to the district court for an assessment of remedies.

Background

Under Medicare Part B, hospitals' payment rates for their outpatient services for the upcoming year are based on the Outpatient Prospective Payment System ("OPPS"), which HHS sets annually through notice and comment rulemaking. As a general matter, payment for most services under the OPPS are bundled into unified payments that encompass most clinical services that would be provided in an outpatient visit. A different policy applies, however, with respect to "specified covered outpatient drugs" ("SCODs"), a category of separately payable drugs that are not bundled with outpatient services but have their own payment classification group.

By statute, Congress directs HHS to pay separately for these drugs, and to calculate payment for SCODs at either:

> "(I) [T]he average acquisition cost for the drug for that year (which, at the option of the Secretary may vary by hospital group…) as determined by the Secretary taking into account the hospital acquisition cost survey data;" (referred to by the Court as "Option 1") or,
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> "(II) If the hospital acquisition cost data are not available, the average price for the drug… as calculated and adjusted by the Secretary as necessary for purposes of this paragraph" (referred to by the Court as "Option 2"). 42 U.S.C. § 1395l(t)(14)(A)(iii)(I)-(II).

CMS has interpreted the Medicare statute to generally set the "average price" as the ASP plus 6%.

Starting in the 2018 OPPS Rule, and continuing to the current year, HHS adopted a different payment policy that was intended to make Medicare payment for SCODs acquired through the 340B program "better… reflect the resources and acquisition costs that [340B] hospitals incur" to acquire those discounted drugs. HHS set the payment rate for SCODs purchased under the 340B program for most 340B hospitals at ASP minus 22.5%. It then applied the $1.6 billion savings from this policy change across outpatient payments to all hospitals. HHS did not conduct a survey of hospital acquisition costs under Option 1 before making this policy change, and instead asserted that the payment policy for 340B drugs was made pursuant to its authority to "adjust" payments "as necessary" under Option 2.

The American Hospital Association led a coalition of some hospitals and hospital industry groups in challenging HHS's 2018 and 2019 reimbursement policies arguing, among other things, that HHS could not impose different reimbursement rates on different groups of hospitals because it did not conduct a survey of the hospitals' acquisition costs. The District Court ruled for the hospitals, but the D.C. Circuit reversed, concluding that HHS was not "unambiguously barred" from adopting its rule, and deferring to the agency's interpretation of its authority in accordance with the precedent set in *Chevron v. Natural Resources Defense Council*. *AHA v. Azar*, 967 F.3d 818 (2020).

The Court granted the hospitals' request for a writ of *certiorari* and oral arguments were held on November 30, 2021.

The Supreme Court Reverses the D.C. Circuit

The Supreme Court reversed the D.C. Circuit and unanimously held that HHS cannot reduce payment rates for SCODs acquired through the 340B program absent a survey of hospital acquisition costs.

As a preliminary matter, the Court rejected HHS's argument that the Medicare statute precludes judicial review of the reimbursement rates for SCODs in the 2018 and 2019 OPPS rule. The Court noted that there is a "strong presumption" in favor of judicial review and "[n]o provision in the Medicare statute precludes judicial review of the 2018 and 2019 reimbursement rates." According to the Court, the preclusion of judicial review in other parts of the OPPS does not imply a preclusion of judicial review in the payment for SCODs.

With respect to the merits, the Court concluded that the plain terms of the statute prevented HHS from varying reimbursements by hospital group absent a survey of hospital acquisition cost. "If the agency has conducted a survey and collected that data, then HHS may use the data to set reimbursement rates equal to 'the average acquisition cost' for the drug," the Court explained. Only in that circumstance, as described in Option 1, may HHS vary reimbursement by hospital group.

But that is not what HHS did. Rather, HHS did not conduct a survey of hospital acquisition costs of SCODs when it initially adopted its policy, and instead relied on its purported authority to "calculate[] and adjust[]" payments for drugs acquired under the 340B program. The Court concluded that, absent the required survey data, HHS must set reimbursement rates based on the average price of the drug under Option 2. HHS's authority to "calculate[] and adjust[]" reimbursement for SCODS "does *not* authorize HHS to vary reimbursement rates by hospital group." [1] Instead, adjustments to reimbursement rates under Option 2 must be uniform among providers.

The Court rejected HHS's argument that its adjustment authority broadly permitted any adjustments to payment rates for SCODs. Instead, the Court concluded that it would undermine the statute if the agency were permitted to "decline to conduct a survey and … proceed under option 2, and then… still do everything under option 2 that it could do under option 1- including varying reimbursement rates by hospital group." Congress intended for the survey to "protect[]" hospitals by "imposing a procedural prerequisite … before HHS may target particular groups of hospitals for lower reimbursement rates." HHS's interpretation would render the prerequisite of a survey "irrelevant." According to the Court, the HHS position would read Option 1 out of the statute entirely; doing so "would eviscerate … significant aspects of the statutory text."

Importantly, the Court made clear that the Medicare statute does not preclude HHS from ever adopting a policy of reduced payments for SCODs from 340B hospitals. Instead, the Court explained that "[i]f HHS believes that this Medicare reimbursement program overpays 340B hospitals, it may conduct a survey of hospitals' acquisition costs to determine whether and how much the data justify varying the reimbursement rates by hospital group—for example, reducing reimbursement rates paid to 340B hospitals as compared to other hospitals." Failing that, the Court explained that HHS could ask Congress to provide the Department with the authority to adjust payments as it did in the 2018 and 2019 rules, but noted that the Department would likely face policy opposition to such a proposal.

Finally, because the Court concluded that the statute unambiguously foreclosed HHS's payment policy, the Court did not address the scope of deference that Court's should give to an agency under *Chevron v. NRDC* ("*Chevron* deference"). Many observers anticipated that the Court might use this case to dramatically curtail the scope of deference Court's give to agencies, and indeed, several friend of the court briefs urged the Court to do so. The Court may elect to limit the scope of *Chevron* deference in other cases this term or in future years.

Potential Remedies and the Budget Neutrality Requirement

The Court noted that the 340B hospitals that brought the lawsuit had argued that any remedy would need to make them whole for the shortfalls in payments. But the Court said that at this stage, it did not need to address potential remedies. Rather, it remanded the case back to the D.C. Circuit, which will likely further remand the case to the district court for further proceedings. That court will in turn address the issue of remedies, or it may direct CMS to fashion a remedy.

The issue of remedies is complicated by the fact that the OPPS statute must be applied in a budget-neutral manner. If, as a result of the Supreme Court decision, 340B hospitals must be reimbursed for the reduced payments for drugs acquired under the program in 2018 and 2019, the statutory budget neutrality requirement may mean that the funds for the corrected payments come from recouping the excess payments made to all hospitals for those years. In the alternative, CMS could repay the 340B hospitals for the reduced payments in a future year, and obtain the funds for the repayment by reducing payments to all hospitals for outpatient services over that future year or over a period of future years. CMS could also derive a remedy based on the survey that it conducted in 2020. We anticipate that CMS will solicit comments on its proposed approach in the 2023 outpatient OPPS rule; that annual rule is usually released in early July.

It is also possible that Congress could step in and provide CMS with new funding, although doing so would likely open a political battle over the 340B program more broadly.

Notably, HHS retained its payment policy for 340B drugs in the 2020 through 2022 OPPS rulemakings. While HHS conducted a survey of hospital acquisition costs in 2020, some stakeholders may argue that HHS did not rely on that survey data to support its adoption of the reduced payment for 340B drugs in those years. If that argument is correct, CMS may adopt a policy to reimburse 340B hospitals for any reductions in payments for SCODS in 2020-2022; failing to do so will surely lead to litigation filed by 340B hospitals challenging the continued application of the policy for 2020-2022.

Conclusion

Although the Supreme Court decision has answered a key question about HHS's authority regarding payment for outpatient drugs, it has left unanswered two key questions: what remedies exist to repay 340B hospitals for the payment cuts that the Court has held were improper; and whether CMS will continue its policy in future years based now on survey data. Please do not hesitate to contact either of the attorneys on this alert if you have any questions.

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[1] The Court did not address the full scope of HHS's authority to "adjust" the average price up or down under Option 2, only stating that those adjustments must be set drug-by-drug and may not vary by hospital or hospital group.

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