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Legal Sidebar

Supreme Court Overturns HHS Regulation Reducing the Medicare Outpatient Drug Reimbursement Rate for 340B Hospitals

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On June 15, 2022, the Supreme Court unanimously decided *American Hospital Association (AHA) v. Becerra*, holding that the Secretary of Health and Human Services (HHS) lacked discretion to cut Medicare's reimbursement to selected hospitals for certain outpatient drugs by 28.5%. As the Court indicated, the payment cut at issue implicated "immense economic consequences" of about $1.6 billion annually for these hospitals, which purchase such drugs at significantly discounted prices through what is known as the 340B Program. Beyond the significant financial stakes at issue for both the hospitals and the Medicare program, this case garnered attention because many commentators expected it to serve potentially as a vehicle for the Court to make changes to the scope of *Chevron* deference enjoyed by agencies. Ultimately, however, the Court concluded that HHS exceeded its discretion in reducing the reimbursement rate without directly addressing the *Chevron* doctrine. This Sidebar provides an overview of the 340B Program and the rate cut at issue, a summary of the Court's decision, and some considerations for Congress.

Background

Under the 340B Program, drug manufacturers agree, as a condition of having their drugs covered by Medicare, to provide substantial purchasing discounts to specified "covered entities," which generally include nonprofit hospitals and other health care providers that care for underserved populations. Because the covered entities generally receive some form of federal financial assistance, Congress imposed the required drug discounts to enable such providers to "stretch scarce Federal resources as far as possible."

Separately, Medicare Part B reimburses hospitals for certain drugs (known as "specified covered outpatient drugs" or "SCODs") using a specific statutory formula provided in 42 U.S.C. § 1395*l*(t)(14), which specifies two paths for determining these drug reimbursement rates. Under the first option, payment is equal to the average *acquisition* cost for a given year, as determined using "hospital acquisition cost survey data." Alternatively, if hospital acquisition cost data are not available, payment for

a drug is based upon the manufacturer's average *sales* price of the drug for the relevant year "as calculated and adjusted by the Secretary of HHS as necessary."

Historically, the hospital survey data have not been available because HHS found the survey process inaccurate and "very burdensome on the hospitals." Therefore, using the second option, Medicare generally reimbursed all hospitals' purchases of SCODs at 106% of the average sales price. In 2018, however, HHS promulgated a rule that "adjusted" the average sales price determination for these hospitals such that the reimbursement rate was reduced to 77.5% of a drug's average sales price. According to HHS, this reduced reimbursement rate "better, and more appropriately" reflected 340B hospitals' acquisition costs, given the discrepancy between the 340B discounts they receive and the relatively higher reimbursement rates under Medicare Part B. The rate reduction was based on a study by the Medicare Payment Advisory Commission (MedPAC) showing that, on average, 340B hospitals acquired SCODs from manufacturers at a 22.5% discount.

Several hospitals and hospital associations challenged the reimbursement reduction. They argued that without the hospital drug acquisition survey data, the only permissible basis for the reimbursement amount is the average sales price. They also argued that the 106% reimbursement rate allows 340B hospitals to offset the costly care they provide to low-income patients, and that Congress intended this outcome. A lower reimbursement rate, they contended, would require hospitals to "dramatically curtail other crucial programs that provide a wide range of medical services in low-income and rural communities."

HHS countered that judicial review of the rule was precluded by Section 1395*l*(t)(12). HHS also argued that the "adjustment" to the average sales price was not clearly precluded by the statutory text, and so should be upheld as a reasonable interpretation of the statute under the Supreme Court's decision in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc*. Under that framework, courts generally defer to an agency's interpretation of a statute if its text is ambiguous and the agency's interpretation is reasonable. As part of its rationale for changing the reimbursement rate after more than a decade, HHS contended that the 106% reimbursement rate was an "overpayment" that "generate[d] significant profits" for 340B hospitals, which were already able to purchase drugs at lower rates than other hospitals.

In July 2020, the D.C. Circuit held that judicial review of HHS's action was not precluded and that the downward adjustment to average sales price was a reasonable interpretation of the statute. The Supreme Court subsequently agreed to review both issues.

The *AHA v. Becerra* Decision

In *AHA v. Becerra*, the Supreme Court held that (1) the Medicare statute does not preclude judicial review of HHS's rate reimbursement determinations; and (2) HHS violated the statute by lowering the rate for 340B hospitals without first conducting a drug acquisition survey.

First, reiterating the Court's long-standing "strong presumption" favoring judicial review of an agency's final agency action unless the underlying statute expressly prohibits it, the Court found no statutory provision expressly forbade judicial review of the reimbursement rate-cut at issue. Although HHS cited other statutory provisions that expressly preclude judicial review—including § 1395*l*(t)(12)(A) and (C)—the Court concluded those provisions relate to HHS's "general methodology" for calculating Medicare reimbursement rates for services rendered. Those provisions, in the Court's view, are separate from the drug reimbursement rate methodology at issue here, which is specific to SCODs. The Court further rejected HHS's argument that judicial review would be impractical because a rule invalidating the rate-cut would potentially require the agency, under Medicare's budget neutrality requirement, to recalculate reimbursement rates for all other Part B services during the relevant years. Although the Court did not discuss the potential remedies available to 340B hospitals or how any offset should be taken into account,

it held that HHS's arguments did not "override the text of the statute," which does not expressly prohibit judicial review.

Second, the Court held that HHS exceeded its statutory discretion in lowering the reimbursement rate for 340B hospitals without first conducting an acquisition cost study. In deciding this issue, the Court did not mention the *Chevron* doctrine. Instead, the Court described the case as "straightforward," highlighting the two statutory options that HHS may use when setting reimbursement rates: (1) an acquisition cost study; or (2) the average sales price charged by manufacturers. The Court reiterated that, under the first option, the statute allows HHS to vary the reimbursement rate, meaning that HHS could reimburse different hospital types at different rates. The second option to use the average sales price allows HHS to calculate and adjust the rate "as necessary for purposes of" the section.

The Court held that HHS's selective rate reduction for 340B hospitals was unlawful because the agency did not first conduct a cost acquisition study, in accordance with option one of the statute. The Court acknowledged that the statute's second option permits HHS to "adjust" the rates "as necessary." The Court reasoned, however, that "HHS's power to increase or decrease the price is distinct from its power to set different rates for different groups of hospitals," and "varying a rate by hospital group is not a lesser-included power of adjusting price" under option two. HHS's interpretation of the statute, in the Court's view, would make these two distinct options "irrelevant" because if HHS were allowed to vary the reimbursement rate under the second option, then it would effectively never need to conduct an acquisition cost survey under the first option. Finally, the Court rejected HHS's argument that Congress could not have intended for the agency to "overpay" 340B hospitals for the relevant outpatient drugs, explaining that "Congress was well aware that 340B hospitals paid less for covered prescription drugs" when it enacted § 1395*l*(t)(14) in 2003.

Considerations for Congress

The Court's decision in *AHA* leaves open several unanswered questions, including the appropriate remedy for 340B hospitals, the fate of the *Chevron* doctrine, and the Secretary's discretion to set future reimbursement rates. Each of these issues is discussed in turn.

What Is the Appropriate Remedy?

Although the Supreme Court found that HHS acted unlawfully in lowering the reimbursement rate for 340B hospitals without first conducting a cost acquisition survey, the Court did not comment on the appropriate remedy. The determination of the appropriate remedy could have important financial implications for 340B hospitals. The Court acknowledged that Medicare SCODs payments have historically resulted in increased funding for 340B hospitals, which helps offset the cost of care for underserved patients that they serve. The Court remanded the case for further proceedings; the case is now pending before the D.C. District Court.

On remand, the parties are outlining their positions with respect to remedies, and several issues have emerged. First, in light of the Court's decision that the 2018 and 2019 reimbursement rates were unlawful and the fact that HHS has continued using these rates to reimburse SCODs from 2018 to the present, the plaintiffs want to be made whole for past SCODs reimbursements that were too low. Second, given that HHS is currently using the unlawful rate for reimbursements in 2022, the plaintiffs have also asked the court to protect plaintiffs from future harm by invalidating the 2022 rule and ordering HHS to increase the reimbursement rate. Third, the parties dispute whether the court should remand the case to HHS for the determination of an appropriate remedy or direct the remedy as part of its ruling.

Much of the parties' arguments about past and future reimbursements center around the extent to which the "budget neutrality rule" should determine past reimbursements. The statutory rule requires the

Secretary to review and revise the payment methodology annually to account for changes in technology, medical practice, and updated data. When making such adjustments, however, HHS cannot increase or decrease the estimated amount of yearly expenditures that were otherwise allocated for that program year. To this effect, in setting the rates for 2018 to 2022, HHS redistributed the $1.6 billion in yearly savings to increase the reimbursement rates for other Part B services across all hospitals reimbursed for outpatient services under Part B. Thus, if HHS were to recalculate payment rates for all of these years, this recalculation would have consequences for other non-340B hospitals that were reimbursed under Part B during those years.

What About *Chevron*?

Many legal scholars thought the Court's decision in *AHA* would address the broader question of whether *Chevron* continues to be the proper framework for judicial review of administrative rulemaking. Several of the Justices have previously indicated their wariness of the *Chevron* analysis, but the Court was silent on this issue and did not cite *Chevron* in its unanimous decision. Even if the Court had used the *Chevron* analysis, however, the outcome would likely have been the same. The Court unanimously decided that "[u]nder the text and structure of the statute, this case is . . . straightforward," which is consistent with the first *Chevron* prong, which analyzes whether the statute directly addresses the interpretive question at issue. If the statute's meaning is clear, the second prong of *Chevron* requires the Court to give effect to that meaning. In *AHA*, the Court appeared to do so in finding that HHS violated the Medicare statute by adjusting the reimbursement rates of 340B hospitals without first conducting an acquisition study, as required by the statute. The Court has indicated a willingness to revisit the Chevron doctrine of agency deference in other recent litigation involving the major questions doctrine.

Other Considerations

In addition to the questions about potential remedies and the fate of the *Chevron* doctrine, the Court leaves open for Congress the question of how HHS might vary rates to different hospital types, given that the agency seemingly believes its mechanism for doing so under option 1 is ineffective. To the extent Congress determines that the Secretary should have the authority to vary rate reimbursement by hospital types without a cost acquisition survey, it could amend the Medicare statute to clarify the circumstances under which such variance may occur. The Court also did not address the issue of how much discretion the Secretary has to "adjust" rates under the second rate reimbursement option, under which HHS uses the average price manufacturers charge. Congress could respond to this aspect of the Court's decision by amending the Medicare statute to clarify how much discretion the Secretary has when making rate adjustments to individual drugs, if it does not vary rates by hospital type.

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