Health Industry Alert

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Supreme Court Upends Medicare 340B Drug Payment Policy

June 22, 2022

Key Points:

- The Supreme Court invalidated 2018 and 2019 cuts to Medicare reimbursement rates for hospital outpatient drugs acquired through the 340B Drug Pricing Program, effectively reinstating the default rate of ASP plus 6 percent for those years.
- CMS now has the difficult task of designing and implementing an appropriate remedy, which itself may be subject to further litigation.
- The most immediate question for the agency is whether to use hospital drug acquisition cost survey data collected in 2020 to maintain reduced payment rates in CY 2023.

Background

The Social Security Act offers the Secretary of Health and Human Services (HHS) two options for setting Medicare reimbursement rates for separately payable outpatient drugs. The first option ("Option 1") is to use the average acquisition cost for the drug for that year, as determined by taking into account hospital acquisition cost survey data.[1] Under this option, the statute allows the Secretary to vary the cost amount by hospital group.[2] The second option ("Option 2"), available if hospital acquisition cost data are not available, is a default rate of average sales price (ASP) plus 6 percent, "as calculated and adjusted by the Secretary as necessary . . . ."[3] The Centers for Medicare & Medicaid Services (CMS), the HHS agency that administers the Medicare program, has historically used the Option 2 default rate and set reimbursement at ASP plus 6 percent.

In a 2017 rulemaking, CMS altered Medicare's payment methodology for separately payable outpatient drugs (including biologics) acquired through the 340B Drug Pricing Program.[4] This change, effective calendar year (CY) 2018, reduced reimbursement for these discounted drugs under the hospital outpatient prospective payment system (OPPS) from the default rate of ASP plus 6 percent to ASP minus 22.5 percent.[5] The agency explained that this change was intended to align payment with the resources of hospitals and their acquisition costs for these 340B drugs based on a "conservative estimate" of the average minimum discount.[6] The effect of this payment change was

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the reallocation of approximately $1.6 billion from 340B hospital drug payments to nondrug item and service payments for all hospitals under the OPPS.[7] Additionally, Medicare beneficiaries who received 340B drugs benefited from the lower reimbursement, as the cost-sharing obligation is generally 20 percent of the Medicare reimbursement rate.[8]

Certain hospitals and hospital associations sued CMS in federal district court over the reduced reimbursement for CY 2018, and later CY 2019, arguing that the agency exceeded its statutory authority by changing reimbursement rates for 340B-acquired drugs without first collecting acquisition cost data from hospitals through a survey, and inappropriately relying on its authority to "adjust" drug payments.[9] The district court found in favor of the plaintiffs. Pointing out that there was no survey data to support the use of the first statutory option (average acquisition costs), the court concluded that the magnitude and breadth of the cuts exceeded the adjustment authority Congress conferred upon the agency.[10] CMS appealed, and the court of appeals reversed, concluding that CMS had reasonably interpreted the Medicare statute and had authority to lower drug reimbursement rates for 340B-acquired drugs.[11]

In the midst of the ongoing litigation, the agency conducted a 340B hospital survey to collect drug acquisition cost data for CY 2018 and CY 2019.[12] Based on analysis of its 2020 survey, CMS concluded that the average acquisition cost for 340B-acquired drugs was ASP minus 34.7 percent.[13]

In the CY 2021 OPPS Proposed Rule, CMS proposed paying for 340B-acquired drugs at ASP minus 28.7 percent based on the 2020 hospital survey data and an add-on payment for CY 2021.[14] However, the agency ultimately decided against the larger cut and maintained its ASP minus 22.5 percent policy for purposes of payment stability during the COVID-19 Public Health Emergency, and to allow additional time for CMS to analyze the hospital survey data.[15] During the CY 2021 rulemaking process, the agency acknowledged stakeholder concerns about the survey, noting that "utilization of survey data is complex," but maintained that its survey methods and methodology for calculating the average 340B discount were valid.[16] Subsequently, CMS maintained its ASP minus 22.5 percent policy for CY 2022 as well.[17]

Summary of Decision

In a unanimous opinion issued June 15, 2022, in *American Hospital Association v. Becerra*, the Supreme Court held that CY 2018 and CY 2019 reimbursement cuts for 340B-acquired drugs were contrary to the Medicare statute and unlawful, reversing the D.C. Circuit's contrary holding.[18] As a threshold matter, the Supreme Court agreed with the lower courts in rejecting the government's contention that the OPPS rate adjustment was not subject to judicial review. On the merits, the opinion primarily focused not on the limits of CMS's adjustment authority, as the lower courts had done, but rather on CMS's authority to vary rates by hospital group in the absence of a hospital acquisition cost survey. The opinion construed the two statutory options for establishing reimbursement rates for outpatient drugs as mutually exclusive, rejecting CMS's argument that it could vary reimbursement rates by hospital group based on its Option 2 authority to set rates based on "the average price" of the drug charged by manufacturers as "calculated and adjusted by the Secretary." Only Option 1 authorizes reimbursing hospital groups at different rates, and it applies only if CMS has surveyed hospital acquisition cost data and bases rates on that data. In the absence of a survey,

CMS must proceed under Option 2 and set reimbursement rates "drug by drug, not hospital by hospital or hospital group by hospital group."[19]

Notably, the Supreme Court left open several key questions that are likely to be answered in lower court proceedings. For instance, the Court did not address the question of the appropriate remedy, or the government's contention that an invalidation of the CY 2018 and CY 2019 reimbursement rates for certain hospitals would require offsets elsewhere in the program. Nor did the Court opine on the validity of the 2020 survey and whether CMS could rely on that survey data to pay for 340B-acquired drugs under Option 1, using average acquisition costs.

What's Next

The Supreme Court remanded the case, so it will return to the district court. The district court could simply remand the matter to CMS to develop an appropriate remedy, as it did in 2019 after it ruled in favor of the hospitals, "allow[ing] the agency more flexibility to determine the least disruptive means of correcting its underpayments to Plaintiffs . . .".[20] The government will ask for the same flexibility when the case returns from the Supreme Court, and the district court may consider further briefing from the parties as to remedy as it did when it first had the case. If the district court again orders remand to CMS, remedy will be up to the agency, at least in the first instance. Whatever remedy the agency chooses may itself be challenged and become the subject of litigation—particularly if it seeks to offset past underpayments with cuts elsewhere in the program—so final resolution of the 340B reimbursement rates may still be a long way off.

Remedying Underpayments in CY 2018 and CY 2019

To remedy 340B hospitals' underpayments, CMS could recalculate reimbursement for those years and pay the difference to the hospitals, or the agency could make an adjustment to the hospitals' reimbursement in the coming calendar year or years.

Plaintiffs in *AHA v. Becerra*, after winning in the district court, sought payment of the difference between (i) their paid reimbursements for CY 2018 and CY 2019 and (ii) ASP plus 6 percent for those years (the rate at which non-340B hospitals were paid). That retroactive remedy is a possibility, though it likely would require the agency to vacate the 2018 and 2019 rules and issue new rules setting reimbursement for all hospitals at ASP plus 6 percent. The presumption against retroactivity could be an obstacle to such an approach.[21]

The "prospective" remedy CMS devised following the invalidation of its "2-midnight policy" may provide the agency some guidance. After that policy—which reduced inpatient prospective payment system (IPPS) rates by 0.2 percent across the board for three fiscal years—was invalidated for issuance in violation of notice-and-comment requirements,[22] the agency chose to remedy the underpayment of 0.2 percent in each of the three years with a one-time 0.6 percent rate increase for the next fiscal year. For 340B hospitals, a prospective increase to the reimbursement for 340B drugs dispensed rate in one or more future years could serve as a remedy for their underpayment.

For either a retroactive or a prospective remedy, the major open question is whether CMS will honor the statutory budget neutrality requirement applicable to OPPS by

making offsetting negative adjustments to nondrug OPPS services. That was not a factor when the agency crafted the prospective rate increase following the 2-midnight policy invalidation because the IPPS payment adjustments were not subject to a budget neutrality requirement. But for OPPS, the Medicare statute requires that any payment adjustments in a given year not change the total "estimated amount of [OPPS] expenditures" for the year.[23] Arguably, the statute's reference to total "estimated" expenditures means the budget neutrality requirement only would apply to a prospective remedy. However, the government has consistently argued the opposite position in its briefing throughout the litigation. If CMS maintains the view that a retroactive payment adjustment would require offsets in the form of recoupments of other payments already made, it's hard to imagine the agency choosing a retroactive remedy. Calculating offsets and recouping payments from providers and possibly beneficiaries would be extremely cumbersome and administratively costly, and would most certainly invite litigation. By contrast, a prospective remedy can be calculated to meet any budget neutrality requirement and would not require retrospective recoupments. A prospective remedy therefore seems more likely. Either way, challenges and further litigation can be expected, including vis-à-vis budget neutrality.

Addressing Payments in CYs 2020–22

Even though the Supreme Court addressed only CY 2018 and CY 2019, its ruling will affect CY 2020, and possibly CYs 2021–2022. The agency paid 340B hospitals the same reduced rate (ASP minus 22.5 percent) for these years, though CMS had completed its 340B hospital survey in advance of setting CY 2021 and CY 2022 reimbursement rates.[24] Given that there were no survey data informing the CY 2020 policy, CMS will presumably concede that any remedy for CY 2018 and CY 2019 underpayments should also be applied for CY 2020. For CY 2021 and CY 2022, for which survey data were available and were considered by the agency, it is possible that CMS could argue that these years are not affected by the Supreme Court's decision. As noted above, the Supreme Court did not address the adequacy of the agency's 2020 survey. Nor has any court been presented the question of whether the agency's consideration of the survey data was the equivalent of "taking into account" the data as required under Option 1.

Setting Payment Policy for CY 2023 and Beyond

We expect CMS to begin implementing *AHA v. Becerra* in the CY 2023 rulemaking cycle. CMS has maintained that it has discretion to establish a payment rate for 340B-acquired drugs based on the 2020 hospital survey data and has even proposed a steeper cut to 340B-acquired drugs based on that survey data.[25] CMS could revive these proposals for CY 2023 and maintain or increase the cuts to 340B-acquired drugs. However, if CMS remains uncertain about using the 2020 hospital survey data, it could revert to the pre-2018 default of ASP plus 6 percent for 340B hospitals for CY 2023 and future years. If CMS reverts to this pre-2018 default, reallocating more OPPS dollars toward drugs, we can expect to see a corresponding negative adjustment to other nondrug OPPS items and services.

[1] 42 U.S.C. § 1395l(t)(14)(A)(iii)(I).

[2] *Id*.

[3] *Id*. § 1395l(t)(14)(A)(iii)(I).

[4] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Program; Final Rule, 82 Fed. Reg. 59,216, 59,369 (Dec. 14, 2017).

[5] *Id*. Rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals were excluded from this negative payment adjustment. *Id*.

[6] *Id*. at 59,355, 59,365.

[7] *Id*. at 59,369–70.

[8] *Id*. at 59,353–54, 364.

[9] *Am. Hosp. Ass'n v. Azar*, 348 F. Supp. 3d 62 (D.D.C. 2018).

[10] *Id*. at 82–83.

[11] *Am. Hosp. Ass'n v. Azar*, 967 F.3d 818 (D.C. Cir. 2020).

[12] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Final Rule, 85 Fed. Reg. 85,866, 86,043 (Dec. 29, 2020).

[13] *Id*. at 86,054.

[14] *Id*. at 86,049–50. Notably, the agency also suggested that it could use the 2020 hospital survey data to "devise a remedy for prior years" should the district court's ruling in favor of the hospitals be upheld on appeal. 84 Fed. Reg. 61,322.

[15] 85 Fed. Reg. 86,051–52.

[16] 85 Fed. Reg. 86,052.

[17] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Final Rule, 86 Fed. Reg. 63,458, 63,648 (Nov. 16, 2021).

[18] *Am. Hosp. Ass'n v. Becerra*, No. 20-1114, 2022 WL 2135490 (June 15, 2022).

[19] *Id*. at 6.

[20] *Am. Hosp. Ass'n v. Becerra*, 385 F. Supp. 3d 1, 14 n.19 (D.D.C. 2019).

[21] *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988) ("[A] statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules unless that power is conveyed by Congress in express terms.").

[22] *Shands Jacksonville Medical Center, Inc. v. Azar*, 139 F. Supp. 3d 240 (D.D.C. 2015).

[23] 42 U.S.C. § 1395l(t)(9)(B) ("If the Secretary makes adjustments …, then the adjustments for a year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made.").

[24] 85 Fed. Reg. 86,051–52; 86 Fed. Reg. 63,648.

[25] 86 Fed. Reg. 63,646.