340B UPDATE: SUPREME COURT ACCEPTS CERTIORARI IN 340B PAYMENT REDUCTION CASE

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U.S. Health Care and FDA Alert

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On 2 July 2021, the Supreme Court announced that it has accepted the American Hospital Association's (AHA) petition for certiorari in *American Hospital Association v. Becerra*. At issue is the Centers for Medicare and Medicaid Services' (CMS) nearly 30 percent cut to payments for specified covered outpatient drugs (SCODs) under the Medicare Outpatient Prospective Payment System (OPPS) for certain hospitals participating in the 340B Drug Pricing Program (340B Program), which provider groups have been challenging in court since 2017. Notably, the Supreme Court's grant of certiorari comes as CMS is expected to release any day now the CY 2022 OPPS proposed rule, which could either reverse or continue the payment cuts. Provider groups have been urging CMS to reverse the payment reductions as part of the CY 2022 OPPS proposed rule. This client alert provides an overview of these developments and what to expect next.

BACKGROUND

As discussed in our client alert here, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 determines how much Medicare will pay hospitals for SCODs. Under subclause (I), reimbursement rates are determined based on each drug's average acquisition cost.[1] Under subclause (II), reimbursement rates are determined according to a statutorily defined default rate based on each drug's average sales price (ASP), namely ASP+6 percent.[2] CMS may only determine rates based on average acquisition cost if it has acquisition cost survey data.[3]

As part of the CY 2018 OPPS final rule, CMS finalized a proposal to adjust reimbursement rates for SCODs from ASP+6 percent to ASP-22.5 percent in an effort to make “payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs.”[4] While CMS did not have acquisition cost data, the agency adjusted the rate reasoning that ASP-22.5 percent “better represents the average acquisition cost for [340B] drugs and biologicals.”[5]

D.C. CIRCUIT DECISION

As discussed in our prior alerts here and here, the AHA, along with other hospital groups, sued the Secretary of the U.S. Department of Health and Human Services challenging CMS' adjustment to payment rates for 340B drugs. The U.S. District Court for the District of Columbia (district court) ruled that the Secretary had exceeded his authority to adjust the payment rates under the existing statutory framework. Notably, the district court reasoned, in part, that the Secretary had not collected the necessary data to set the payment rates based on acquisition costs.[6]

Last year, however, the U.S. Court of Appeals for the District of Columbia Circuit (D.C. Circuit) reversed the district court's holding, concluding that CMS may reduce OPPS reimbursement for a specific service and that it may implement that cut because Congress did not "unambiguously forbid" the agency from doing so.[7] Because the D.C. Circuit could not find that it was impossible to read the statute in the way preferred by the agency, the court upheld the agency's decision.

SUPREME COURT'S GRANT OF CERTIORARI

Earlier this year, the AHA filed a certiorari petition to the Supreme Court arguing, among other things, that the D.C. Circuit's decision misapplies *Chevron* and departs from proper principles of statutory interpretation. Specifically, the AHA argues that by applying *Chevron* deference to CMS' interpretation of the statute, the D.C. Circuit permitted the agency to set the boundary of judicial power in violation of separation of powers.[8] The AHA asked that the Supreme Court clarify that deference is only applicable to an agency's decision when true statutory ambiguity exists.

On 2 July 2021, the Supreme Court accepted the AHA's petition. The Supreme Court is likely to hold oral arguments in the fall. However, it is worth noting that the Supreme Court is asking the parties to revisit the question of statutory preclusion of judicial review. It is therefore possible that the Supreme Court may dismiss the case on procedural grounds rather than address the merits as to deference afforded an agency interpreting an unambiguous statute. With CMS poised to release any day now the CY 2022 OPPS proposed rule, stakeholders should stay alert.

K&L Gates will monitor future developments. K&L Gates' health care and FDA practice regularly advise stakeholders on 340B Program and Medicare reimbursement matters, including comments on proposed regulations, and is available to assist stakeholders in this regard.

FOOTNOTES

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

[2] 42 U.S.C. 1395l(t)(14)(A)(iii)(II).

[3] 42 U.S.C. 1395l(t)(14)(A)(iii)(I).

[4] 82 Fed. Reg. 52,356, 52,362 (Nov. 13, 2017); 82 Fed. Reg. 33,558, 33,634 (July 20, 2017).

[5] 82 Fed. Reg. 33,634.

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

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

[8] *See* Petition for Writ of Certiorari, Am. Hosp. Ass'n v. HHS, at 26, *available* here.

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