SUPREME COURT ISSUES DECISION FAVORABLE TO HOSPITALS ON 340B PAYMENT REDUCTION: WHAT TO DO NEXT

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On 15 June 2022, the Supreme Court issued the long-awaited decision in the *American Hospital Association v. Becerra* case examining whether the Centers for Medicare & Medicaid Services (CMS) had the authority to make certain payment cuts.[1] CMS implemented payment cuts to 340B Program safety net hospitals in 2018, such that reimbursement for drugs purchased under the 340B Program would be paid at average sales price (ASP) minus 22.5%, instead of the standard ASP plus 6%. Those payment cuts remain in effect today. The American Hospital Association and several other trade associations, along with some individual hospitals, sued CMS over this policy. The plaintiffs won at the district court level, but the DC Circuit Court of Appeals overturned that decision, finding that the applicable statute does not "directly foreclose" CMS's interpretation allowing for this policy. In a unanimous decision, the Supreme Court reversed.[2]

The Supreme Court's opinion exhibits brevity that is rare for opinions raising Administrative Procedure Act considerations. In part, this reflects that the Supreme Court considered the answer relatively straightforward from simply reviewing the plain meaning of the statute. CMS suggested that it had "adjustment" authority for drug reimbursement from one provision, even though another provision required that CMS could only discriminate against certain hospitals if it had drug acquisition cost survey data. The Supreme Court, however, stated that this argument "make[s] little sense."[3] The Supreme Court questions "why, then, would Congress have constructed this elaborate statute premised on the U.S. Department of Health and Human Services' survey of hospital acquisition costs."[4] The Supreme Court thus reversed the DC Circuit opinion and remanded for further action.

While, of course, it is salutary anytime that the Supreme Court agrees that an agency, especially CMS, must stick within the scope of the authority granted to it by Congress, the decision is not necessarily self-implementing. For instance, in response to CMS's stated concerns about the need for outpatient payments to be budget neutral, the Supreme Court stated "we need not address potential remedies."[5] This leaves open the door for CMS to claim the right to use discretion in its implementation of the decision, possibly defying hospitals' expectation of the outcome here in light of the favorable decision. It is also unclear if CMS will implement whatever change it decides on for only 2018 and 2019. CMS did, in fact, perform a survey of drug acquisition costs in 2020. However, that survey was widely disregarded by 340B Program covered entity hospitals, and CMS would be on shaky grounds if it relies on it. The Administrative Procedure Act requires that agencies rely on "substantial evidence" in their rulemaking, but the anemic response to the survey calls into question if it is "substantial" evidence of anything, and the Supreme Court noted in its opinion that even CMS admitted that such surveys do not "produce results that are all that accurate."[6] Nevertheless, given these uncertainties, there could be additional back and forth between CMS and private parties, including litigation, that could require years to resolve.

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In the meantime, hospitals need to decide what to do right now. The first question hospitals need to ask is whether they should continue to append the JG modifier to their claims when they administer 340B Program drugs, which results in reduced payment. CMS has not officially rescinded that policy, but the Supreme Court implicitly stated that they never had the authority to require the use of that modifier *ab initio*. Like many issues, different hospitals will likely take different approaches on this question. The second question is whether the only option for hospitals now is to passively wait for CMS to implement the decision. Hospitals do in fact have appeal rights for claims that are not paid correctly, and they may decide that it is worth at least going on record that they protest the current payment amount as to their specific, underpaid claims. That garners them specific appeal rights in federal court, as opposed to more generic rights under the Administrative Procedure Act. Of course, keeping track of underpaid claims is not without its costs, and thus, hospitals need to do a cost-benefit analysis. However, it must also be recognized that without specific claims under appeal, hospitals are at the mercy of whatever action CMS ultimately decides to pursue, which may result in substantially less relief than they were expecting. Hospitals should also not lose sight of their Medicare Advantage Plan agreements, which have their own dispute resolution procedures. Reduced payments based on the fee for service Medicare rate are now susceptible to challenge.

In sum, the Supreme Court decision is a very welcome development, but it is not the final chapter in this saga. Glimpses of CMS's thinking will be evident in the outpatient prospective payment system proposed rule due to be published in a couple of weeks. In the meantime, hospitals should consider their options, even if some will ultimately take a “wait and see” approach.

K&L Gates Health Care practice routinely assists health systems, hospitals, and other providers and suppliers with legal advice and strategic considerations, including providing advice on Medicare reimbursement appeals and 340B Program matters.

FOOTNOTES

[1] Am. Hosp. Ass'n v. Becerra, No. 20-1114, slip. op. (S. Ct. June 15, 2022).

[2] *Id*. at 2.

[3] *Id*.

[4] *Id*. at 12.

[5] *Id*. at 8.

[6] *Id*. at 4.

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