Supreme Court Saves Hospitals from $1.6B Cut to 340B Program

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On June 15, 2022, in a win for hospitals, the Supreme Court issued its opinion in *American Hospital Association et. al. v. Becerra* ("*Becerra*"), overturning massive reimbursement reductions in the 340B drug pricing program ("340B Program").

The 340B Program, in which some 40% of U.S. hospitals participate, requires drug manufacturers to provide outpatient drugs to participating providers at heavily discounted rates. Participating hospitals rely on profits from the differential between the reimbursement they receive for these drugs and the discounted rates they pay to fund patient care services.

Becerra reversed a D.C. Circuit ruling that upheld the U.S. Department of Health and Human Services' ("HHS") $1.6 billion annual cut to reimbursement in the 340B Program. Writing for a unanimous Court, Justice Brett Kavanaugh noted that "all agree that HHS did not conduct a survey of hospitals' acquisition costs" before reducing reimbursement in the 340B Program several years ago. The Court found that "under the text and structure of the statute, this case is therefore straightforward," and concluded that HHS' decision to vary reimbursement rates only for hospitals in 2018 and 2019 was unlawful because it did not conduct a survey of hospitals' acquisition costs in those years.

HHS' move to reduce 340B drug reimbursement originated in 2017, when it issued a final rule reducing hospital reimbursement under the 340B Program for 2018 from 6% over each drug's average sales price to 22.5% below the average sales price, resulting in a total reimbursement reduction of $1.6 billion. Several hospital groups sued to challenge this reduction in the U.S. District Court for the District of Columbia, claiming that the change was in violation of federal law and exceeded HHS' statutory authority. The District Court ruled in favor of the hospitals in December 2018, and ordered additional briefing to determine an appropriate remedy. Nevertheless, on January 1, 2019, HHS effectuated its 2019 Outpatient Prospective Payment System rule, which continued the 340B Program cuts first implemented in the prior year, and expanded them to additional hospital locations. In May 2019, the District Court also found the 2019 rule unlawful, but did not vacate either rule, choosing instead to remand the rules to HHS for the agency to figure out how to “unscramble the egg,” given the complexities of Medicare reimbursement.

HHS did not revert to its prior payment methodology for 340B Program drugs, nor did it make retroactive payment adjustments to providers. Instead, HHS appealed the District Court decisions to the U.S. Court of Appeals for the District of Columbia Circuit. In July 2020, a three-judge panel of the Court of Appeals reversed the District Court, ruling in favor of HHS and cleared the way for HHS to continue and build up their cuts to 340B Program drug reimbursement. In August 2020, HHS proposed further cuts to 340B reimbursement, with drugs to be reimbursed at average sales price minus 34.7%, plus an add-on of 6% of the products average sales price, for a net payment rate of average sales price minus 28.7%.

If HHS decides to move forward with its plan to slash payments under the 340B Program after *Becerra*, it will take time to conduct surveys and future rulemaking. For now, hospitals can take a sigh of relief as they are no longer facing a 10-figure reduction in reimbursement from the 340B Program.

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