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340B Hospitals Score a Win With The U.S. Supreme Court

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On Wednesday, June 15, 2022, in a unanimous decision, the U.S. Supreme Court decided in favor of the American Hospital Association in the case of *American Hospital Association vs. Becerra*, that the nearly 30 percent cuts in Medicare outpatient drug payments under the 340B program were unlawful. The decision sends the case back to a lower court to determine next steps, including the question of remedies to the affected hospitals.

The reduction in Medicare outpatient drug payments and pricing restrictions from drug manufacturers have affected the savings hospitals need to support medical services for at-risk populations.

The facts of the case center on the reimbursement rate for specified covered outpatient drugs (SCODs), which are covered under Medicare Part B and are higher in costs than other Part B drugs. In 2018, Health and Human Services (HHS) reduced the SCODs reimbursement rate for 340B hospitals to 22.5 percent below average manufacturer price. Non-340B hospitals still received reimbursement at six percent above sales price. HHS justified the different rate for 340B hospitals by arguing that it should not reimburse 340B hospitals more than what they paid to acquire the drugs.

During oral arguments before the Supreme Court, HHS urged the Court to apply the Chevron Doctrine, which gives judicial deference to federal agencies on their authority to make decisions when the statute is not clear. Writing on behalf of the Court, Justice Kavanaugh rejected this argument and emphasized that HHS failed to present any "textual basis" to apply the Chevron Doctrine. He also included note of the critical role that the 340B program plays in caring for patients in need.

The Supreme Court emphasized in its ruling that CMS must make future reimbursement changes based on hospital survey data or ask Congress to change the law. The 2017 and 2018 cuts were made by CMS without any survey data. CMS performed a hospital survey in 2020 and claims its data supports deeper cuts. Many hospitals refused to participate in the 2020 survey because it only looked at acquisition costs.

Despite the uncertainty of future CMS action, 340B hospitals should consider assessing the financial impact of the rate reductions and strategize for more changes to the 340B program. The Supreme Court ruling in favor of AHA presents an opportunity for 340B hospitals to possibly be entitled to additional reimbursement to compensate for years of underpayments.

If you have any questions about this decision, please contact Sheila P. Burke or a member of Baker Donelson's Health Law Group.