U.S. Supreme Court to Hear 340B Case

On July 2, 2021, the Supreme Court of the United States agreed to hear a case between the hospital industry and federal government disputing cuts to the 340B Drug Discount Program (340B program) in the term beginning October 2021.[1] The case, entitled *American Hospital Association v. Becerra*, reached the Court after a series of legal battles that began in 2017, when the Centers for Medicare & Medicaid Services (CMS) published a final rule cutting Medicare Part B and state Medicaid payments in the 340B program by an estimated $1.6 billion.[2] This Health Capital Topics article will review the history of the 340B program,[3] the procedural history of the case, and reactions from hospital industry stakeholders on the Court's undertaking of the case.

Congress created the 340B program in 1992 to help vulnerable or uninsured patients access prescription medication at safety-net hospitals, i.e., hospitals that serve a large population of vulnerable or uninsured patients.[4] The intent of the program was to create a ceiling on how much drug manufacturers could charge safety-net hospitals for medications; in turn, hospitals would pass these savings on to low-income patients through providing prescription medications at no cost or at heavily discounted rates.[5] In 1994, the Health Resources and Services Administration (HRSA) released guidance that extended the 340B program to hospital-owned outpatient clinics, and in 1996 it allowed hospitals and their clinics without an on-site pharmacy to contract with one off-site pharmacy.[6] In 2010, HRSA extended its guidance even further, allowing covered entities to have an unlimited number of contract pharmacies, including for-profit drug store chains, such as Walgreens and CVS.[7] 340B was most recently expanded under the Patient Protection and Affordable Care Act (ACA) to include critical access hospitals, sole community hospitals, rural referral centers, and cancer centers.[8] These expansions have resulted in the proliferation of contract pharmacies – in January 2010 (two months before the passage of the ACA), the number of contract pharmacies was less than 1,300; that number has jumped to nearly 28,000 as of July 2020, a more than 2,000% increase in slightly over a decade.[9]

As early as 2015, the Secretary of the Department of Health and Human Services (HHS) warned the Senate Finance Committee that the 340B program "ha[d] expanded beyond its bounds," and asserted that the number of 340B participants had grown to an unsustainable number.[10] With nearly half of U.S. hospitals purchasing pharmaceuticals under the 340B program, the out-of-control spending prompted the nonpartisan Government Accountability Office (GAO) to publish a report calling for the need to reduce financial incentives for over-prescribing.[11] While HHS believed that the unbounded number of contract pharmacy arrangements was fostering numerous violations and causing financial strain against the 340B program, hospital lobbyists pushed back on behalf of safety-net hospitals serving vulnerable or uninsured populations.[12] Ultimately, HHS found a significant gap between the discounted payment rates for prescription drugs at which providers were buying and the much higher rates at which the providers were reimbursed, began taking steps in 2017 to reduce reimbursements and close that gap.[13]

In November 2017, CMS released their 2018 Hospital Outpatient Prospective Payment System (OPPS) final rule, which included significant reimbursement cuts to the 340B program.[14] Under the final rule, CMS changed its coverage of outpatient drugs and biologicals to the drug's average sales price (ASP)[15] *minus* 22.5%, a significant change from the previous rate of ASP *plus* 6%.[16] Subsequently, the American Hospital Association (AHA), Association of American Medical Colleges (AAMC), and America's Essential Hospitals (AEH) filed a lawsuit against HHS in the D.C. District Court as an attempt to prevent CMS from enacting the reduced reimbursements under the 2018 OPPS.[17] Although CMS's rule sought to reduce overall prescription drug spending, it resulted in significantly higher drug expenditures for 340B hospitals.[18] The associations argued that HHS did not establish an average-price metric, and the agency lacked the authority to reduce payments by nearly 30%, which is too large of a change to qualify as an "adjustment."[19] However, CMS's chosen ASP-minus-22.5% rate was based on the Medicare Payment Advisory Commission's estimate of the average minimum discount that eligible hospitals received for drugs acquired under the 340B program.[20] Further, certain drugs prescribed in exempt settings under 340B could still receive the original ASP-plus-6% payment rate.[21] The lower court sided with the HHS, and the plaintiffs appealed to the U.S. Court of Appeals for the D.C. Circuit; however, the appellate court upheld the lower court's decision and allowed the payment cuts for

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2018 to continue, under the reasoning that the associations filed the suit prematurely, as hospitals had not yet experienced the payment cuts (and had not yet exhausted their administrative remedies by first formally filing complaints with HHS).[22]

In July 2018, CMS proposed to further reduce 340B spending by expanding the reduced payment rate to non-excepted off-campus provider-based departments.[23] After hospitals served vulnerable or uninsured patients for more than six months under the new payment rate (ASP minus 22.5%), AHA, AAMC, and AEH refiled in the D.C. District Court; in December 2018, the court ruled in favor of the hospital associations, finding that HHS overstepped its authority.[24] HHS appealed the lower court's decision in July 2019, and continued these cuts in its 2020 OPPS final rule.[25] One year later, the appellate court reversed the lower court's decision and found in favor of HHS, arguing that the agency's lower drug reimbursement rate "rests on a reasonable interpretation of the Medicare statute."[26] Shortly after the appellate court released their decision, CMS released their 2021 OPPS proposed rule, which proposed increasing 340B reimbursement cuts to a net rate of ASP minus 28.7%.[27] However, in their final rule released on December 2, 2020, CMS reverted back to the previous ASP-minus-22.5% rate and proposed to maintain that rate in the 2022 OPPS rule, which was release on July 19, 2021.[28]

The hospital associations appealed the federal appellate court's decision to the Supreme Court, and on July 2, 2021, the Court agreed to pick up the case in their next term, beginning October 2021.[29] The Court's decision to hear the case was met with excitement and anticipation from several stakeholders. AHA's general counsel, Melinda Hatton, commented she is hopeful the Supreme Court will reject the lower court's decision as their interpretation of Medicare statutes puts the sustainability of 340B participants and the important services they provide at risk.[30] Maureen Testoni, CEO of the advocacy group 340B Health, hopes the Supreme Court will rule in favor of the hospitals that treat patients with low incomes.[31] Additionally, she added that 340B Health will continue to urge the Biden Administration to abandon the harmful payment cuts in the 2022 OPPS and beyond.[32] AAMC CEO and President, David Skorton, added that the payment cuts are not only harmful to low-income, uninsured patients, but also to the future physician workforce, as many hospitals are safety-net providers in addition to teaching hospitals.[33] Further, he stated that "[a] reversal of the cuts will ensure that low-income, rural, and other underserved patients and communities are able to access the vital services they need."[34] As of the date of publication, neither HHS nor CMS has commented on the Supreme Court's decision to hear the case.

While the Trump Administration's HHS defended many of the cases that supported drug cuts, the Biden Administration will likely approach the lawsuits in their own way, albeit with the same intent. President Biden is concerned with lowering drug prices, and has asserted his desire to give Medicare the power to negotiate lower drug prices to provide to covered entities at discounted rates.[35] However, many fear that the 340B covered entities are using the discount to increase their profit, instead of passing the savings on to low-income patients.[36] If covered entities are not passing the discounts to patients, Congress believes that the entities should not continue to receive discounted drugs while also receiving higher reimbursement rates.[37] Hospitals have fought back on these assertions, arguing that the discounts provide the funds needed to improve the overall health of communities with large numbers of vulnerable or uninsured patients; thus, reimbursement cuts will affect their ability to deliver care to patients.[38] The Supreme Court will hear the 340B reimbursement cuts case in their new term beginning October 2021, with a decision expected by July 2022.[39]

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(Continued on next page)

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