

Supreme Court Hears Oral Arguments on 340B Cuts

On November 30, 2021, the U.S. Supreme Court heard oral arguments regarding the challenges arising from the cuts made by the Centers of Medicare & Medicaid Services (CMS) to the 340B Drug Pricing Program. The 340B Drug Pricing Program allows hospitals and clinics that treat low-income, medically underserved patients to purchase certain “specified covered outpatient drugs”¹ at discounted prices (applying a ceiling to what drug manufacturers may charge certain healthcare facilities) – 25% to 50% of what providers would typically pay – and then receive reimbursement pursuant to the rates set forth in the Outpatient Prospective Payment System (OPPS) at the same rate as all other providers.² This results in a margin for these participants between the amount paid for the drug and the amount received, which enables covered entities to stretch scarce federal resources as far as possible, reaching more patients and providing more comprehensive services.³ However, many healthcare industry stakeholders assert that 340B participants are realizing substantial profits by purchasing deeply discounted cancer drugs, which are then reimbursed by Medicare at full cost – providing hospitals with up to 100% profit margins on these expensive drugs.⁴

CMS originally announced cuts to the reimbursement rates for 340B drugs in the 2018 OPPS rule, to address “recent trends of increasing drug prices, for which some of the cost burden falls to Medicare beneficiaries.”⁵ Prior to 2018, the reimbursement rate for these outpatient drugs was the drug’s average sales price (ASP) *plus* 6%.⁶ In the 2018 OPPS final rule, however, CMS finalized a reduction to this reimbursement rate, specific to 340B participants only, of ASP *minus* 22.5%, beginning in 2018.⁷ CMS claimed in the final rule that it had authority to enact such a cut under federal law that allows for calculation and adjustment of the rates “as necessary.”⁸

In 2017, three hospital associations, including the American Hospital Association (AHA), and several non-profit hospitals filed a lawsuit in the U.S. District Court for the District of Columbia to challenge the cuts and enjoin the implementation of the cuts, asserting that the U.S. Department of Health & Human Services (HHS), of which CMS is part, violated its authority by changing the rates and that the reduced drug payments would negatively affect access to care (as the 340B Drug Pricing Program is largely comprised of safety-net hospitals).⁹ According to the plaintiffs, the 340B statute requires CMS to conduct a survey as to the hospitals’ average

drug acquisition costs prior to enacting reimbursement cuts.¹⁰ In December 2017, the court dismissed that lawsuit on procedural grounds because the policy was not yet effective.¹¹ The hospital associations and hospitals re-filed the suit once the reimbursement cuts took effect, leading to the current challenge.¹² Plaintiffs argued that the reduction exceeded HHS’s statutory authority and violated the Administrative Procedure Act (APA) and the Social Security Act.¹³ On December 27, 2018, a the district court ruled in favor of the plaintiffs, finding that HHS’s authority to make “adjustments” does not equate to “fundamentally rework[ing] the statutory scheme.”¹⁴ HHS subsequently appealed the case and the appellate court reversed the lower court’s decision, finding that HHS had the power to make the cuts.¹⁵ The case was then appealed to the U.S. Supreme Court, which agreed to hear the dispute.

The key point of contention in the case is whether HHS acted within its authority in making cuts in the 2018 OPPS Final Rule that singled out 340B hospital participants.¹⁶ The plaintiffs argue that HHS does not have the authority under the 340B statute to make cuts and therefore cannot single out 340B hospital participants.¹⁷ On the other side, HHS argues that the cuts were necessary in order to reimburse hospitals for the acquisition costs of the drugs.¹⁸ Justice Steven Breyer seemed to agree with the agency’s position, stating that “the point seems to be to pay the hospitals what they actually pay for the drugs, which sometimes you can figure out and sometimes you can’t...When it says adjust for purposes, they mean adjust so that you get closer to what hospitals are really paying for these drugs.”¹⁹ The plaintiffs responded to this line of reasoning by asserting that HHS should do a cost study prior to enacting rate changes for a specific group of hospitals, which the agency began doing in 2020.²⁰ Justice Elena Kagan questioned why HHS had not conducted cost studies prior to 2020, as she interpreted the 340B statute as requiring a cost study prior to changing rates.²¹ Justice Brett Kavanaugh raised the concern of many healthcare industry stakeholders in seeking to ascertain from the plaintiffs whether 340B hospital participants are being overpaid as HHS asserts.²²

The potential implications of the U.S. Supreme Court’s decision in this case are likely to be impactful, although whether that impact is negative or positive is indeterminate. According to David J. Skorton, M.D.,

President and CEO of the Association of American Medical Colleges (one of the plaintiffs in the lawsuit):

“The current reimbursement rates reduce the 340B drug discounts granted to safety-net providers, many of which are teaching hospitals. These hospitals use the current savings to deliver critical health care services to low-income and vulnerable patients, which includes providing free or substantially discounted drugs to low-income patients, establishing neighborhood clinics, and improving access to specialized care previously unavailable in some areas. 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.”²³

On the other hand, proponents of the cuts have repeatedly argued that the payment reductions have saved money for Medicare beneficiaries, i.e., seniors and people with disabilities, through lowered out-of-pocket costs.²⁴ Some proponents have gone so far as to argue that reversing the cuts will cost these beneficiaries millions of dollars.²⁵

A decision on this case is likely to be released by the Supreme Court sometime in the first half of 2022.

- 1 These are “a subset of ‘separately payable drugs,’ which are not bundled with other Medicare Part B outpatient services and are therefore reimbursed on a drug-by-drug basis.” “Memorandum Opinion: Denying Defendants’ Motion to Dismiss; Granting Plaintiffs’ Motion for a permanent Injunction; Denying as Moot Plaintiffs’ Motion for a Preliminary Injunction” in “The American Hospital Association, et al., v. Azar, et al.” Civil Action No. 18-2084 (RC) (D.C. Cir. Dec. 27, 2018), p. 4 (citing “Payment of benefits” 42 U.S.C. § 1395l(t)(14)(A)).
- 2 “Supreme Court Will Determine Whether 340B Hospitals Retain Discounts on Medicare Part B Drugs” Allison Hoffman, Commonwealth Fund, November 21, 2021, <https://www.commonwealthfund.org/blog/2021/supreme-court-340b-hospitals-discounts-medicare-part-b> (Accessed 12/15/21).
- 3 “340B Drug Pricing Program”, HRSA, December 2021, <https://www.hrsa.gov/opa/index.html> (Accessed 12/15/21).
- 4 “How Abuse of the 340B Program is Hurting Patients” Community Oncology Alliance, September 2017, https://communityoncology.org/wp-content/uploads/2018/06/COA_340B-PatientStories_FINAL.pdf (Accessed 12/15/21).
- 5 “CMS Issues Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System and Quality Reporting Programs Changes for 2018 (CMS-1678-FC)” Centers for Medicare & Medicaid Services, November 1, 2017, <https://www.cms.gov/newsroom/fact-sheets/cms-issues-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-payment> (Accessed 12/20/21).
- 6 “Federal Court Says 2018 OPPS 340B Program Rate Cuts Unlawful, Orders Briefing to Avoid Havoc on Medicare Program” By Lee Nutini, JDSupra, January 3, 2019, <https://www.jdsupra.com/legalnews/federal-court-says-2018-opps-340b-87971/> (Accessed 12/15/21).
- 7 *Ibid.*
- 8 *Ibid.*, (citing “Payment of benefits” 42 U.S.C. § 1395l(t)(14)(A)(iii)(II)).
- 9 “340B Drug Payment Case Heads to Supreme Court” Rev Cycle Intelligence, July 6, 2021, <https://RevCycleIntelligence.com/news/340b-drug-payment-case-heads-to-supreme-court> (Accessed 12/15/21). “Impact analysis: federal court blocks 2018 Cuts to 340B drug discount program payments” Health Law News, January 11, 2019, <https://www.hallrender.com/2019/01/11/impact-analysis-federal-court-blocks-2018-cuts-to-340b-drug-discount-program-payments/> (Accessed 12/15/21).
- 10 “Supreme Court hears case on 340B payments” By Jessie Hellmann, Modern Healthcare, November 30, 2021, <https://www.modernhealthcare.com/legal/supreme-court-hears-case-340b-payments> (Accessed 12/20/21).
- 11 Health Law News, January 11, 2019.
- 12 *Ibid.*
- 13 Nutini, January 3, 2019.
- 14 The American Hospital Association, et al., v. Azar, et al.” Civil Action No. 18-2084 (RC) (D.C. Cir. Dec. 27, 2018), p. 28.
- 15 “Supreme Court justices grill HHS in lawsuit surrounding nearly 30% cut to 340B Payments” Fierce Healthcare, December 1, 2021, <https://www.fiercehealthcare.com/hospitals/supreme-court-justices-grill-hhs-lawsuit-surrounding-nearly-30-cut-to-340b-payments> (Accessed 12/15/21).
- 16 “Supreme Court To Hear Case Impacting Medicare Reimbursement for 340B Drugs” By Erin Atkins and Stephanie Trunk, JDSupra, July 9, 2021, <https://www.jdsupra.com/legalnews/supreme-court-to-hear-case-impacting-7170581/> (Accessed 12/15/21).
- 17 Fierce Healthcare, December 1, 2021.
- 18 *Ibid.*
- 19 *Ibid.*
- 20 *Ibid.*
- 21 *Ibid.*
- 22 *Ibid.*
- 23 “AAMC statement on supreme court decision to hear arguments in 340B drug pricing cuts case” July 2, 2021, <https://www.aamc.org/news-insights/press-releases/aamc-statement-supreme-court-decision-hear-arguments-340b-drug-pricing-cuts-case> (Accessed 12/15/21).
- 24 “Undoing Medicare 340B cuts would not cost patients or taxpayers anything” 340Binformed, April 23, 2021, <https://340binformed.org/2021/04/undoing-medicare-340b-cuts-would-not-cost-patients-or-taxpayers-anything/> (Accessed 12/15/21).
- 25 *Ibid.*



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