

U.S. Supreme Court Rules Against HHS in 340B Case

On June 15, 2022, the U.S. Supreme Court released its decision regarding the cuts made by the Department of Health and Human Services (HHS) to the 340B Drug Pricing Program, finding that HHS acted outside its statutory authority in changing reimbursement rates for one group of hospitals without first surveying them on their costs.

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 under 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 drugs, which are then reimbursed by Medicare at full cost – providing hospitals with up to 100% profit margins on these expensive drugs.⁴

Pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, HHS must follow a statutory formula (consisting of two options) in setting the annual reimbursement rate for 340B drugs. Beginning in 2006, HHS’s reimbursement rate for each covered drug “shall be equal” to either:

- “(I) to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group...), as determined by the Secretary taking into account the hospital acquisition cost survey data...; or
- (II) if hospital acquisition cost data are not available, the average price for the drug...as calculated and adjusted by the Secretary as necessary for purposes of this paragraph.”⁵
 [Emphasis added.]

From 2006 to 2018, the reimbursement rate for these outpatient drugs was determined using Option 2: the drug’s average sales price (ASP) *plus* 6%.⁶ In the rulemaking for the 2018 OPPS, however, HHS instead

finalized a reduction to this reimbursement rate, specific to 340B participants only, of ASP *minus* 22.5%, pursuant to the formula set forth in Option 1 (non-340B participants are still reimbursed ASP plus 6%). HHS finalized these cuts for 2018 (and continued them through 2019), to address “recent trends of increasing drug prices, for which some of the cost burden falls to Medicare beneficiaries.”⁷ HHS 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.”⁹

Subsequently, 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 their implementation, asserting that HHS, 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).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 because the statute requires the agency to survey the hospitals’ average drug acquisition costs *prior* to enacting reimbursement cuts, particularly if only one group of hospitals would be affected by the cuts.¹³

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 U.S. Supreme Court’s unanimous opinion, authored by Justice Brett Kavanaugh, reversed the appellate court. The Court found that a reading of the statutory language makes clear that without surveying hospitals as to their drug acquisition costs, HHS may not change drug reimbursement rates for a subset of hospitals. The court noted that this “protects all hospitals by imposing an important procedural prerequisite—namely, a survey of hospitals’ acquisition costs for prescription drugs—before HHS may target particular groups of hospitals for lower reimbursement rates.”¹⁶ As to HHS’s assertion that

the agency has the authority under Option 2 to adjust the average price, the Court stated that:

“[r]egardless of the scope of HHS’s authority to ‘adjust’ the average price up or down under the statute, the statute does not grant HHS authority to vary the reimbursement rates by hospital group unless HHS has conducted the required survey of hospitals’ acquisition costs...Otherwise stated, HHS’s power to increase or decrease the price is distinct from its power to set different rates for different groups of hospitals”¹⁷

The potential implications of the U.S. Supreme Court’s decision in this case are still unclear, but it may be difficult to “put the genie back in the bottle.” HHS argued that allowing judicial review of the now-unlawful reimbursement rates is impractical because HHS is required to operate the program on a budget-neutral basis. As a result, the Court’s decision may require HHS to repay some amounts to the 340B participants,

necessitating offsets elsewhere in the OPSS to account for those repayments. However, the Court stated in its opinion that “[a]t this stage, we need not address potential remedies,” and remanded the case back to the lower court. A University of Pennsylvania law professor has stated that the implications “will be really quite limited both from a practical perspective and from a legal perspective.”¹⁸ But from where that money will come to repay the 340B drug claims for 2018 and 2019 is an “open issue” according to a health lawyer with Foley Hoag, and attempting to redistribute the money “could penalize more hospitals than are benefited...[as t]here are way more hospitals that got the extra money than benefit from 340B.”¹⁹ The 2023 OPSS proposed rule is expected to be released in July 2022 and is anticipated to address how the 340B money will be reapportioned and the reimbursement rates for drug costs going forward. Stay tuned for a future Health Capital Topics article examining the 2023 OPSS proposed rule once it is released.

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 “Payment of benefits” 42 USC § 1395l(t)(14).

6 “Federal Court Says 2018 OPSS 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-opss-340b-87971/> (Accessed 12/15/21).

7 “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).

8 Nutini, JDSupra, January 3, 2019.

9 *Ibid.*

10 “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).

11 “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).

12 *Ibid.*

13 Nutini, JDSupra, January 3, 2019; “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).

14 “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. 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 “American Hospital Association et al. v. Becerra, Secretary of Health and Human Services, et al.” 596 U.S. ____ (2022), Slip Opinion, Certiorari to the United States Court of Appeals for the District of Columbia Circuit, available at: https://www.supremecourt.gov/opinions/21pdf/20-1114_09m1.pdf (Accessed 6/15/22), p. 10.

17 *Ibid.*, p. 11.

18 “Hospitals win 340B lawsuit at Supreme Court” By Maya Goldman, Modern Healthcare, June 15, 2022, <https://www.modernhealthcare.com/legal/hospitals-win-340b-lawsuit-supreme-court> (Accessed 6/15/22).

19 *Ibid.*



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