

Healthcare & Life Sciences Practice

Drug Pricing Digest

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Drug Pricing Initiatives: Discussion continues of [H.R. 5376](#) (the Build Back Better Act, or BBBA), the approximately \$2.2 trillion social safety net, climate, and tax bill that includes measures related to drug pricing and healthcare. The House of Representatives passed the BBBA on Nov. 19, 2021, but the Senate has not yet taken up the legislation.

Sources: [Generics Bulletin](#), Bloomberg Law ([link](#), [link](#)), [Politico Pro](#)

MEDICAID DRUG REBATE PROGRAM (MDRP)

No developments to report.

340B PROGRAM

Contract Pharmacy Updates: The Health Resources and Services Administration (HRSA) published a statement on its [website](#) in response to recent court rulings in three contract pharmacy cases. The statement says HRSA is “pleased that two of three recent U.S. District Court opinions involving the 340B Program agree with HRSA that three pharmaceutical manufacturers have unlawfully restricted access to 340B discounted drugs by covered entities that dispense medications through contract pharmacy arrangements.” In addition, “HRSA respectfully disagrees with the recent District Court opinion finding that two other manufacturers had not violated the statute, and continues to evaluate its options.”

Source: 340B Report ([link](#), [link](#))

Two additional pharmaceutical manufacturers have announced contract pharmacy policies, bringing the total number of manufacturers with such policies to 10.

Source: 340B Report ([link](#), [link](#))

US Supreme Court Oral Argument in Medicare / 340B Drug Payment Rate Case: On Nov. 30, 2021, the US Supreme Court heard oral argument in its review of a decision from the US Court of Appeals for the District of Columbia Circuit. That decision upheld a US Department of Health and Human Services (HHS) policy establishing a reduced Medicare payment rate of Average Sales Price (ASP) minus 22.5% for certain separately payable drugs or biologicals purchased under the 340B Drug Pricing Program at or below the ceiling price (exempting rural sole community hospitals, children’s hospitals, and PPS-exempt cancer hospitals).

In a 2-1 decision, the DC Circuit gave deference to HHS’s interpretation of the agency’s statutory authority to set these payment rates, applying the administrative law principles of *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), and held that “HHS’s decision to lower drug reimbursement rates for 340B hospitals rests on a reasonable interpretation of the Medicare statute.” The case is *Am. Hosp. Ass’n v. Azar*, 967 F.3d 818 (D.C. Cir. 2020), *cert. granted sub nom. Am. Hosp. Ass’n v. Becerra*, 141 S. Ct. 2883 (2021).

During the oral argument, the Supreme Court Justices asked whether Congress had precluded judicial review of these Medicare payment rates and posed questions regarding interpretation of the statute at issue, [42 U.S.C. § 1395l\(t\)\(14\)\(A\)\(iii\)\(II\)](#), as well as the level of deference owed to HHS's interpretation of that statute. Several Justices also asked whether the Court should overturn *Chevron* to resolve this matter. A decision in this case is expected by the end of the Supreme Court's term in June.

Sources: Law360 ([link](#), [link](#)), [InsideHealthPolicy](#), [Pink Sheet](#), Bloomberg Law ([link](#), [link](#)), [Fierce Healthcare](#), [Oyez](#) (including argument recording and unofficial transcript), [Official Transcript](#) (subject to final review by the Court), [340B Report](#)

MEDICARE PART B

No developments to report.

STATE LAW DEVELOPMENTS

No developments to report.

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