

Healthcare & Life Sciences Practice

Drug Pricing Digest

June 21, 2022 | Number 30

Drug Pricing Initiatives: Congress and stakeholders continue to discuss drug pricing reform measures, including those that were originally part of [H.R. 5376](#) (the Build Back Better Act, or BBBA).

Source: [InsideHealthPolicy](#), [Politico](#)

In a related development, the Federal Trade Commission (FTC) [announced](#) that it will “launch an inquiry into the prescription drug middleman industry, requiring the six largest pharmacy benefit managers [(PBMs)] to provide information and records regarding their business practices.” The FTC will “scrutinize the impact of vertically integrated [PBMs] on the access and affordability of prescription drugs.”

Sources: Bloomberg Law ([link](#), [link](#)), Law360 ([link](#), [link](#), [link](#)), [InsideHealthPolicy](#), Pink Sheet ([link](#), [link](#)), [BioWorld](#), [Politico](#), [STAT](#), [340B Report](#)

The FTC also issued a [policy statement](#), explaining that the FTC has received “complaints about rebates and fees paid by drug manufacturers to [PBMs] and other intermediaries.” According to the statement, the FTC “intends to closely scrutinize the impact of rebates and fees on patients and payers to determine whether any [antitrust] provisions have been violated. In addition, the Commission will monitor private litigation and file amicus briefs where it can aid courts in analyzing unlawful conduct that may raise drug prices.”

Sources: [Bloomberg Law](#), [STAT](#)

MEDICAID DRUG REBATE PROGRAM (MDRP)

No developments to report.

340B PROGRAM

Contract Pharmacy Updates: Litigation related to manufacturer contract pharmacy policies continued, with United Therapeutics and Novartis Pharmaceuticals responding to the government’s appeal by filing their respective briefs in *United Therapeutics Corp. v. Johnson*, No. 21-5304 (D.C. Cir.) and *Novartis Pharmaceuticals Corp. v. Johnson*, No. 21-5299 (D.C. Cir.). For more information on these cases, see Issues [No. 14](#) and [No. 28](#) of this digest.

Sources: [Bloomberg Law](#), [340B Report](#)

Related litigation challenging the Administrative Dispute Resolution (ADR) process remains pending.

Source: [340B Report](#)

An additional manufacturer announced the implementation of a contract pharmacy policy, bringing the total number of manufacturers that have done so to 17.

Source: [340B Report](#)

MEDICARE PART B

Supreme Court Strikes Down Medicare Reimbursement Policy for 340B Drugs: On June 15, 2022, the Supreme Court unanimously [held](#) that it was unlawful for the Department of Health and Human Services (HHS) to implement a policy for CY 2018 and CY 2019 of lowering Medicare reimbursement for drugs purchased under the 340B program to average sales price (ASP) *minus* 22.5%, as opposed to ASP *plus* 6%, without having first conducted a survey of hospital acquisition costs for such drugs. The case is *American Hospital Association v. Becerra*, 596 U.S. ____ (2022).

The decision reverses an earlier decision of the Court of Appeals for the District of Columbia Circuit, which had given deference to HHS's interpretation of its statutory authority to set such payment rates and held that HHS's policy rested on a reasonable interpretation of the Medicare statute. The Supreme Court held that the Medicare statute required HHS to conduct a survey of hospital acquisition costs before varying the reimbursement rate for 340B hospitals, and that "HHS's 2018 and 2019 reimbursement rates for 340B hospitals were therefore contrary to the statute and unlawful." The Supreme Court has remanded the case to the D.C. Circuit for proceedings consistent with its opinion.

In implementing the policy, HHS had estimated that it would save Medicare approximately \$1.6 billion annually. As noted Issues [No. 2](#) and [No. 16](#) of this digest, HHS has renewed this same policy for each year beyond 2018 and 2019, explaining in the latest [rulemaking](#) that it was declining to suspend the policy during the Supreme Court litigation "in order to maintain consistent and reliable payment."

Sources: Law360 ([link](#), [link](#)), Bloomberg Law ([link](#), [link](#)), [InsideHealthPolicy](#), [STAT](#), [Pink Sheet](#), [BioWorld](#), [Fierce Healthcare](#), 340B Report ([link](#), [link](#))

STATE LAW DEVELOPMENTS

No developments to report.

If you have questions about the Drug Pricing Digest, please contact the Government Price Reporting team listed below or the Latham lawyer with whom you normally consult:

Christopher H. Schott

chris.schott@lw.com
+1.202.637.2208
Washington, D.C.

Stuart S. Kurlander

stuart.kurlander@lw.com
+1.202.637.2169
Washington, D.C.

Eric C. Greig

eric.greig@lw.com
+1.202.637.3330
Washington, D.C.

James M. Deal

jamie.deal@lw.com
+1.202.637.2290
Washington, D.C.

Maria Malas

maria.malas@lw.com
+1.202.637.2334
Washington, D.C.

Lee B. Staley

lee.staley@lw.com
+1.617.880.4663
Boston

The Drug Pricing Digest is published by Latham & Watkins as a news reporting service to clients and other friends. Sources listed in this digest cannot be supplied by Latham & Watkins LLP and may require subscription access. The information contained in this publication should not be construed as legal advice. Should further analysis or explanation of the subject matter be required, please contact the lawyer with whom you normally consult. The invitation to contact is not a solicitation for legal work under the laws of any jurisdiction in which Latham lawyers are not authorized to practice. A complete list of Latham's thought leadership publications can be found at www.lw.com. If you wish to update your contact details or customize the information you receive from Latham, [visit our subscriber page](#).