

Healthcare & Life Sciences Practice

Drug Pricing Digest

August 16, 2022 | Number 34

Congress Passes Inflation Reduction Act: On Aug. 7, 2022, the Senate approved [H.R. 5376](#), the Inflation Reduction Act of 2022 (the Act), along party lines, with support from 50 Democratic and independent senators and Vice President Kamala Harris casting the tie-breaking vote. The House of Representatives approved the Act on Aug. 12, 2022, also along party lines, and President Biden is expected to sign the Act into law shortly.

The Act is a reduced version of the Build Back Better Act, which the House passed in November 2021. The drug pricing provisions date back even further, to [H.R. 3](#) (the Elijah E. Cummings Lower Drug Costs Now Act), which the House passed in December 2019 (at a time when the Senate was under Republican control).

Three areas of the Act directly impact the pharmaceutical industry:

- **Medicare price negotiation.** In a significant departure, selected drugs will be subject to mandatory price negotiations under Medicare beginning in 2026, with negotiated prices subject to a cap.
- **Medicare Part B and D inflation rebates.** Certain drugs with price increases that outpace inflation will become subject to rebates. Under Medicare Part B, the rebate will first be due with respect to Q1 2023. Under Medicare Part D, the rebate will first be due with respect to the period from Oct. 1, 2022, to Sept. 30, 2023.
- **Medicare Part D benefit redesign.** Among other things, the coverage gap will be eliminated, and beginning Jan. 1, 2025, manufacturers will be subject to mandatory discounts on certain drugs in the initial coverage and catastrophic coverage phases.

To learn more about the key provisions in these areas, see this Latham & Watkins [Client Alert](#). It provides a roadmap to the legislation that presents the topics in a thoughtful order, while providing citations to the Act for easy reference to the legislative text.

Leading up to and in the wake of the Act's passage, stakeholders have been debating the likely impact of the drug pricing provisions in light of how they have been revised since 2019.

Sources: Bloomberg Law ([link](#), [link](#), [link](#), [link](#), [link](#), [link](#)), Politico ([link](#), [link](#), [link](#), [link](#), [link](#)), Pink Sheet ([link](#), [link](#), [link](#), [link](#)), [Scrip](#), [Law360](#), [InsideHealthPolicy](#), Stat ([link](#), [link](#)), [BioWorld](#)

MEDICAID DRUG REBATE PROGRAM (MDRP)

No developments to report.

340B PROGRAM

Contract Pharmacy Updates: Litigation related to manufacturer contract pharmacy policies continues. Meanwhile, Carole Johnson, administrator of the Health Resources and Services Administration, addressed the topic during remarks at the 340B Coalition summer conference.

Sources: [Law360](#), [Pink Sheet](#)

Hospitals Make Filing in Medicare Reimbursement Policy Litigation: As described in Issue [No. 30](#) of this digest, 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 Supreme Court remanded the case to the D.C. Circuit court for proceedings consistent with its opinion. The D.C. Circuit court has, in turn, remanded the case to the D.C. District court to again determine the proper remedy.

In recent court filings, the American Hospital Association, the Association of American Medical Colleges, and America's Essential Hospitals urged the district court to order HHS to promptly pay hospitals the higher reimbursement rate for prior periods. The Supreme Court opinion addressed only CY 2018 and CY 2019, but the hospitals in their filings ask for additional payments for all years up to 2022, as well as implementing the higher payment for the remainder of 2022. The case is *American Hospital Association v. Becerra*, Civil Action No. 18-2084 (RC).

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

MEDICARE PART B

No developments to report.

STATE LAW DEVELOPMENTS

No developments to report.

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