

Healthcare & Life Sciences Practice

Drug Pricing Digest

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Drug Pricing Initiatives: The Senate is expected to vote on a [revised](#) version of H.R. 5376 (the Build Back Better Act, or BBBA), now styled as the Inflation Reduction Act of 2022 (IRA). The House originally passed [H.R. 5376](#) in November 2021. Senator Joe Manchin, one of the Democratic senators whose previous opposition to the BBBA had derailed earlier efforts at Senate passage, now has indicated that he will support the IRA.

Democrats intend to adopt the IRA as part of the budget reconciliation process, which allows passage in the Senate by a simple majority, avoiding a Republican filibuster. Passage would require all 50 Democratic and independent senators' votes, which has given individual senators disproportionate leverage.

Key drug pricing measures that are part of the IRA include:

- Forced price negotiations with the government with respect to certain high-spend drugs, with negotiated prices subject to a cap
- Manufacturer Medicare Part B and Part D rebates tied to price increases that outpace inflation
- Part D benefit redesign that shifts more costs to manufacturers

While these measures were included in the BBBA that the House passed, they have been modified in the IRA. For example, unlike in the BBBA, the cap on negotiated prices would not be based on international reference pricing.

Sources: [New York Times](#), [Washington Post](#), Politico Pro ([link](#), [link](#)), Bloomberg Law ([link](#), [link](#)), [Law360](#)

A separate Senate bill on the cost of insulin may be folded into the IRA.

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

FDA Update: The Food and Drug Administration (FDA) issued two documents that are potentially relevant to price reporting:

- **NDC Format** — On July 25, 2022, FDA published a [proposed rule](#) that would impose a uniform, 12-digit format for the National Drug Code (NDC). As proposed, the labeler code would have six digits (currently, it has five), the product code would have four digits, and the product code two digits. Existing NDCs would be required to be converted to the new 12-digit format five years after publication of any final rule. Comments are due by Nov. 22, 2022.
- **Orange Book FAQ** — FDA issued a [final guidance](#) document titled "Orange Book: Questions and Answers, Guidance for Industry," which "provides answers to questions that have been received by the FDA staff that publishes and manages the Orange Book." Among other things, the guidance addresses how frequently FDA updates the Orange Book and how sponsors can notify FDA when the status of their drugs changes.

Sources: Regulatory Focus ([link](#), [link](#)), [BioWorld](#)

MEDICAID DRUG REBATE PROGRAM (MDRP)

Government Does Not Appeal Co-Pay/PBM Accumulator Regulation Ruling: As noted in Issue [No. 28](#) of this digest, the US District Court for the District of Columbia vacated and set aside the portions of the December 2020 Medicaid [final rule](#) related to the price reporting treatment of manufacturer-sponsored patient programs, including co-pay assistance programs, when the patient's health plan or its pharmacy benefit manager (PBM) has implemented a so-called accumulator adjustment program. The case is *PhRMA v. Becerra*, No. 1:21-cv-01395 (D.D.C.).

The government did not file an appeal by the 60-day deadline, which passed on July 18, 2022, and as a result, the portions of the 2020 final rule that the District Court set aside will not become effective.

340B PROGRAM

Contract Pharmacy Updates: Litigation related to manufacturer contract pharmacy policies continued. **Source:** [340B Report](#)

HHS Completes Repeal of Trump Regulations Regarding Agency Guidance: On July 25, 2022, the Department of Health and Human Services (HHS) published a [final rule](#) in the Federal Register that repeals two final rules: "Department of Health and Human Services Good Guidance Practices," published in the [Federal Register](#) on Dec. 7, 2020, and effective Jan. 6, 2021; and "Department of Health and Human Services Transparency and Fairness in Civil Administrative Enforcement Actions," published in the [Federal Register](#) on Jan. 14, 2021, and effective Jan. 12, 2021. For more information about the repealed rules, see Issue [No. 13](#) of this digest.

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

MEDICARE PART B

No developments to report.

STATE LAW DEVELOPMENTS

No developments to report.

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