

Healthcare & Life Sciences Practice

Drug Pricing Digest

December 20, 2021 | Number 17

Drug Pricing Initiatives: President Biden has indicated that a Senate vote on [H.R. 5376](#) (the Build Back Better Act, or BBBA) will likely not occur until 2022. This follows conversations between President Biden and Senator Joe Manchin, who is being described as the primary Democratic holdout. The BBBA is an 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.

The BBBA is part of the budget reconciliation process, which allows passage in the Senate by a simple majority. Passage would require all 50 Democratic and Independent Senators' votes, with Vice President Harris casting the tie-breaking vote. No Republican Senators are expected to support the measure.

Sources: Politico Pro ([link](#), [link](#), [link](#)), [Pink Sheet](#), [InsideHealthPolicy](#)

The Senate Finance Committee has released its own version of the BBBA, with various modifications to the version passed by the House of Representatives. The modifications include exempting certain generic drugs from inflation rebates and attempting to prevent 340B covered entities from obtaining duplicate discounts on drugs subject to price negotiations.

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

During remarks at the Biopharma Virtual Congress, Jonathan Blum, deputy administrator and chief operating officer of the Centers for Medicare and Medicaid Services (CMS), indicated that CMS will seek stakeholder input, including from the private sector, with regard to establishing a drug price negotiation process, if such a process is enacted through the BBBA or other legislation. He stated that CMS "would talk to all stakeholders throughout the supply chain to understand what is best practice, how do things work and how do we build this skill set in a way that meets congressional intent."

Source: [Pink Sheet](#)

New Reports on Drug Pricing: Three reports addressing drug pricing were issued in recent days:

- The House Committee on Oversight and Reform, currently led by Democrats, issued a [report](#) titled "Drug Pricing Investigation: Majority Staff Report" following a multiyear investigation.
- The Republican minority on the committee issued its own [report](#), "A View from Congress: Role of Pharmacy Benefit Managers in Pharmaceutical Markets."
- CMS issued its annual National Health Expenditures [report](#), which will appear in the January 2022 issue of *Health Affairs*.

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

Bi-Annual Regulatory Agenda: On Dec. 10, 2021, the Biden Administration published an updated regulatory [agenda](#). Among other things, it includes additional information regarding the [proposal](#) to replace the 340B Administrative Dispute Resolution (ADR) final rule, which became effective on Jan. 13, 2021. The description of the new proposed rule, which has not yet been published, states that it "better

aligns with the President’s priorities on drug pricing, better reflects the current state of the 340B Program, and seeks to correct procedural deficiencies in the 340B ADR process.”

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

MEDICAID DRUG REBATE PROGRAM (MDRP)

No developments to report.

340B PROGRAM

Contract Pharmacy Updates: Litigation related to manufacturer contract pharmacy policies continues, with one manufacturer modifying its contract pharmacy policy to focus on a data reporting requirement.

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

MEDICARE PART B

No developments to report.

STATE LAW DEVELOPMENTS

No developments to report.

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