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<u>Drug Pricing Initiatives</u>: On Nov. 19, 2021, the House of Representatives passed <u>H.R. 5376</u> (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. Among other things, the BBBA would provide new authority for Medicare to negotiate prices for certain drugs and would impose rebates under Medicare Part B and Part D, triggered by price increases that outpace inflation. The BBBA would also block the <u>rebate rule</u> proposed by the Trump Administration. The Nov. 19 vote followed the release by the Congressional Budget Office (CBO) of its score of the BBBA.

The BBBA now moves to the Senate, where Democratic Senators will likely seek to further revise the legislation, which is strongly opposed by Republicans. 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. **Sources:** New York Times, Washington Post, InsideHealthPolicy (<u>link, link, link</u>), Politico Pro (<u>link, link</u>), Law360, <u>Bloomberg Law</u>, Pink Sheet (<u>link, link</u>), <u>BioWorld</u>

On Nov. 15, 2021, President Biden signed into law the other bill that is part of the reconciliation process, H.R. 3684 (the Infrastructure Investment and Jobs Act).

Source: New York Times

# MEDICAID DRUG REBATE PROGRAM (MDRP)

<u>CMS Finalizes Delay of Multiple Best Price Reporting, Inclusion of US Territories:</u> On Nov. 19, 2021, the Centers for Medicare and Medicaid Services (CMS) published a <u>final rule</u> in the Federal Register to implement the following delays, which CMS had proposed in May:

- Multiple Best Price reporting for Value-Based Purchasing this provision from the December 2020 Medicaid <u>final rule</u> is being delayed by six months, from January 1, 2022, to July 1, 2022.
- Medicaid inclusion of the US territories (American Samoa, Northern Mariana Islands, Guam, Puerto Rico, and the Virgin Islands) — territory inclusion is being delayed from April 1, 2022 (the date established by a 2019 interim final rule with comment period) to Jan. 1, 2023.

Sources: Bloomberg Law, 340B Report

**New MDP System Is Available:** As of Nov. 19, 2021, the Medicaid Drug Program (MDP) system, which replaces the Drug Data Reporting for Medicaid (DDR) system, is now available. Within the new system, CMS posted links to video demonstrations of different areas of the MDP.

# **340B PROGRAM**

<u>Contract Pharmacy Updates</u>: Litigation related to manufacturer contract pharmacy policies continues, with two manufacturers appealing recent court decisions.

**Sources:** InsideHealthPolicy, 340B Report (link, link, link, link)

OMB Reviews Administrative Dispute Resolution Proposed Rule: On Nov. 18, 2021, the Office of Management and Budget (OMB) received a <u>proposed rule</u> titled "340B Drug Pricing Program; Administrative Dispute Resolution." The content of the proposed rule is unknown, and it is unclear how it might relate to the Administrative Dispute Resolution <u>final rule</u> that became effective Jan. 13, 2021.

Source: 340B Report

#### MEDICARE PART B

No developments to report.

# STATE LAW DEVELOPMENTS

No developments to report.

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