

Healthcare & Life Sciences Practice

Drug Pricing Digest

January 4, 2022 | Number 18

Drug Pricing Initiatives: The pathway to Senate passage of [H.R. 5376](#) (the Build Back Better Act, or BBBA) is unclear, following Senator Joe Manchin's withdrawal of his support for the measure. 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.

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

MEDICAID DRUG REBATE PROGRAM (MDRP)

Stakeholders Discuss Copay Accumulator Programs With Biden Administration: In two separate meetings, representatives of pharmacy benefit managers (PBMs) and patient advocates discussed copay accumulator and copay maximizer programs with Biden Administration officials. The programs, which PBMs established in recent years, detect manufacturer-provided patient copay assistance and do not apply those funds toward the patient's deductible and out-of-pocket maximum. Patient advocates urged the administration to ban such programs in upcoming rulemakings.

Source: [InsideHealthPolicy](#)

As discussed in the [May 24, 2021](#), and [June 7, 2021](#), issues of this digest, Pharmaceutical Research and Manufacturers of America (PhRMA) filed suit in the US District Court for the District of Columbia, challenging the portions of the December 2020 Medicaid [final rule](#) related to the price reporting treatment of manufacturer-provided patient copay assistance programs when a copay accumulator program is in place. That litigation remains ongoing.

340B PROGRAM

Contract Pharmacy Updates: An additional pharmaceutical manufacturer has implemented a contract pharmacy policy focusing on data reporting.

Source: [340B Report](#)

Litigation related to manufacturer contract pharmacy policies continues, with the government appealing the Nov. 5, 2021, ruling by the US District Court for the District of Columbia.

Source: [340B Report](#)

MEDICARE PART B

CMS Withdraws Most Favored Nation Model: As [proposed](#) on Aug. 6, 2021, the Centers for Medicare and Medicaid Services (CMS) issued a [final rule](#) on Dec. 29, 2021, to rescind the Most Favored Nation (MFN) Model [interim final rule](#).

The MFN Model interim final rule was intended to “test an alternative way for Medicare to pay for certain Medicare Part B single source drugs and biologicals” by linking payment rates for these products to international reference prices in select countries, beginning on Jan. 1, 2021. In December 2020, federal courts enjoined CMS from implementing the MFN Model, and CMS thereafter announced that the agency would not implement the MFN Model without further rulemaking.

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

STATE LAW DEVELOPMENTS

Oregon’s Annual Drug Price Transparency Report: The Oregon Department of Consumer and Business Services (DCBS), which oversees the state’s [Prescription Drug Price Transparency Program](#), published its [annual report](#) on prescription drug price transparency for 2021. Under Oregon law, manufacturers must submit reports to DCBS in connection with introducing new prescription drugs and implementing wholesale acquisition cost (WAC) increases above certain thresholds. DCBS has been collecting manufacturer information for nearly three years and is required to publish an annual report on drug pricing, with findings and recommendations for legislative changes.

In the 2021 report, DCBS addresses general drug pricing trends, as well as drug pricing for specific manufacturers and products, and proposes that the legislature expand manufacturer reporting requirements for patient assistance programs and clarify the WAC increase threshold for annual price increase reports. DCBS also addresses trends in certain “data elements,” including increasing claims for trade secret protection of reported information.

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