

Healthcare & Life Sciences Practice

Drug Pricing Digest

September 13, 2021 | Number 10

Drug Pricing Initiatives: Congress is proceeding with the budget reconciliation process, which includes proposed measures related to drug pricing. House committees are beginning to mark up sections of the legislation related to their areas of jurisdiction, after which the process will continue in the Senate, with markups by the relevant Senate committees. The budget reconciliation process allows passage in both chambers by a simple majority, providing an opportunity for the Democratic majority to advance President Biden's policy initiatives, including with respect to drug pricing.

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

The Congressional Budget Office (CBO) [issued](#) "an updated version of the model used to inform estimates of the effects of H.R. 3 on the number and timing of new drugs entering the U.S. market." The CBO had [initially](#) scored [H.R. 3](#) (the Elijah E. Cummings Lower Drug Costs Now Act) in December 2019. In this updated model, the CBO stated that a "15 percent to 25 percent reduction in expected returns for drugs in the top quintile of expected returns is associated with a 0.5 percent average annual reduction in the number of new drugs entering the market in the first decade under the policy," which then increases "to an 8 percent average annual reduction in the third decade." H.R. 3 is the Democratic drug pricing measure that, among other things, would empower the Department of Health and Human Services (HHS) to negotiate drug prices directly with manufacturers, subject to a cap based on international reference pricing.

Sources: [Scrip](#), Pink Sheet ([link](#), [link](#)), [340B Report](#)

HHS Publishes Plan Addressing Drug Prices: As noted in the [August 30 issue](#) of this digest, HHS Secretary Xavier Becerra submitted a plan regarding drug prices to the White House on Aug. 23, 2021. HHS has now published a [Comprehensive Plan for Addressing High Drug Prices](#), which was prepared pursuant to President Biden's [Executive Order](#) on Promoting Competition in the American Economy. The plan parallels many aspects of Democratic drug pricing measures pending in Congress but does not mention international reference pricing (a feature of H.R. 3).

Sources: [InsideHealthPolicy](#), [Bloomberg Law](#), [Law360](#), [Pink Sheet](#)

MEDICAID DRUG REBATE PROGRAM (MDRP)

No developments to report.

340B PROGRAM

Contract Pharmacy Updates: Litigation continues in connection with manufacturers that have adopted contract pharmacy policies.

Source: [340B Report](#)

Michelle Herzog Becomes Acting Director of OPA: In connection with the reorganization of the Health Resources and Services Administration (HRSA), Michelle Herzog has reportedly assumed the role of Acting Director of the Office of Pharmacy Affairs (OPA). The transition follows the appointment of Rear Admiral Krista Pedley, who had headed OPA since 2010, as director of HRSA's new Office of Special Health Initiatives (OSHI). For more on the HRSA reorganization, see the [August 30 issue](#) of this digest.
Source: [340B Report](#)

MEDICARE PART B

No developments to report.

STATE LAW DEVELOPMENTS

Oregon Drug Price Transparency Program Update: Oregon's prescription drug price transparency program, which has been in effect since 2019, requires pharmaceutical manufacturers to submit pricing information regarding certain wholesale acquisition cost (WAC) increases and the introduction of certain new prescription drugs. To date, Oregon reportedly has not imposed any penalties on manufacturers for non-compliance with these reporting obligations — nor has the program published any reported pricing information that manufacturers have labeled as subject to trade-secret protection. Oregon's program coordinator notes that with a staff of two, the program has limited ability to review assertions of trade-secret protections and manufacturer submissions overall.
Source: [The Lund Report](#)

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