

Healthcare & Life Sciences Practice

Drug Pricing Digest

August 16, 2021 | Number 8

\$1 Trillion Infrastructure Bill Includes Two Drug Pricing Provisions: On Aug. 10, 2021, the Senate passed [H.R. 3684](#), the Investing in a New Vision for the Environment and Surface Transportation in America Act, or the INVEST in America Act. Two provisions are of particular relevance for drug manufacturers:

- The [rebate rule](#), which would modify the anti-kickback safe harbor for rebates to apply only when the price concessions are passed through to the patient at the point of sale, would be delayed until Jan. 1, 2026.
- Manufacturers would be required to refund to Medicare the cost of discarded units of physician-administered drugs packaged in single-dose containers or single-use packages above a particular threshold.

The final vote on H.R. 3684 was 69 in favor, 30 against. On Aug. 11, 2021, the Senate adopted a \$3.5 trillion budget resolution, with a narrower vote of 50 to 49.

Sources: [The New York Times](#), Pink Sheet ([link](#), [link](#)), Bloomberg Law ([link](#), [link](#), [link](#), [link](#)), InsideHealthPolicy ([link](#), [link](#)), 340B Report ([link](#), [link](#))

President Biden Addresses Drug Pricing in Speech: On Aug. 12, 2021, President Biden delivered [remarks](#) on how his “Build Back Better” agenda will help lower prescription drug prices. He stated that “all of us ... can agree that prescription drug prices are outrageously expensive in America,” while acknowledging “the groundbreaking and lifesaving work that many pharmaceutical companies are doing.” The White House issued an accompanying [fact sheet](#) to the President’s speech.

The President’s remarks built on his recently issued [Executive Order](#) on Promoting Competition in the American Economy, which calls for multiple federal initiatives to address drug pricing. (For more on the Executive Order, see the [July 19 issue](#) of this digest.)

In his remarks, the President said the following components of Build Back Better would address and, when applicable, encourage further congressional action on prescription drug pricing reform:

- **Medicare price negotiation:** Medicare should negotiate a “fair price” for prescription drugs — “one that reflects the cost of the research and development and the need for providing for a significant profit, but that’s still affordable for consumers,” instead of “whatever the market will bear.” The President stated that “Congress is currently debating a more narrow vision letting Medicare negotiate some of the most expensive drugs, particularly from those companies that don’t face competition for that drug.”
- **Further inflation penalties:** Drug companies that raise prescription drug prices faster than inflation should have to pay a penalty. Currently, the Medicaid Drug Rebate Program incorporates such a penalty with respect to covered outpatient drugs that are paid for under state Medicaid programs; the President’s agenda seeks to impose inflation-based penalties under Medicare, as does currently proposed legislation.

- **Out-of-pocket spending caps:** Medicare beneficiaries should have a firm cap of “no more than about \$3,000 per year” on out-of-pocket costs for prescription drugs.
- **Generic and biosimilar development and approval:** The President stated that he has directed the Food and Drug Administration (FDA) to pursue accelerated development and approval of generic drugs and biosimilars, explaining that “[t]his is going to increase competition, lower drug prices for everyone.”
- **Drug importation from Canada:** The President stated that he has “ordered the FDA to work with states and Tribes to import prescription drugs safely from Canada,” noting the FDA will have determined such drugs to be safe.

Sources: [The New York Times](#), [The Hill](#), [InsideHealthPolicy](#), [Bloomberg Law](#), [BioWorld](#), [Law 360](#), [Pink Sheet](#), [Scrip](#), [340B Report](#)

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 ([link](#), [link](#), [link](#))

Mosaic Health, a New York health center, filed an antitrust suit against four major insulin manufacturers, alleging that they conspired to stop offering 340B discounts to covered entities through contract pharmacies.

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

Two additional manufacturers, Boehringer Ingelheim and Merck, have announced the implementation of contract pharmacy policies, bringing the number of manufacturers that have taken this step to eight.

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

MEDICARE PART B

CMS Proposes to Withdraw Most Favored Nation Model: On Aug. 6, 2021, the Centers for Medicare and Medicaid Services (CMS) issued a [proposed rule](#) to rescind the Most Favored Nation (MFN) Model [interim final rule](#), which was published on Nov. 27, 2020. Comments on the proposed rule are due by Oct. 12, 2021.

The MFN 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 starting 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.

CMS explained in the proposed rule that rescinding the interim final rule would permit the agency “to take time to further consider the issues identified by commenters” and to address the interim final rule’s procedural deficiencies. Notably, however, this proposed action “is limited to the codification of the November 2020 interim final rule, and does not reflect any judgment...regarding future policy.” CMS further explained that, consistent with the Biden Administration’s [Executive Order](#) on Promoting Competition in the American Economy, the agency “is exploring opportunities to promote value-based care for our beneficiaries; to address the high cost of Medicare Part B drugs, manufacturers’ pricing, and the resulting growth in Medicare Part B drug spending; and to modernize the Medicare program to improve the quality and cost of care for beneficiaries.”

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

STATE LAW DEVELOPMENTS

No developments to report.

If you have questions about the Drug Pricing Digest, please contact the Government Price Reporting team listed below or the Latham lawyer with whom you normally consult:

Christopher H. Schott

chris.schott@lw.com
+1.202.637.2208
Washington, D.C.

Stuart S. Kurlander

stuart.kurlander@lw.com
+1.202.637.2169
Washington, D.C.

Eric C. Greig

eric.greig@lw.com
+1.202.637.3330
Washington, D.C.

James M. Deal

jamie.deal@lw.com
+1.202.637.2290
Washington, D.C.

Ali Lakhani

ali.lakhani@lw.com
+1.202.637.2271
Washington, D.C.

Maria Malas

maria.malas@lw.com
+1.202.637.2334
Washington, D.C.

Lee B. Staley

lee.staley@lw.com
+1.617.880.4663
Boston

The Drug Pricing Digest is published by Latham & Watkins as a news reporting service to clients and other friends. Sources listed in this digest cannot be supplied by Latham & Watkins LLP and may require subscription access. The information contained in this publication should not be construed as legal advice. Should further analysis or explanation of the subject matter be required, please contact the lawyer with whom you normally consult. The invitation to contact is not a solicitation for legal work under the laws of any jurisdiction in which Latham lawyers are not authorized to practice. A complete list of Latham's thought leadership publications can be found at www.lw.com. If you wish to update your contact details or customize the information you receive from Latham, [visit our subscriber page](#).
