

Healthcare & Life Sciences Practice

Drug Pricing Digest

July 18, 2022 | Number 32

Drug Pricing Initiatives: Democrats renewed their efforts to pass drug pricing reform measures in the form of a revised [H.R. 5376](#) (the Build Back Better Act, or BBBA). Democrats intend to adopt the BBBA as 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 Kamala Harris casting the tie-breaking vote.

Senator Joe Manchin, one of the Democratic senators whose previous opposition to the BBBA derailed efforts at Senate passage, has indicated that he will only support certain measures intended to lower prescription drug prices and an extension of expanded Affordable Care Act subsidies that would otherwise expire at the end of 2022. President Biden issued a [statement](#) in response, urging prompt passage of drug pricing reform measures and vowing to address climate change and clean energy via Executive Order.

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

Meanwhile, a Senate bill on the cost of insulin faces delays.

Source: [Bloomberg Law](#)

Condolences

Latham & Watkins is saddened to learn that Jonathan Connell, executive director and assistant general counsel, U.S. Value, Access and Payment, Policy and Government Affairs at Bristol Myers Squibb, [passed away](#) unexpectedly on June 27, 2022. Jonathan was an important voice in the drug pricing and market access conversation, and we will miss his viewpoints and insight. Our condolences and best wishes go out to Jonathan's family, friends, and colleagues.

MEDICAID DRUG REBATE PROGRAM (MDRP)

No developments to report.

340B PROGRAM

CMS Issues Proposed 2023 Hospital Outpatient Prospective Payment System (OPPS) Rule: On July 15, 2022, the Centers for Medicare & Medicaid Services (CMS) issued the 2023 OPPS proposed rule with an accompanying [fact sheet](#). The deadline for submitting comments is Sept. 13, 2022.

This proposed rule comes after last month's Supreme Court decision in *American Hospital Association v. Becerra*, which held that it was unlawful for CMS to implement a policy for CY 2018 and CY 2019 of lowering Medicare reimbursement for drugs purchased under the 340B program to average sales price (ASP) minus 22.5%, as opposed to ASP plus 6%. For more information on this litigation, see Issue [No. 30](#) of this digest.

The 2023 OPSS proposed rule proposes to continue the ASP minus 22.5% reimbursement for 340B-purchased drugs, but CMS notes that this is "in accordance with the policy choices and calculations that CMS made in the months leading up to publication of this proposed rule before the Supreme Court issued its decision." CMS explains that in light of the Court's decision, CMS anticipates "applying a rate of ASP + 6 percent to such drugs and biologicals in the final rule for CY 2023," and that the agency is "still evaluating how to apply the Supreme Court's recent decision to prior calendar years."

Sources: [Law360](#), [340B Report](#)

Contract Pharmacy Updates: Litigation related to manufacturer contract pharmacy policies continued, with an additional manufacturer filing suit against the government in response to a letter threatening enforcement action.

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

MEDICARE PART B

CMS Issues Proposed 2023 Physician Fee Schedule: On July 7, 2022, CMS [issued](#) the 2023 Physician Fee Schedule proposed rule with an accompanying [fact sheet](#). The deadline for submitting comments is Sept. 5, 2022.

Provisions in the proposed rule include:

- **Manufacturer refunds for discarded drugs** — The proposed rule would implement Section 90004 of the Infrastructure Investment and Jobs Act, [Pub. L. 117-9](#), beginning January 2023. The law requires manufacturers to provide a refund to CMS on certain single-dose container or single-use package drugs if the value of the unused drug discarded with the container exceeds an applicable percentage of the allowable cost for the drug. The statute sets the applicable percentage at 10% and gives CMS the authority to modify it. CMS does not propose to do so in this rulemaking, but is soliciting comments regarding drugs with unique circumstances that may warrant a higher applicable percentage.
- **Elimination of separate ASP-based reimbursement for HCT/P products** — Effective Jan. 1, 2024, CMS proposes to incorporate the cost of human cells, tissues, and cellular and tissue-based products (HCT/Ps) into the practice expense (PE) relative value units (RVUs) for the associated procedure. For calendar year 2023, CMS would continue to make separate payments for these products under the current ASP-based payment methodology.

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

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.

Daniel Machado

danny.machado@lw.com
+1.202.637.2363
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

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