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Drug Pricing Initiatives: The pathway to Senate passage of H.R. 5376 (the Build Back Better Act, or BBBA) remains unclear. President Biden has suggested splitting up the BBBA and individually passing those provisions that have the support of the full Democratic caucus. Meanwhile, some Democratic Senators are pressing for passage of the bulk of such provisions in advance of President Biden's State of the Union address on March 1, 2022. House Speaker Nancy Pelosi has said she expects efforts to focus on a single, but scaled-back BBBA bill. The BBBA's drug pricing measures are reportedly backed by the full Democratic caucus, making it likely they will be included in efforts at passage. The BBBA, in its current form, 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: Politico Pro (link), InsideHealthPolicy (link, link, link, link), Bloomberg Law, Pink Sheet, 340B Report

MEDICAID DRUG REBATE PROGRAM (MDRP)

Manufacturer Legal Challenge to "Line Extension" Regulation: Incyte Corporation filed a complaint in the US District Court for the District of Columbia challenging the 2020 MDRP final rule provisions on "line extensions." The provisions became effective Jan. 1, 2022. Under the MDRP, a drug that qualifies as a line extension of an initial drug is potentially subject to an alternative Medicaid rebate formula, generally resulting in higher rebate obligations by applying the inflation penalty from the initial drug to the line extension. The concept was introduced to the MDRP by the Patient Protection and Affordable Care Act (ACA) in 2010. After a decade of issuing guidance, the 2020 MDRP final rule marked the first time the Centers for Medicare and Medicaid Services (CMS) addressed line extensions in regulation.

Incyte alleges that the 2020 MDRP final rule exceeds statutory authority and therefore unlawfully requires the company to pay higher rebates for a recently approved dermatology drug (considered a "line extension" under the 2020 MDRP final rule) that has the same active ingredient as its existing oral tablet cancer drug. The case is *Incyte Corp. v. Becerra*, No. 1:21-cv-3378 (D.D.C.).

CMS Proposed Rule to Maintain PBM Accumulator Policy: On Jan. 5, 2022, CMS published a proposed rule titled "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023." Of note to drug manufacturers, the proposed rule would maintain CMS's existing policy concerning copayment "accumulator" programs that are operated by pharmacy benefits managers (PBMs) and health plans. In general, these programs detect manufacturer-provided patient copayment assistance and do not apply those funds toward the patient's deductible and out-of-pocket maximum. The existing policy, established in a final rule that became effective July 13, 2020, states that "amounts paid toward reducing the cost sharing incurred by an enrollee using any form of direct support offered by drug manufacturers for specific prescription drugs may be, but are not required to be, counted toward the annual limitation on cost sharing."
***Source*:** Pink Sheet

Pursuant to provisions in the 2020 MDRP final rule that will become effective Jan. 1, 2023, manufacturer-provided patient copayment assistance is excludable from price reporting under the MDRP only "to the extent that the manufacturer ensures the program benefits are provided entirely to the patient," which CMS asserts would not be the case when a PBM accumulator program is in place. As reported in previous editions of this digest (Issue No. 2 and Issue No. 18), this policy is currently being challenged in federal court by the Pharmaceutical Research and Manufacturers of America (PhRMA), with summary judgment briefing underway. The case is *PhRMA v. Becerra*, No. 1:21-cv-1395 (D.D.C.).

340B PROGRAM

Contract Pharmacy Updates: Two more pharmaceutical manufacturers have implemented contract pharmacy policies, bringing the number of manufacturers with a published policy to 13.
Sources: 340B Report (link, link), Pink Sheet

Litigation related to manufacturer contract pharmacy policies continues.
Sources: In Vivo, 340B Report (link, link)

Arkansas Litigation: Litigation regarding an Arkansas state law that purports to govern the relationship between manufacturers and 340B contract pharmacies remains pending, as reported in previous editions of this digest (Issue No. 1, Issue No. 9, and Issue No. 14).
Source: 340B Report

MEDICARE PART B

No developments to report.

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.

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

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.