

Healthcare & Life Sciences Practice

Drug Pricing Digest

August 30, 2021 | Number 9

Drug Pricing Initiatives: On Aug. 24, 2021, the House of Representatives approved a \$3.5 trillion budget framework, [S. Cons. Res. 14](#), while also voting to advance the \$1 trillion infrastructure bill. The deadline for the House to pass the infrastructure bill is Sept. 27, 2021. The Senate adopted a version of the infrastructure bill earlier this month, [H.R. 3684](#) (the Investing in a New Vision for the Environment and Surface Transportation in America Act, or the INVEST in America Act). For more on the INVEST in America Act, see the [August 16 issue](#) of this digest.

In this context, House Democrats continue to discuss [H.R. 3](#) (the Elijah E. Cummings Lower Drug Costs Now Act), which, 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. 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: [InsideHealthPolicy](#), [Bloomberg Law](#), Pink Sheet ([link](#), [link](#)), [BioWorld](#), [340B Report](#)

HHS Delivers Plan Addressing Drug Prices to White House: As required by President Biden's recent Executive Order on Promoting Competition in the American Economy ([link](#)), HHS Secretary Xavier Becerra submitted a plan to the White House on Aug. 23, 2021, to address prescription drug prices. As described in the Executive Order, the plan should "enhance domestic pharmaceutical supply chains" and "reduce the prices paid by the federal government for such drugs." (For more on the Executive Order, see the [July 19 issue](#) of this digest.) It is unclear when the White House will make the HHS plan public.

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

MEDICAID DRUG REBATE PROGRAM (MDRP)

CMS Provides Timeline for Transition From DDR to MDP: In a message posted to the Drug Data Reporting for Medicaid (DDR) system, the Centers for Medicare and Medicaid Services (CMS) announced that the manufacturer transition from price reporting in DDR to the replacement system, the Medicaid Drug Program (MDP) system, "is planned for November 2021." State Medicaid programs have now begun submitting State Drug Utilization Data (SDUD) using the MDP, and SDUD will no longer be posted in DDR, beginning with Q2 2021.

340B PROGRAM

HRSA Announces Reorganization: On Aug. 27, 2021, the Health Resources and Services Administration (HRSA) [published](#) a "Statement of Organization, Functions, and Delegations of Authority" in the Federal Register. This replaces a prior organization [statement](#) published in January, which had been put on hold by the Biden Administration. According to the new statement, two offices within HRSA will be involved with the 340B program:

- “The *Immediate Office of the Administrator* for the Health Resources and Services Administration (HRSA) leads and directs programs and activities of the agency and advises the Office of the Secretary of Health and Human Services on policy matters concerning them.” The functions of the Immediate Office of the Administrator include providing “leadership and policy development in the administration of the 340B Drug Pricing Program.”
- “The *Office of Special Health Initiatives* (OSHI) provides a crosscutting focal point for HRSA to deliver on population health and Secretarial priorities, especially those that may be more clinical in nature.” The functions of this new office include providing “agency-wide leadership and policy development in the administration of the 340B Drug Pricing Program to promote access to clinically and cost effective pharmacy services to the country’s most vulnerable patient populations.”

It was reported in January that Rear Admiral Krista Pedley, longtime Director of the Office of Pharmacy Affairs (OPA), which administers the 340B program, would be promoted to become the inaugural Director of OSHI, but that promotion has not yet been publicly announced.

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

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

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

Litigation regarding the Administrative Dispute Resolution process also continues.

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

A related controversy arose in Arkansas with respect to a state law that purports to govern the relationship between manufacturers and 340B contract pharmacies.

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.

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](#).
