

Healthcare & Life Sciences Practice

Drug Pricing Digest

December 12, 2022 | Number 42

Holiday Notice

The next issue of this digest will appear in January. We wish you and your loved ones a joyful holiday season.

Inflation Reduction Act Implementation: On Dec. 1, 2022, the Centers for Medicare & Medicaid Services (CMS) distributed an invitation addressed to “All Drug Manufacturers” announcing that CMS “will host monthly one-hour calls on the implementation of the Medicare provisions” of the Inflation Reduction Act (IRA). The first call is scheduled for Dec. 13, 2022.

Sources: [Pink Sheet](#), [InsideHealthPolicy](#), [Politico Pro](#)

President Biden continues to focus on the IRA, with a spokesperson stating that “one of the biggest priorities for us right now is the change to the Part D benefits so that seniors will have a \$2,000 cap on their spending at the pharmacy.”

Source: [Bloomberg Law](#)

To learn more about the IRA’s key provisions regarding the pharmaceutical industry, please see this Latham & Watkins [Client Alert](#). It provides a roadmap to the legislation that presents the topics in a thoughtful order, while providing citations to the IRA for easy reference to the legislative text.

Health Reform and Midterm Results: Republicans are expected to use their House majority to initiate oversight of CMS, including its implementation of the IRA. Separately, some members from both sides of the aisle appear to share a renewed focus on the 340B program.

Sources: [Pink Sheet](#), [Politico Pro](#), [340B Report](#)

A Senate bill that aims to limit the cost of insulin for beneficiaries with private insurance is facing an unlikely path to passage in the Senate, which is scheduled to remain in session only until Dec. 22, 2022.

Source: [Bloomberg Law](#)

MEDICAID DRUG REBATE PROGRAM (MDRP)

No developments to report.

340B PROGRAM

HRSA Publishes Proposed Administrative Dispute Resolution Proposed Rule: On Nov. 30, 2022, the Health Resources and Services Administration (HRSA) released a proposed 340B Administrative Dispute Resolution (ADR) [rule](#). Comments are due on Jan. 30, 2023.

The proposed rule would replace the current ADR final [rule](#), which became effective on Jan. 21, 2021. Key differences between the proposed and current rule include the following:

- The 2020 final rule established that the 340B ADR board must consist of an equal number of members from HRSA, CMS, and the Health and Human Services (HHS) Office of General Counsel (OGC). The proposed rule would make HRSA's Office of Pharmacy Affairs (OPA) the exclusive source of panel members.
- The proposed rule would no longer require ADR proceedings to be governed by the Federal Rules of Evidence (FRE) and Civil Procedure (FRCP).
- The current minimum relief threshold of \$25,000 for claims would be eliminated.

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

A coalition of health centers that had challenged the existing ADR regulation in court dropped its suit in response to the proposed rule. The case is *Nat'l Ass'n of Community Health Centers v. Azar, et al.*, No. 1:20-cv-03032 (D.D.C.). The litigation was discussed in issue [No. 1](#) of this digest. A related case brought by an association of Ryan White clinics remains ongoing.

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

340B Reform Initiatives: A recent proposal to create a separate program for non-hospital covered entities, dubbed the 340C program, continues to be a focus of discussion. The program was proposed by the Advocates for Community Health ([ACH](#)), a newly formed group composed of Federally Qualified Health Centers.

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

Two recent studies analyzed the impact of the 340B program on drug pricing. One [study](#), commissioned by the Pharmaceutical Research and Manufacturers of America (PhRMA), found that "on average, biosimilar utilization at 340B outpatient hospitals is lower than at non-340B outpatient hospitals" during the period studied. The second [study](#) noted that research "suggests that 340B is one of many factors putting upward pressure on launch prices."

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

MEDICARE PART B

No developments to report.

STATE LAW DEVELOPMENTS

Colorado Pursues Drug Importation: Colorado is pursuing its aim to import prescription drugs from Canada. The state submitted the list of drugs it seeks to import to the federal government. The importation mechanism and related litigation is discussed in issues [No. 3](#) and [No. 29](#) of this digest.

Source: [The Colorado Sun](#)

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

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](#).
