

August 29, 2022 | Number 35

Inflation Reduction Act Signed Into Law: On Aug. 16, 2022, President Biden signed into law H.R. 5376, the Inflation Reduction Act of 2022 (the Act). To learn more about the Act's key provisions regarding the pharmaceutical industry, please see this Latham & Watkins <u>Client Alert</u>. It provides a roadmap to the legislation that presents the topics in a thoughtful order, while providing citations to the Act for easy reference to the legislative text.

Sources: Politico Pro (link, link), InsideHealthPolicy, Law360, Bloomberg Law

Commentators continue to analyze how the Act may impact the pharmaceutical industry. **Sources:** BioWorld, Scrip, InsideHealthPolicy, Pink Sheet (link, link), In Vivo (link, link), Bloomberg Law, Stat (link, link, link), The Hill

The Centers for Medicare & Medicaid Services (CMS) reportedly is beginning the process of recruiting staff to operate the Act's negotiation program. **Source:** U.S. News & World Report

## MEDICAID DRUG REBATE PROGRAM (MDRP)

No developments to report.

### 340B PROGRAM

**Program Growth Continued in 2021:** According to data obtained from the Health Resources and Services Administration (HRSA) through a Freedom of Information Act request, 340B program sales amounted to approximately \$43 billion in 2021, an increase of approximately 16% over 2020. **Sources:** Drug Channels, Stat, Pink Sheet

<u>Contract Pharmacy Updates</u>: Litigation related to manufacturer contract pharmacy policies continues. *Sources:* 340B Report (<u>link</u>, <u>link</u>)

<u>Medicare Reimbursement Policy Litigation Updates</u>: Litigation continues related to the proper remedy following the recent Supreme Court ruling that the CY 2018 and 2019 Medicare reimbursement rate for drugs purchased under the 340B program of average sales price (ASP) minus 22.5%, as opposed to ASP plus 6%, was unlawful. The Court's opinion is described in Issue <u>No. 30</u> of this digest. **Sources:** InsideHealthPolicy, 340B Report (link, link, link)

<u>Arkansas 340B Statute Litigation Updates</u>: Litigation continues regarding an Arkansas state law that purports to govern the relationship between manufacturers and 340B contract pharmacies, as reported in previous editions of this digest (Issues <u>No. 1</u>, <u>No. 9</u>, <u>No. 14</u>, <u>No. 22</u>, and <u>No. 27</u>). *Source:* <u>340B Report</u> <u>"Patient" Definition Litigation Updates</u>: Litigation challenging HRSA's definition of "patient" continues. The case is described in Issue <u>No. 31</u> of this digest. *Source:* <u>340B Report</u>

### **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.

#### Daniel Machado

danny.machado@lw.com +1.202.637.2363 Washington, D.C.

# Stuart S. Kurlander

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

#### Maria Malas

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

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

### Lee B. Staley

lee.staley@lw.com +1.617.880.4663 Boston

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