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Inflation Reduction Act: Stakeholders and commentators continue to review H.R. 5376, the Inflation Reduction Act of 2022 (the Act), which became law on Aug. 16, 2022. **To learn more about the Act'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 Act for easy reference to the legislative text.

Republican leaders on the House Energy & Commerce and Ways & Means committees sent a letter to the Secretary of the Department of Health and Human Services (HHS) asking 18 questions about how HHS will implement the mandatory negotiation provisions of the Act and requesting monthly briefings. The letter highlights many of the areas in which the Act is unclear or provides significant discretion to HHS in its implementation.

One question concerns the use of guidance by HHS. The Act instructs that many provisions initially may be implemented by program instruction or other forms of program guidance, rather than through notice and comment rulemaking.
Sources: InsideHealthPolicy, Pink Sheet, 340B Report

Commentators continue to analyze how the Act may impact the pharmaceutical industry, including how the negotiation process could be implemented, the interplay between negotiated prices and the Medicare Part D benefit redesign, how HHS might consider comparative effectiveness in the negotiation process, and whether states could expand the areas in which the negotiated price will be charged.
Sources: Pink Sheet (link, link), In Vivo, InsideHealthPolicy

Legal Challenge to Regulation Permitting Co-Pay/PBM Accumulator Programs: Patient advocacy groups have filed a legal challenge to a Trump-era regulation that allows insurers and pharmacy benefit managers (PBMs) to implement so-called co-pay accumulator programs. Under these programs, manufacturer-provided co-pay assistance is not applied to reduce the patient deductible or out-of-pocket maximum. This often results in the patient unexpectedly needing to satisfy the full deductible / out-of-pocket maximum when the manufacturer co-pay assistance is exhausted. The case is *HIV & Hepatitis Pol'y Inst. v. Dep't of Health & Human Servs.*, No. 1:22-cv-02604 (D.D.C. filed Aug. 30, 2022).
Sources: Bloomberg Law, InsideHealthPolicy, Pink Sheet, Politico Pro, Stat

Florida Files FOIA Suit Against FDA Over Drug Importation Plan: Florida's application with the Food and Drug Administration (FDA) regarding the state's Canadian Prescription Drug Importation Program, which relies on a Trump-era final rule, has been pending since 2019. The state has now filed litigation against FDA, following the agency's failure to timely respond to a Freedom of Information Act (FOIA) request that Florida had filed in order to obtain documents related to its own application as well as those of other states, including New Mexico and Colorado. The case is *Florida v. FDA*, No. 8:22-cv-01981 (M.D. Fla. filed Aug. 29, 2022).

As noted in Issue No. 29 of this digest, FDA recently issued a guidance document with frequently asked questions related to the importation final rule. The final rule remains subject to litigation by the Pharmaceutical Research and Manufacturers of America (PhRMA) (see Issue No. 3), which alleges that the final rule will weaken the drug distribution system, undermine regulatory protections designed to protect consumers, and "violate manufacturers' First Amendment rights, and raise serious questions under the Fifth Amendment Takings Clause." The case is *PhRMA v. HHS*, No. 1:20-cv-03402 (D.D.C. filed Nov. 23, 2020).
Sources: Bloomberg Law, The Hill

MEDICAID DRUG REBATE PROGRAM (MDRP)

No developments to report.

340B PROGRAM

Contract Pharmacy Updates: Litigation related to manufacturer contract pharmacy policies continues.
Source: 340B Report (link, link)

Antitrust litigation (discussed in Issues No. 19 and No. 22) filed by Mosaic Health, a New York health center, alleging that four major insulin manufacturers had conspired to stop offering 340B discounts to covered entities through contract pharmacies, was dismissed.
The case is *Mosaic Health, Inc. v. Sanofi Aventis U.S., LLC*, No. 6:21 cv 6507-EAW (W.D.N.Y.).
Source: Bloomberg Law

MEDICARE PART B

MedPAC Discusses Payment Caps for Accelerated Approval Drugs: At a recent meeting, the Medicare Payment Advisory Commission (MedPAC), an independent agency that advises Congress on issues affecting the Medicare program, again discussed drugs approved under the accelerated pathway. MedPAC is considering whether coverage with evidence development (CED) requirements for such drugs should be "uncoupled" from Medicare reimbursement caps.

As noted in previous editions of this digest, drugs approved under the accelerated pathway have been the focus of recommendations by MedPAC (Issues No. 26 and No. 13) and the Medicaid and CHIP Payment and Access Commission (MACPAC) (Issue No. 1).
Sources: Pink Sheet, MedPage Today, 340B Report

STATE LAW DEVELOPMENTS

No developments to report.

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