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Drug Pricing Reform: 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.
Sources: STAT, BioWorld, Pink Sheet (link, link)

Ahead of the November midterm elections, House Republicans have released details of their legislative healthcare agenda.
Sources: Bloomberg Law, InsideHealthPolicy

Meanwhile, drug prices continue to be a topic of discussion, with the Medicare Payment Advisory Commission (MedPAC) urging further changes in the Medicare Part B space, and other organizations focusing on the impact of middlemen, such as pharmacy benefit managers.
Sources: Pink Sheet, Bloomberg Law

New EU Regulation on Health Technology Assessments, Effective 2025: Following several years of deliberation, the Regulation on Health Technology Assessment (Regulation (EU) 2021/2282) was adopted in December 2021. This regulation for the first time introduces a permanent legal framework for joint, EU-level health technology assessment (HTA) work that will cover joint clinical assessments, joint scientific consultations, the identification of emerging health technologies, and voluntary cooperation between Member States. Importantly, Member States are to remain responsible for all non-clinical aspects of HTA, including pricing and reimbursement. At present, HTA procedures within the EU are conducted at a national or regional level, against the backdrop of some voluntary EU-funded project-based cooperation between Member States.

While the HTA regulation entered into force in January 2022, it will only begin to apply from January 2025, with preparatory and implementation-related steps to take place in the interim. Thereafter, it will have a staggered implementation in relation to different classes of medicinal products.

To learn more about the HTA regulation, please see this Latham & Watkins Client Alert, which provides an overview of the key aspects of the regulation, including details of its phased implementation.

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)

In a related development, the Government Accountability Office (GAO) is reportedly preparing a study on whether 340B hospitals share 340B savings with patients at their in-house and contract pharmacies.
Source: 340B Report

Covered Entity's "Patient" Definition Challenge Continues: Litigation continues related to Genesis Healthcare Inc.'s challenge to the "patient" definition set forth under guidance from the Health Resources and Services Administration (HRSA). The litigation is discussed in more detail in Issue No. 31 of this digest.
Source: 340B Report

Arkansas 340B Statute Litigation Updates: 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 No. 1, No. 9, No. 14, No. 22, No. 27, and No. 35).

Meanwhile, the Arkansas Insurance Department (AID) released a final regulation implementing the statute.
Source: 340B Report (link, link)

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:

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