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Health Reform and Midterm Results: In the wake of the midterm elections, leadership changes of key committees are underway. Commentators note that while both parties may agree on problems in the pharmaceutical and healthcare industries, agreement on potential solutions is limited. Areas of overlap may include facilitating drug importation. House Republicans are expected to use their oversight function to scrutinize implementation of the Inflation Reduction Act (IRA).
Sources: Bloomberg Law, BioWorld, InsideHealthPolicy (link, link, link, link), Pink Sheet

Inflation Reduction Act Implementation: Dr. Meena Seshamani, M.D., Ph.D. as deputy administrator and director of Center for Medicare at the Centers for Medicare & Medicaid Services (CMS) indicated that she has begun to meet with stakeholders, such as health plans and pharmaceutical manufacturers. CMS is seeking to fill nearly 100 positions in the new Medicare Drug Rebate and Negotiations Group.
Source: Bloomberg Law

Pharmaceutical manufacturers reportedly have begun to take corporate actions in response to the IRA provisions.
Source: Pink Sheet

Commentators are focusing on the potential impact of the different treatment of drugs and biologics under the IRA's negotiation provision. Drugs approved under New Drug Applications become eligible for forced negotiation seven years after approval, while products approved under Biologics License Applications do not become eligible until 11 years after approval.
Sources: Bloomberg Law (link, link), Pink Sheet

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.

MEDICAID DRUG REBATE PROGRAM (MDRP)

No developments to report.

340B PROGRAM

Contract Pharmacy Updates: Oral argument in three consolidated cases, brought by Sanofi Aventis, Novo Nordisk, and AstraZeneca, took place on Nov. 15, 2022, before a three-judge panel of the US Court of Appeals for the Third Circuit. The judges' questioning focused on whether the 340B statute prohibits manufacturers from imposing any conditions whatsoever on contract pharmacy orders, which is the position advanced by the government. Additional discussion explored whether the notice and comment rulemaking that resulted in the 2020 Administrative Dispute Resolution regulation was defective.

The cases are:

AstraZeneca Pharm. LP v. Sec'y U.S. Dep't of Health & Human Servs., No. 22-1676 (3d Cir. 2022)
Novo Nordisk Inc. v. U.S. Dep't of Health & Human Servs., No. 21-3168 (3d Cir. 2021)
Sanofi Aventis US LLC v. U.S. Dep't of Health & Human Servs., No. 21-3167 (3d Cir. 2021)

Sources: Law360, Bloomberg Law, 340B Report (link, link)

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, No. 35, No. 37, and No. 39).

On Nov. 17, 2022, an Arkansas hospital submitted a complaint to the Arkansas insurance commissioner seeking to enforce the Arkansas state law and implementing regulation against Novo Nordisk Inc. in connection with the manufacturer's contract pharmacy policy. ***Source:*** 340B Report (link, link)

MEDICARE PART B

2023 Physician Fee Schedule (PFS) Implements Refunds for Discarded Units: CMS is finalizing its proposals for implementing Section 90004 of the Infrastructure Investment and Jobs Act, Pub. L. 117-9. The law requires manufacturers to provide a refund to CMS on certain single-dose container or single-use package drugs if the value of the unused drug discarded with the container exceeds an applicable percentage of the allowable cost for the drug. The PFS final rule finalizes the proposed definition of a refundable single-dose container or single-use package as a drug or biological for which payment is made under Part B and that is furnished from a single-dose container or single-use package. The refund will first be due with respect to Q1 2023.

The statute sets the applicable percentage at 10% and gives CMS discretion to modify the percentage. Upon reviewing comments from stakeholders, CMS retained the 10% threshold, but finalized an increased applicable percentage of 35% for drugs reconstituted with a hydrogel that meet certain administration requirements. In addition, CMS plans to collect additional information and engage stakeholders through future notice and comment rulemaking regarding other drugs with unique circumstances that may merit higher percentages.

Finally, while CMS had proposed invoicing manufacturers for discarded drug amounts annually, starting Oct. 1, 2023, CMS instead will delay invoicing in order to create "system efficiencies" related to the new IRA Part B inflation rebate. That rebate also first applies Q1 2023, but the IRA gives CMS until Sept. 30, 2025, to invoice the rebate for quarters in 2023 and 2024. It is unclear how long CMS will delay invoicing for the discarded unit refund amount. The PFS states that CMS intends "to address the timing of these reports in future rulemaking" but also indicates that CMS will issue "a preliminary report on estimated discarded [drug] amounts based on available claims data" for the first two calendar quarters of 2023 no later than Dec. 31, 2023.
Sources: BioWorld, Pink Sheet

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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