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Visit in Person With Latham's Government Price Reporting Team at the 2022 Medicaid Drug Rebate Program Summit

The conference, which provides live as well as virtual access, will take place Oct. 12-14 in Chicago. Latham partner Christopher H. Schott will speak at two sessions on Oct. 12 and 13. We look forward to connecting in person at the Latham booth or through the conference's virtual platform.

Drug Pricing Reform: President Biden, in remarks delivered on Sept. 27, 2022, touted insulin pricing provisions in H.R. 5376, the Inflation Reduction Act of 2022 (IRA), which became law on Aug. 16, 2022. He referred to reducing the cost of prescription drugs as "one of my top priorities," stating that "for years, Big Pharma has stood in the way," but that this year "the American people won, and Big Pharma lost."
Sources: InsideHealthPolicy, MedPage Today

Other developments related to the IRA include:

- Four Republican Senators Introduce Repeal of Medicare Price Negotiation — S. 4953, the Protect Drug Innovation Act, would repeal the IRA's mandatory drug negotiation provision. Senator James Lankford, a member of the Senate Finance Committee and a sponsor of the bill, said in a statement that we "need more competition, not price controls," and noted that the "ongoing issues with pharmacy benefit managers, the drug pricing middlemen, were also not addressed" in the IRA.
  Source: Politico Pro
- CMS Begins Staffing of Drug Pricing Function — Reportedly, the Centers for Medicare & Medicaid Services (CMS) outlined plans to lawmakers to create a "Medicare Drug Rebate and Negotiations Group" with six divisions and 95 full-time employees. The IRA appropriated $3 billion to CMS to carry out the negotiation provisions.
  Sources: STAT (link, link), Bloomberg Law
- Higher Biosimilar Add-On Payment — Beginning on Oct. 1, 2022, the IRA increases the Medicare Part B payment rate for qualifying biosimilars from Average Sales Price (ASP) of the reference drug plus 6% to ASP of the reference drug plus 8% for five years. Qualifying biosimilars have a lower ASP than the reference drug. Oct. 1 also marks the beginning of the first period for which the Medicare Part D inflation rebate will be due.
  Sources: InsideHealthPolicy, Pink Sheet, Bloomberg Law
- Comments on the Basis for Medicare Inflation Rebates — Commentators noted that the Medicare Parts B and D inflation rebates, while due only on Medicare units, will have an amount determined by reference to commercial prices. That is because the Part B rebate is linked to ASP and the Part D rebate to Average Manufacturer Price (AMP), and both of these price types include commercial pricing.
  Sources: InsideHealthPolicy, STAT, 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.

FDA User Fee Program Reauthorized: On Sept. 30, 2022, President Biden signed into law H.R. 6833, the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023 (the Act), which contains Food & Drug Administration (FDA) user fee reauthorizations. The Act reauthorizes FDA's prescription drug and biological product, generic drug, biosimilar biological product, and medical device user fee programs from FY 2023 through FY 2027 and authorizes FDA to increase the total amount of annual user fees for all product categories compared to prior user fee authorization programs. While no material reforms to the Federal Food, Drug, and Cosmetic Act are attached to the reauthorization, several members of Congress have identified a future omnibus appropriations bill as a vehicle for potential further reforms to the FDA regulatory framework.

To learn more about the FDA user fee program reauthorization, please see this Latham & Watkins Client Alert.

MEDICAID DRUG REBATE PROGRAM (MDRP)

No developments to report.

340B PROGRAM

Contract Pharmacy Updates: The Department of Health and Human Services (HHS) Office of Inspector General (OIG) has reportedly notified a group of House members that it does not plan to impose civil monetary penalties on manufacturers in connection with their contract pharmacy policies. OIG reportedly wants to wait for resolution of the various pending contract pharmacy lawsuits.
Source: 340B Report

The litigation related to manufacturer contract pharmacy policies continues, with oral arguments in various cases now scheduled for Oct. 24, Oct. 31, and Nov. 15.
Source: 340B Report (link, link)

A ninth manufacturer has filed suit against the Health Resources and Services Administration (HRSA) to challenge a letter from the agency threatening enforcement action in connection with the manufacturer's contract pharmacy policy.
Source: 340B Report

CBO Analysis Notes 340B Program May Incentivize Provider Consolidation: In an analysis titled "Policy Approaches to Reduce What Commercial Insurers Pay for Hospitals' and Physicians' Services" published Sept. 29, 2022, the Congressional Budget Office (CBO) identifies consolidation of providers as a source of increased costs to commercial insurers. The study notes that the desire to become 340B eligible may incentivize consolidation of providers, and suggests that applying 340B discounts "on a patient-level basis—that is, to patients with certain characteristics rather than to all patients at certain sites of care—might reduce hospitals' and physicians' incentives to consolidate."

The 340B "patient" definition remains subject to Genesis Healthcare Inc.'s legal challenge, as discussed in more detail in Issue No. 31 of this digest.
Sources: InsideHealthPolicy, 340B Report

Medicare 340B Reimbursement Policy Litigation Updates: The US District Court for the District of Columbia ruled on Sept. 28, 2022, that the Medicare reimbursement rate for drugs purchased under the 340B program of ASP minus 22.5%, as opposed to ASP plus 6%, cannot remain in place until the end of

the year and must end immediately. In a court filing, CMS indicated that it would take approximately two weeks to implement the ASP plus 6% payment rate. These developments follow the recent Supreme Court ruling in the matter, which is described in Issue No. 30 of this digest.
Sources: Law360, Bloomberg Law, InsideHealthPolicy (link, link), 340B Report (link, link)

Administrative Dispute Resolution (ADR) Matter Dismissed: The HHS Administrative Dispute Resolution (ADR) Panel has dismissed claims brought by community health centers related to certain manufacturers' contract pharmacy policies, on the grounds that the dispute had already been resolved by a federal district court.
Source: InsideHealthPolicy

MEDICARE PART B

No developments to report.

STATE LAW DEVELOPMENTS

No developments to report.

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