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2022 Medicaid Drug Rebate Program Summit Concludes: The annual Medicaid Drug Rebate Program Summit took place Oct. 12-14 in Chicago. Latham partner Christopher H. Schott spoke at two sessions: the panel "Ask the Attorneys: What Keeps Them Up at Night," and a presentation on Health Resources and Services Administration (HRSA) manufacturer audits under the 340B program.

Adam Freeman, Deputy Regional Inspector General at the US Department of Health and Human Services (HHS) Office of Inspector General (OIG), and Michael Kvassay, Social Science Research Analyst and Team Leader at the HHS OIG, presented a session titled "Recent OIG Work Involving Prescription Drug Pricing and Payment." The speakers highlighted three recent OIG reports:

- Part D Plan Preference for Higher-Cost Hepatitis C Drugs Led to Higher Medicare and Beneficiary Spending — OIG found that Medicare beneficiaries were more likely to be prescribed brand-name versions of hepatitis C treatments, as compared to Medicaid beneficiaries. The report attributes this pattern to a lack of authorized generics on Part D formularies and recommends that the Centers for Medicare & Medicaid Services (CMS) encourage Part D plans to increase access to authorized generic hepatitis C drugs.
- Medicare Part D and Beneficiaries Could Realize Significant Spending Reductions With Increased Biosimilar Use — OIG found that biosimilars are used less frequently than reference products and recommends that CMS encourage Part D plans to increase access to and use of biosimilars.
- Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2020 Average Sales Prices — When certain conditions exist for a drug, CMS substitutes the Average Sales Price (ASP)-based payment amount with an Average Manufacturer Price (AMP)-based payment amount. The report concluded that CMS did not correctly implement this substitution during the period evaluated in the report.

The speakers explained that Congress has directed OIG to submit a report no later than Jan. 1, 2023, "on the accuracy of ASP information submitted by manufacturers and to include any recommendations on how to improve the accuracy of that information." They noted that drug spending is an OIG priority, particularly in light of the Inflation Reduction Act of 2022 (IRA) and that there is internal coordination across OIG components on this effort.

President Biden Signs Drug Cost Executive Order: On Oct. 14, 2022, President Biden signed Executive Order (EO) 14087, Lowering Prescription Drug Costs for Americans. The purpose of the EO is to "take additional actions to complement the IRA and further drive down prescription drug costs." Among other things, the EO requires the Secretary of HHS to "consider whether to select for testing by the

[Center for Medicare and Medicaid Innovation] new health care payment and delivery models that would lower drug costs and promote access to innovative drug therapies for beneficiaries enrolled in the Medicare and Medicaid programs, including models that may lead to lower cost-sharing for commonly used drugs and support value-based payment that promotes high-quality care."
Sources: Bloomberg Law, Law360, InsideHealthPolicy, Pink Sheet, The Hill, 340B Report

Inflation Reduction Act: CMS has begun issuing guidance to implement the IRA, consisting of an FAQ document and a timeline. A separate FAQ document addresses the temporary Part B reimbursement increase for qualifying biosimilars.

In addition, CMS has published a Federal Register notice establishing the Medicare Drug Rebate and Negotiations group. Major tasks of the group include developing "policy, including identifying and vetting policy options and preparing policy memoranda, rulemaking and technical guidance," establishing "operational processes to collect data from manufacturers and other sources," and conducting "pharmacoeconomic analyses and assessments of selected drugs."
Sources: Bloomberg Law, Pink Sheet (link, link)

Meanwhile, stakeholders continue to discuss the IRA and its implications.
Sources: STAT (link, link, link), Bloomberg Law, Scrip, Wall Street Journal, In Vivo

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.

Drug Pricing Reform: The IRA has been criticized for failing to address the role of Pharmacy Benefit Managers (PBMs) and other middlemen involved in pharmaceutical distribution. S. 4293, the Pharmacy Benefit Manager Transparency Act of 2022, which was introduced in the Senate in May, would focus on PBMs.
Source: FDLI

The Medicare Payment Advisory Commission (MedPAC) is reviewing Medicare Part D rebate data to analyze the impact of rebates on Medicare Part D drug pricing, but that analysis may be complicated by the recent passage of the IRA. MedPAC is also considering Medicare Part B reimbursement changes.
Sources: Pink Sheet, 340B Report

MEDICAID DRUG REBATE PROGRAM (MDRP)

No developments to report.

340B PROGRAM

Contract Pharmacy Updates: 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. Meanwhile, HRSA has sent violation notices to two additional manufacturers and has referred an additional manufacturer to the OIG.
Source: 340B Report (link, 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, and No. 37).
Source: 340B Report

Medicare 340B Reimbursement Policy Litigation Updates: In a Medicare Learning Network newsletter dated Oct. 13, 2022, CMS announced that it is uploading revised Hospital Outpatient

Prospective Payment System (OPPS) files "that will apply the default rate (generally ASP plus 6%) to 340B-acquired drugs for the rest of the year." CMS also stated that it "will reprocess claims our contractors paid on or after September 28, 2022, using the default rate (generally ASP plus 6%)." This action comes in response to a ruling by the US District Court for the District of Columbia following the recent Supreme Court ruling in the matter, as described in Issues No. 38 and No. 30 of this digest.
Source: 340B Report

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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