wiley

ALERT

Recent Developments in Pharmacy-Related Legislation and Regulations

May 14, 2024

Over the last two months, there has been a steady influx of regulatory and legislative efforts regarding drug pricing and the pharmacy industry. To streamline your review, we summarize below a few noteworthy developments that are currently shaping the regulatory landscape.

GAO Publishes Report on PBM State Regulation

In April, the U.S. Government Accountability Office (GAO) published a report examining the regulation of pharmacy benefit managers (PBMs) in five states. Through the report, GAO aimed to identify the current framework for PBM regulation and the lessons learned from regulators. While there were nuances particular to each of the five states, GAO's general framing of the regulators' common themes included tackling drug pricing and pharmacy payments by (i) regulating the way in which PBMs use or design the tiered method of reimbursing pharmacies for drugs; (ii) targeting "spread pricing" practices (where a PBM charges health plans more than they pay the pharmacies); and (iii) restricting a PBMs' use of manufacturer rebates. GAO also reviewed other regulatory approaches seeking to curb the trend of rising drug costs. It can be expected that any future proposed legislation concerning PBMs by other states or nationally will consider the GAO findings and address PBM regulation similarly, albeit more expansively, than the five states evaluated in the report.

HRSA Finalizes 340B ADR Process

On April 19, 2024, the U.S. Department of Health and Human Services (HHS) Health Resources and Services Administration (HRSA) issued a final rule for the 340B Program's administrative dispute resolution

Authors

Dorthula H. Powell-Woodson
Partner
202.719.7150
dpowell-woodson@wiley.law

Jordan Ross
Associate
202.719.3264
jross@wiley.law

Brooke M. DeLoatch
Associate
202.719.3765
bdeloatch@wiley.law

Practice Areas

Health Care

Medicare Drug Pricing

Pharmacy Benefit Manager (PBM) Contracting

(ADR) process. The final rule further establishes the 340B ADR process, which has been an ongoing regulatory development since its inception under the Affordable Care Act. Some key changes to the ADR process include but are not limited to (i) removing adherence to the Federal Rules of Evidence and Civil Procedure; (ii) requiring ADR panel members to be subject matter experts and undergo additional screening for conflicts; (iii) limiting claims to disputes involving overcharges, duplicate discounts, and diversion; (iv) no longer suspending claims with the same or similar issue pending in a federal court; and (v) explicitly allowing claims regarding a manufacturer's restriction on sales of drugs at or below the 340B ceiling price to be brought before the ADR panel. The final rule will be effective on June 18, 2024, with supplemental information to be provided by HRSA in the coming months.

Draft Legislation Introduced to Address Prescription Drug Shortages

On May 3, 2024, Senate Finance Committee Chairman Ron Wyden (D-OR) and Ranking Member Mike Crapo (R-ID) released a quite ambitious draft legislative proposal to address prescription drug shortages. The proposal would set forth a new program within Medicare to improve contracting and purchasing in the drug supply chain. The proposal would offer prevention and mitigation incentive payments to certain Medicare providers that adopt certain proscribed standards designed to ameliorate generic drug shortages. Other measures in the draft legislation include (i) minimum three-year contracts with manufacturers for generic drugs with high risk of shortages; (ii) purchase volume commitments and stable pricing; (iii) contingency contracts with alternate manufacturers; (iv) prohibitions on anticompetitive practices; and (v) transparency requirements regarding manufacturer quality control. The draft has yet to be introduced in Congress, but Wiley will continue to monitor its legislative trajectory.

CMS Issues Draft Guidance for IRA Drug Price Negotiation Program for 2027

Also on May 3, 2024, the Centers for Medicare & Medicaid Services (CMS) issued new draft guidance for the second cycle of negotiations for the Medicare Drug Price Negotiation Program (Negotiation Program) established by the Inflation Reduction Act of 2022 (IRA). The Negotiation Program allows CMS to negotiate drug prices for certain Medicare Part B and Part D drugs (for more information, see Wiley's alert summarizing the Price Negotiation Program).

The Negotiation Program has continued to move forward despite challenges from segments of the pharmacy industry, including claims from drugmakers that the Negotiation Program is unconstitutional and violates the due process clause. As the program is undergoing scrutiny, it is important to acknowledge that the fundamental structure and implementation schedule of the Negotiation Program may be altered due to these litigation efforts. While only one case has made it to the appellate level, litigation against the Negotiation Program remains ongoing.

Assuming any pending litigation does not substantively impact the Negotiation Program's structure and timing, the second cycle of negotiations will occur during 2025 and may result in negotiated Maximum Fair Prices (MFPs) that would be effective beginning in 2027. CMS's draft guidance sets forth the requirements and parameters for these negotiations. The draft guidance is similar to the approach previously adopted by CMS;

however, there are a few changes (see Wiley's alert summarizing CMS's initial guidance for the first cycle of negotiations). Notable apparent changes include but are not limited to (i) use of a Medicare Transaction Facilitator (MTF) to facilitate the exchange of data and payment between pharmaceutical supply chain entities; (ii) obligating manufacturers to timely report certain updates to data submissions when negotiating the MFP for a selected drug; and (iii) a civil monetary penalty for a manufacturer's failure to meet the MTF reporting requirements.

CMS issued an accompanying fact sheet with a timeline for the upcoming negotiations, noting CMS's final guidance can be expected in Fall 2024.

***

Wiley's multidisciplinary Health Care team of experienced attorneys and advisors is closely monitoring these developments and is available to assist with any questions.