Q3 2024 State and Federal Regulatory and Legislative Activity Update

carelon Rx

The drug pricing regulatory and legislative landscape continues to evolve rapidly at both federal and state levels. Below we highlight a few of the major changes that have occurred between June 25 and August 23, 2024.

Federal regulatory activity

General drug update

Federal Trade Commission (FTC) interim PBM report

On July 9, 2024, the FTC released an interim report from its investigation into the business practices of six PBMs — CVS Caremark, Express Scripts, OptumRx, Humana, Prime, and MedImpact. The report largely relied on anecdotes and public comments.

Following the release of the interim report, FTC Commissioner Melissa Holyoak issued a dissenting statement noting that the report was plagued by process irregularities, devoid of empirical evidence, and built entirely around unsupported assertions.

FTC Commissioner Andrew Ferguson also criticized the study's approach in a statement and noted that the interim report relied heavily on anonymous public comments submitted to the FTC that cannot be verified and therefore should not be treated as fact-based.

Draft biosimilar interchangeable guidance

On June 20, 2024, the FDA issued draft guidance that would eliminate switching studies as a requirement for biosimilar manufacturers seeking interchangeable status and would make it easier for manufacturers to receive the interchangeable designation. Under the draft guidance, biosimilar manufacturers may choose to provide an assessment (such as comparative analytical data), rather than switching studies, to satisfy that the interchangeable status has been met. Comments on the guidance are due to the FDA by September 20, 2024.

Congressional activity

Senate activity

Patent thicket legislation

On July 11, 2024, the Senate passed the Affordable Prescriptions for Patients Act of 2023 (S.150) by unanimous consent. The legislation would end "patent thickets" and "patent evergreening" by enforcing the tenets of the Hatch-Waxman patent law. Hatch-Waxman provides a time-limited market exclusivity for branded prescription drugs before allowing market competition from generic and biosimilar alternatives. However, the legislation was amended so it no longer includes a "product-hopping" prohibition. The Congressional Budget Office (CBO) estimated the legislation — before the product-hopping prohibition was cut — would reduce the federal deficit by more than $3 billion over 10 years. Without that provision, the CBO said it would save $1.8 billion over ten years.

House and Senate Republican Committee leaders request review of Medicare Part D premium stabilization demonstration

On August 5, 2024, House Ways & Means Committee Chair Smith (R-MO), House Energy & Commerce Committee Chair Rodgers (R-WA) and Senate Finance Committee Ranking Member Crapo (R-ID) sent a letter to the U.S. Government Accountability Office (GAO) requesting a review and accusing the Administration of deflating seniors' premiums without budgetary analysis and clear statutory basis or credible research goals.

House activity

Anti-obesity legislation

On June 27, 2024, the House Ways and Means Committee advanced the Treat and Reduce Obesity Act of 2023 that would allow Medicare prescription drug plans starting in 2027 to cover weight-loss medications to treat obesity if the patient already had received insurance coverage for the drugs on a health plan in the year before joining Medicare. The committee advanced the bill by a 36-4 vote. The next step for the bill remains unclear but could be considered by Congress in the lame-duck period after the 2024 elections.

House Oversight and Accountability Committee PBM hearing

On July 23, 2024, executives from Express Scripts, CVS Caremark, and OptumRx testified before the House Oversight and Accountability Committee. The executives focused their testimony on the ways in which PBMs lower drug costs for patients despite the high list prices set by manufacturers.

State legislative activity

Recently enacted major legislation

Louisiana

On June 25, 2024, Governor Jeff Landry signed SB 444 into law that will prohibit a PBM from reimbursing pharmacies or pharmacists less than the acquisition cost for the drug, device, or service. The new law takes effect on January 1, 2025, and applies to pharmacies and pharmacists that do not own more than five shares or five percent interest in a pharmaceutical wholesale purchasing group or vendor of covered drugs, devices, or services.

Pennsylvania

On July 17, 2024, Governor Josh Shapiro signed HB 1993 into law. This law (Act 77 of 2024) prohibits a PBM from mandating the use of an affiliated pharmacy/mail order or the unilateral altering of any contract with a pharmacy or PSAO. A health benefit plan, health insurer, or PBM contracting with a health benefit plan or health insurer may not collect from the member any difference in cost sharing the member pays to the pharmacy and the member's cost sharing defined in the member's benefit plan. The Act also prohibits a PBM from designating a prescription drug as a specialty drug or require a prescription drug to be dispensed exclusively at a specialty pharmacy unless it meets the criteria of a specialty drug under this Act. The Act requires a PBM to pass through 95% of all rebates. These provisions are effective November 14, 2024.

Beginning July 1, 2026, and annually thereafter, each registered PBM shall submit to the department a transparency report containing data for each health insurer client in this Commonwealth from the prior calendar year. The provisions of Act 77 "do not apply to a self-insured health benefit plan subject to ERISA or exempted from ERISA under section 4(b) of ERISA."

Pending major legislation

California

SB 966 cleared the House and Senate before the conclusion of the legislative session on August 30, 2024, and now awaits action by the Governor. This bill would apply to Medicaid, fully insured, and self-insured plans and would require the option of a non-spread pricing option, pass through of 100% of manufacturer rebates to offset cost sharing and a prohibition on steering. In addition, the bill includes vague fiduciary language and would allow a private right of action. The Governor has until September 30, 2024 to sign, veto, or allow the legislation to go into effect in 2025.

Massachusetts

The Massachusetts legislature adjourned on August 1, 2024, without taking action on HB 4891. However, there is a possibility that the legislature could still address this bill during an interim session before the end of 2024. HB 4891 includes PBM licensure, a ban on spread pricing (Medicaid and commercial), affiliate language, co-pay coupons applied to a patient's deductible and would require 80% of rebates to the offered at the point of sale. The bill's application to ERISA plans is unclear due to ambiguous legislative text.

Other state activity

ALEC Model PBM regulation legislation

The Health and Human Services Task Force of the American Legislative Exchange Council (ALEC) was slated to vote on model PBM regulation legislation in July. However, the Task Force met and formally withdrew "The Patient and Pharmacy Protection Act" from the agenda. The author of the bill indicated that she is creating a subcommittee to work on amendments to the model bill before the end of the year.

Wells Fargo sued over employee prescription costs

On July 30, 2024, a lawsuit was filed against Wells Fargo for a breach of fiduciary duty in selecting and failing to monitor the PBM (Express Scripts) and the impact of the PBM's practices on its plan participants. This lawsuit is similar to a class action lawsuit filed in February against Johnson and Johnson (J&J). J&J has moved to dismiss the case, arguing that its plan has saved participants money and that the named plaintiff lacks legal standing to bring suit.

PCMA files brief in response to Oklahoma's petition to Supreme Court

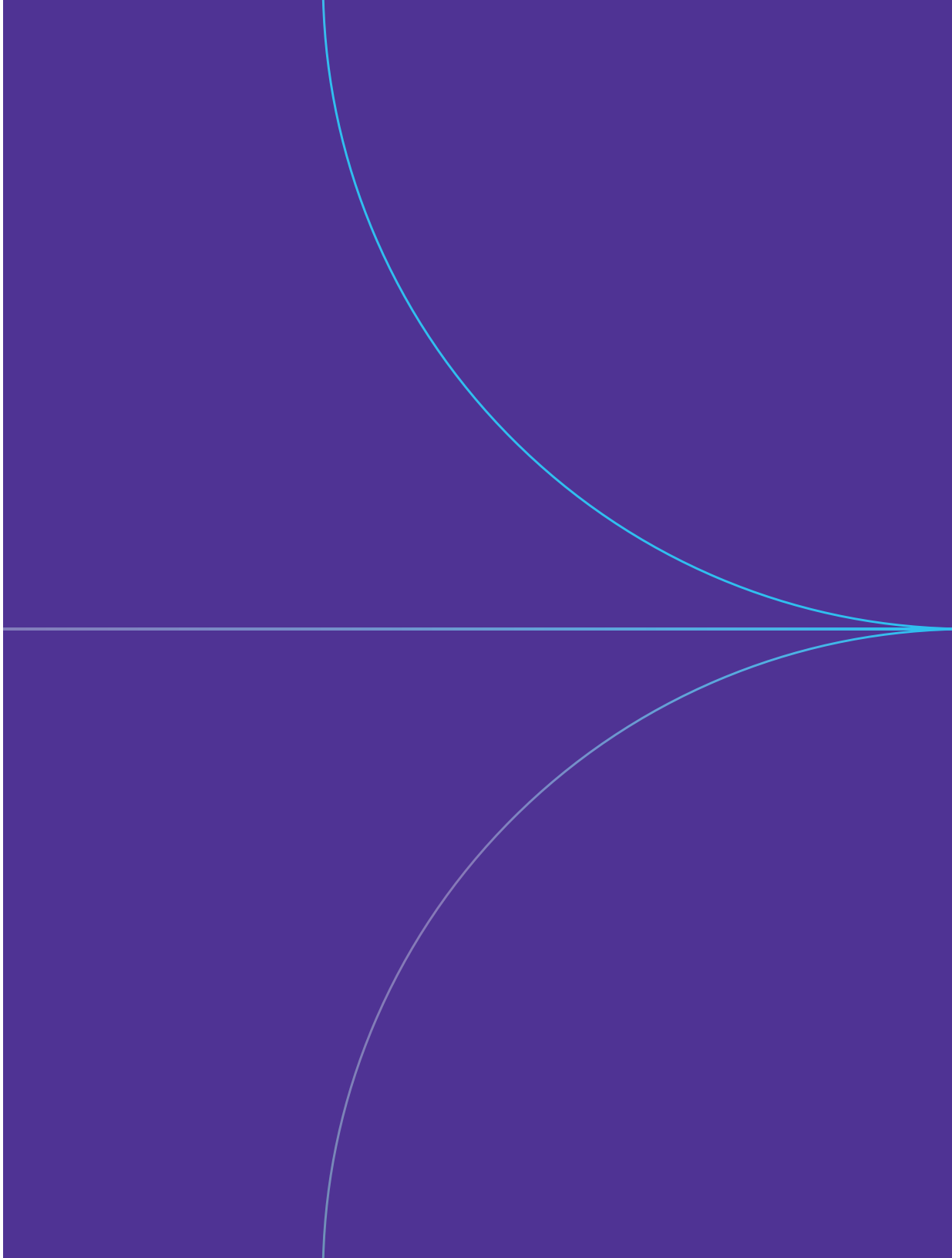
On July 29, 2024, the Pharmaceutical Care Management Association (PCMA) filed a brief in response to Oklahoma's certiorari petition for the U.S. Supreme Court (Court) to review a lower court's decision in PCMA v. Mulready. PCMA argues against the Court's review based on (1) the lack of a clear circuit split on the underlying issues, and (2) the quality and reasonableness of the Tenth Circuit Court of Appeal's decision that ERISA and Medicare Part D preempt Oklahoma's PBM law. In the ruling, expected to be issued in early October, the Court may deny or accept the petition or request the views of the U.S. Solicitor General (SG). Engaging the SG would postpone the Court's final decision until late spring 2025.

Arkansas Insurance Department fines four PBMs

On August 6, 2024, the Arkansas Insurance Department announced it would be seeking fines against Caremark, Magellan, Express Scripts, and MedImpact with a combined total of $1.47 million. These fines are in response to the state's determination that these entities had reimbursed pharmacies or pharmacists below the National Average Drug Acquisition Cost (NADAC) in violation of a 2019 state law.

Conclusion

We hope you found this summary of federal and state legislative and regulatory activity helpful. While topics that legislators and regulators are focusing on are constantly evolving, this summary captures many of the issues that are currently in review.



The information in this report is current as of August 30, 2024.

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