Q4 2024 State and Federal Regulatory and Legislative Activity Update

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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 August 23 and November 22, 2024.

Federal regulatory activity

Commercial

Preventative drugs

On October 21, 2024, the U.S. Departments of Health and Human Services (HHS), Labor, and the Treasury (the Departments) issued a proposed rule that would require group health plans and individual insurance issuers to cover recommended over the counter (OTC) contraceptive items without cost-sharing or a prescription. Comments on the proposed rule are due on December 27, 2024.

On October 21, 2024, the Departments also released additional guidance addressing plans' and issuers' coverage of other recommended preventive services, as required under the Affordable Care Act (ACA). This guidance focuses on coverage of pre-exposure prophylaxis (PrEP), medication that reduces the risk of HIV infection, reiterating the requirement to cover preventive PrEP and related services without cost sharing.

Notice of Benefit and Payment Parameters Proposed rule

On October 4, 2024, CMS released the Notice of Benefit and Payment Parameters (NBPP) proposed rule for benefit year 2026. In the rule, CMS noted the Departments intend to issue future rulemaking addressing the applicability of drug manufacturer support to the annual limitation on cost sharing. The final rule is currently under review at the Office of Management and Budget.

General drug update

Telehealth prescribing rule

On November 18, 2024, The Drug Enforcement Administration (DEA) released a third temporary extension of the telemedicine flexibilities for prescribing controlled medications through December 31, 2025. The flexibilities were initially provided during the COVID-19 public health emergency and were scheduled to expire on December 31, 2024. The DEA stated that this extension will give it time to promulgate proposed and final rules on telemedicine prescribing.

Congressional activity

Senate activity

Patent legislation

On November 21, 2024, the Senate Judiciary Committee advanced the PREVAIL Act (S.2220), a bill that would make changes to the Patent Trial and Appeal Board aimed at ensuring the U.S. Patent and Trademark Office has the resources it needs to effectively administer a patent system that incentivizes American innovation and enables U.S. innovators to compete.

Drug shortages

On November 21, 2024, Senator Tim Kaine (D-VA) introduced the End Drug Shortages Act which aims to help reduce the prevalence and severity of drug shortages by requiring drug manufacturers to notify the U.S. Food and Drug Administration (FDA) when there is a surge in demand of a drug that is likely to lead to a disruption in the supply of the drug and ensuring that the FDA considers information reported by patients, health care professionals, and manufacturers when designating a drug shortage.

Hearing on drug prices

On October 29, 2024, the Senate Judiciary Committee held a hearing on drug prices and competition. The hearing's panel included Democratic Members of Congress, supply chain experts, lawyers, and a Medicare beneficiary. The hearing focused on the drug price negotiation and out-of-pocket cost cap policies included in the IRA. Witnesses highlighted the need for more affordable medications and expressed concerns about anticompetitive practices, citing a lack of transparency in the drug supply chain.

Hearing on weight loss drug prices

On September 24, 2024, the Senate Committee on Health, Education, Labor and Pensions (HELP) held a hearing with Novo Nordisk CEO Lars Fruergaard Jørgensen who faced bipartisan pressure over the high U.S. prices of Ozempic and Wegovy. During the hearing, members asserted that there is a significant disparity in drug pricing between the United States and other countries. Senators also discussed how the high cost of drugs disproportionately affects low-income individuals and those without insurance.

Hearing on the IRA

On September 17, 2024, the Senate Finance Committee held focused on how the IRA's drug provisions have impacted beneficiary costs and pharmaceutical innovation. Democrats focused on how the IRA has lowered prescription drug costs for Medicare beneficiaries and could encourage quicker drug development by shifting industry incentives. Republicans criticized the IRA for raising premiums, restricting beneficiary choices, and reducing drug research and development investment. Republicans also criticized the Biden Administration's demonstration project to stabilize and lower Part D premiums, which they claim is politically motivated.

House activity

Hearing on PBMs

On September 11, 2024, the House Judiciary Administrative State, Regulatory Reform, and Antitrust Subcommittee held a hearing on PBMs. The hearing highlighted the high level of market concentration among PBMs, which many committee members and witnesses argued contributes to reduced competition and potential conflicts of interest in drug pricing and access.

State legislative activity

Recently vetoed major legislation

California

On September 30, 2024, Governor Gavin Newsom vetoed the omnibus anti-PBM bill (SB 966) that would have applied to Medicaid and fully insured and self-insured commercial plans and would have drastically altered the traditional PBM business model. Primary concerns with the bill included the requirement to pass through 100% of manufacturer rebates to offset member cost sharing at the point of sale, extensive reporting and licensing fees, and the requirement to contract with any willing pharmacy. Governor Newsom's veto message indicated that the bill would not address high drug prices. The Governor expressed his support for greater transparency throughout the entire supply chain to inform further policy decisions.

Pending major legislation

California

On December 3, 2024, California Senator Scott Wiener introduced SB 41 which is a reintroduction of Wiener's omnibus anti-PBM legislation (SB 966) from last year, which was ultimately vetoed by Governor Newsom. This legislation includes provisions on delinking, a spread pricing ban, anti-steering and fiduciary duty. Senator Wiener also introduced SB 40 that would cap the out-of-pocket price of insulin at $35 for a 30-day supply and prohibit health insurance plans from charging more or putting restrictions on patients' access. It's nearly identical to Wiener's SB 90, which Governor Newsom vetoed in 2023.

Ohio

The Ohio lame duck session began on November 12, 2024, and the House Insurance Committee held a hearing on November 14, 2024, to introduce a substitute amendment to HB 505, a bill that would limit the use of pharmacy accreditation, impose maximum allowable cost (MAC) disclosures and reporting requirements, and establish a mandatory dispensing fee. An additional hearing was held on November 20, 2024, for interested parties and to receive opposition testimony. As we go to press, we have learned that HB 505 is not expected to receive a vote before the end of the year.

New Jersey

An omnibus anti-PBM bill (AB 4953) was introduced in mid-October as well as a Senate companion bill, S 3842. This legislation includes a delinking provision (requirements for flat-fee PBM reimbursement), a pharmacist acquisition cost mandate, a PBM fiduciary requirement, and a prohibition on mail order. A hearing is likely to occur in mid-December 2024.

Other state activity

ALEC Model PBM regulation legislation

The Health and Human Services Task Force of the American Legislative Exchange Council (ALEC) will be considering a revised version of model PBM legislation during ALEC's December Conference. The Model Act being discussed in December is comprised of Wisconsin's current PBM law (2021 Act 9), and a verbatim of last session's (2024) Wisconsin PBM bill (AB 773 and SB 737) that would ban accumulator programs, institute any willing pharmacy requirements, and dictate dispensing fees among other requirements.

New York Releases PBM market conduct regulations

On November 21, 2024, the New York Department of Financial Services (DFS) issued market conduct regulations for PBMs. These regulations implement legislation enacted in 2021 (S. 3762/A. 1396) and include restrictions on mail order and pharmacy audits. In addition, the regulations include anti-steering pharmacy provisions and require PBMs to publish formulary and pharmacy network directories.

Legal activity

PCMA v. Mulready

On October 7, 2024, the U.S. Supreme Court requested the U.S. solicitor general file a brief in the *PCMA v. Mulready* case. In May 2024, Oklahoma filed a certiorari petition with the Supreme Court seeking a reversal of the Tenth Circuit's August 2023 decision, which found that certain provisions of Oklahoma's Patient's Right to Pharmacy Choice Act were preempted by Employee Retirement Income Security Act (ERISA) or Medicare Part D.

Federal Trade Commission Litigation

On September 20, 2024, the Federal Trade Commission (FTC) filed a complaint against CVS Caremark, Express Scripts, Optum Rx, and each PBM's associated group purchasing organization (GPO). The FTC's complaint alleges that the PBMs engaged in unfair methods of competition and unfair acts or practices under Section 5 of the FTC Act resulting from the PBMs' insulin rebating practices. On November 19, 2024, CVS Caremark, Express Scripts, and Optum Rx sued the FTC, asking the U.S. District Court for the Eastern District of Missouri to issue an injunction to halt proceedings in the FTC's in-house case against the PBMs regarding insulin rebating practices. The companies argue that the FTC's private administrative forum violates the due process rights under the Fifth Amendment and further involves private rights that should be litigated in federal court.

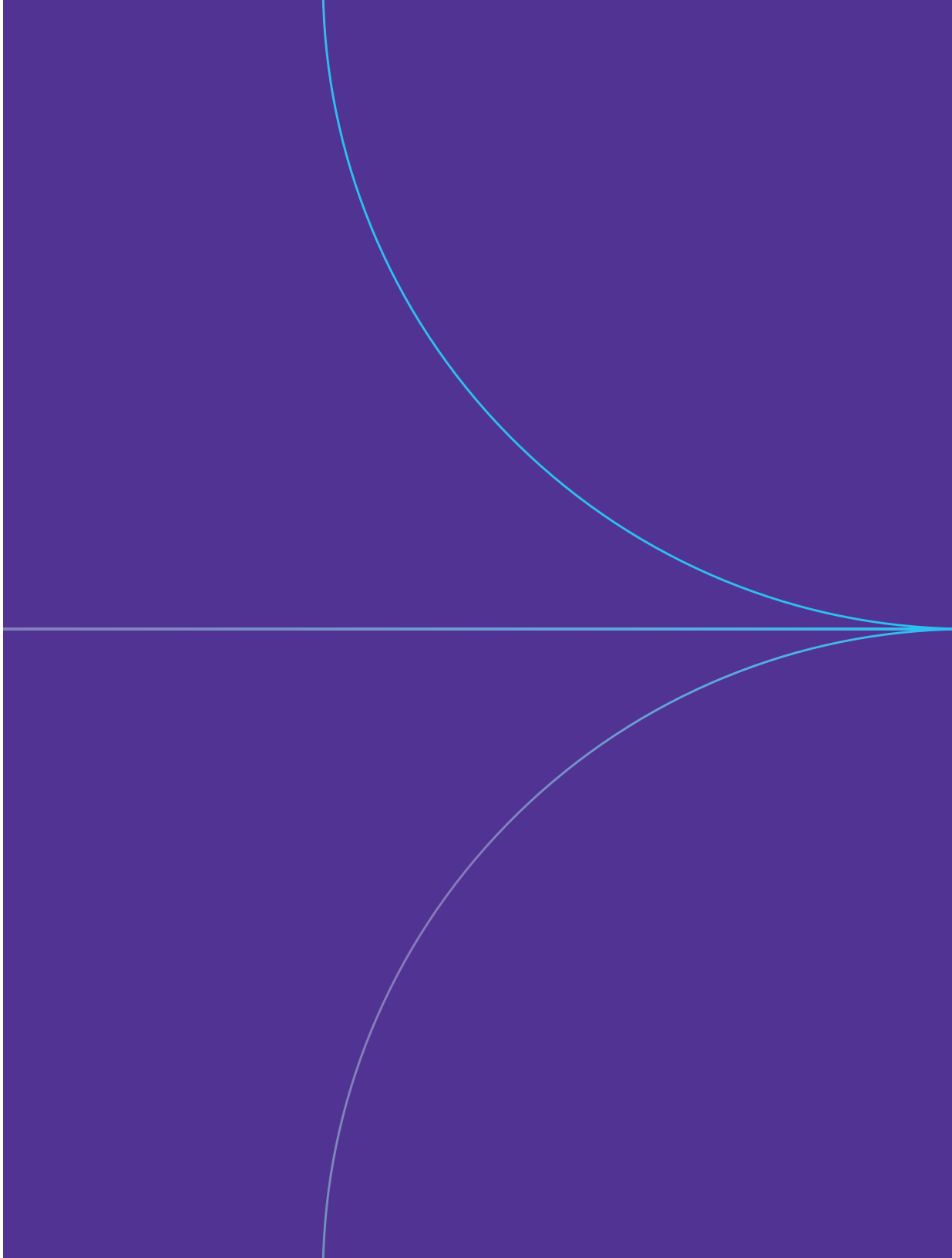
On September 17, 2024, Express Scripts filed a lawsuit against the FTC in the U.S. District Court for the Eastern District of Missouri. The lawsuit challenges the FTC's interim PBM report, alleging the report is defamatory, unlawful, and violates the company's statutory and constitutional rights.

Pharmaceutical manufacturers challenge HRSA over 340B rebate model

Three drug manufacturers have separately sued the Health Resources and Services Administration (HRSA) for prohibiting the implementation of rebate models for drugs sold under the 340B Drug Pricing Program and another has entered the fight. In August 2024, Johnson & Johnson (J&J) announced it would transition from point-of-sale discounts to post-dispensing rebates for Stelara and Xarelto. In response, HRSA declared implementing the model without prior secretarial approval was illegal and warned that enforcement action would be forthcoming. On November 12, 2024, J&J filed suit against HHS and HRSA arguing that the rebate plan is legal under the 340B statute. On November 14, 2024, Eli Lilly filed suit against HRSA to defend its proposal that would require all 340B entities to pay full price for all of their products before receiving weekly cash rebates. Bristol Myers Squibb filed suit on November 26, 2024, after HRSA rejected its rebate model exclusively targeted to its Eliquis blood thinner product starting in the spring of 2025. Sanofi has not filed suit against HRSA, but announced that beginning in early 2025, they would require certain hospitals to submit claims data before they would provide a “credit” that could be used to purchase drugs from wholesalers.

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 November 22, 2024.

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