Q4 2025 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 the federal and state levels. Below, we highlight a few of the major changes that have occurred between September 1 and December 2, 2025.

Federal update

Medicare

CY 2027 Medicare Part C and Part D Technical Proposed Rule

On November 25, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule on policy and technical changes to the Medicare Advantage program, the Medicare Part D Prescription Drug Benefit Program, and the Medicare Cost Plan Program for Contract Year (CY) 2027, also known as the "Proposed Part C and D Technical Rule." The proposed rule includes proposals to codify a variety of Medicare Part D changes under the Inflation Reduction Act, as well as proposals and requests for feedback on Medicare Advantage (MA) risk adjustment, quality bonuses, and MA Special Needs Plan (SNP) issues. Public comments on this proposed rule are due on January 26, 2026.

CY 2026 Physician Fee Schedule Final Rule – drug/pharmacy highlights

CMS released the calendar year 2026 Medicare Physician Fee Schedule Final Rule on October 31, outlining new and continued policies related to Medicare physician payments and the Quality Payment Program. Notably, CMS maintained its standard refund thresholds for discarded drug amounts and clarified how manufacturers should report Average Sales Price (ASP) for drugs sold at a Maximum Fair Price (MFP). The agency also finalized a definition for "bundled arrangements," reaffirmed the existing definition of bona fide service fees (BFSFs) while requiring new certification letters, and confirmed that tissue procurement costs for autologous cell-based therapies will be included in ASP and product payment calculations beginning in 2026. CMS further finalized a change to treat skin substitutes as incident-to supplies rather than biologicals effective January 1, 2026.

White House Agreement – Eli Lilly & Novo Nordisk

On November 6, the White House announced a Most Favored Nation (MFN) pricing agreement with Eli Lilly and Novo Nordisk aimed at lowering the cost of GLP-1 medications for patients with diabetes, obesity, heart disease, and related conditions. Under the deal, drugs such as Ozempic, Wegovy, Mounjaro, and Zepbound will be priced at $245 per month, with Medicare copays capped at $50. The agreement also extends coverage under Medicare and Medicaid for weight-loss indications, reversing previous policy restrictions that prohibited anti-obesity medications for such purposes. Program implementation details and timing are still developing.

Medicare Drug Price Negotiation Program

In November, CMS announced prices for the second cycle of Part D drugs under the Medicare Drug Price Negotiation Program, with prices taking effect in 2027. Discounts off 2024 list prices range from 38% (Austedo) to 85% (Janumet), with Wegovy, Ozempic, and Rybelsus discounted by 71%. CMS is also removing Entresto, Stelara, and Xarelto from the selected drug list starting in 2027 due to approval of their biosimilar or generic versions.

On September 30, CMS issued final guidance on the third cycle of negotiations and the first cycle of renegotiations under the Medicare Drug Price Negotiation Program. The guidance outlines the processes for manufacturer effectuation of MFPs between 2026 and 2028 and clarifies eligibility for Part B drugs. Negotiated maximum fair prices will take effect January 1, 2028.

Medicaid

CMMI GENEROUS Medicaid drug pricing model

The Center for Medicare and Medicaid Innovation (CMMI) announced on November 6, the voluntary, five-year GENEROUS Medicaid Model. This program allows participating states to purchase select drugs at MFN prices through CMS-negotiated supplemental rebates. The model, running from January 2026 through December 2030, applies to single-source and innovator multiple-source drugs. MFN pricing will be derived from average net prices across comparator countries, including the U.K., France, Germany, Italy, Canada, Japan, Denmark, and Switzerland. Manufacturers may submit applications through March 31, 2026, and states will have rolling enrollment through August 2026.

General

Most Favored Nation (MFN) Agreements & direct-to-consumer discounts

Over the past several months, the White House has entered into a series of MFN-style drug pricing agreements with major pharmaceutical companies including Pfizer, AstraZeneca, EMD Serono, Eli Lilly, and Novo Nordisk. These deals aim to align U.S. drug prices more closely with those in peer countries while offering significant discounts on certain drugs through the TrumpRx platform beginning in 2026. In exchange, participating companies receive temporary tariff relief and commit to expanding domestic manufacturing and R&D investments.

Actions on IVF

On October 16, the Departments of Health and Human Service (HHS), Labor, and Treasury jointly released new guidance to help employers offer standalone fertility benefit packages, including coverage for in vitro fertilization (IVF). The guidance clarifies that employers may provide fertility coverage through existing excepted benefit categories. The Departments also announced plans to propose new rulemaking to further expand eligibility for fertility benefits under limited excepted benefit rules.

Tariffs

On September 25, the Administration announced a potential 100% tariff on imported branded/patented pharmaceuticals, with exemptions for products where U.S. plant construction has begun.

On October 1, a White House official stated that implementation of the tariffs is being delayed. The Administration is instead "beginning to prepare" tariffs against companies that do not build in the U.S. or agree to pricing deals — likely using potential tariffs as leverage to pressure drugmakers into pricing agreements to lower U.S. list prices in exchange for tariff relief.

On November 5, the U.S. Supreme Court heard oral arguments concerning the President's authority under the International Emergency Economic Powers Act to impose broad tariffs on imported goods, including pharmaceuticals. An expedited decision is expected later this year.

On December 1, the Office of the United States Trade Representative, the Department of Commerce, and HHS, announced an agreement in principle on pharmaceutical pricing between the United States and the United Kingdom that removes tariffs on U.K. origin pharmaceuticals, pharmaceutical ingredients, and medical technologies and pauses certain U.S. pricing-related trade actions. In exchange, the U.K. will increase the net price it pays for new medicines by 25% and lower the rebate drugmakers pay to the U.K.'s state-run health system from about 23% to a maximum of 15%.

FDA/DEA

FDA Request for Information on OTC medications

On December 1, the U.S. Food and Drug Administration (FDA) issued a request for information (RFI) seeking stakeholder input on ways to improve access to over-the-counter (OTC) medications. The agency intends to use this feedback to inform a public meeting planned for 2026. Comments on the RFI are due at the end of January.

Hormone replacement therapy labeling

On November 10, the FDA began a process to remove black box warnings from certain hormone replacement therapies used to treat menopause, citing updated scientific evidence and expert review. It also approved two related drugs, including a generic estrogen mixture and a non-hormonal therapy for vasomotor symptoms.

Commissioner's National Priority Voucher (CNPV)

On October 16, the FDA announced that a lower-cost fertility drug, previously approved only in Europe, has been granted a Commissioner's National Priority Voucher (CNPV) to accelerate its review and potential U.S. market entry. The approval aligns with the administration's broader efforts to expand access to in vitro fertilization (IVF) treatments and reduce out-of-pocket costs.

On November 6, the FDA awarded its second round of CNPVs to six therapies, including Zongertinib for HER2 lung cancer, Bedaquiline for pediatric drug-resistant tuberculosis, Casgevy for sickle cell disease, and Orforglipron and Wegovy for obesity and related health conditions.

Draft guidance on biosimilars

On October 29, the FDA issued draft guidance allowing biosimilar developers to use comparative analytical assessments instead of full comparative efficacy studies, a move expected to streamline approvals and reduce development costs.

Telemedicine prescribing

The Drug Enforcement Administration (DEA) has submitted a rule to the Office of Management and Budget that would extend telemedicine prescribing flexibilities for controlled substances beyond December 31.

Vaccines

On November 13, the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) announced it will convene on December 4–5, 2025, to discuss and potentially update recommendations related to childhood immunization schedules and hepatitis B vaccines.

On October 8, the CDC issued updates to the U.S. immunization schedules, reflecting several changes. The revisions include a new shared clinical decision-making approach for the COVID-19 vaccine, emphasizing provider-patient discretion based on individual risk and exposure factors. Additionally, the schedule now recognizes standalone varicella immunization for toddlers, expanding flexibility for pediatric care providers.

340B

HRSA rebate model

At the end of October, the Health Resources and Services Administration (HRSA) announced that it had approved eight drug manufacturers to participate in the 340B Rebate Model Pilot Program, scheduled to launch on January 1, 2026.

Under this model, covered entities will purchase designated drugs at full price and submit claims data within 45 days of dispensing. After receiving the data, manufacturers must issue rebate payments within 10 days.

Congressional activity

Recently introduced legislation

- On November 20, House Democratic leaders introduced the Lowering Drug Costs for American Families Act (H.R. 4895) legislation that would expand Medicare's authority to negotiate prescription drug prices and apply those negotiated prices to the commercial insurance market. The bill would also cap annual out-of-pocket spending for prescription drugs at $2,000 and limit insulin copays to $35 per month in commercial plans.
- On October 21, Senators Peter Welch (D-VT), Catherine Cortez Masto (D-NV), and Ron Wyden (D-OR), introduced the No Big Blockbuster Bailouts Act (S. 3019) to reverse policies in the One Big Beautiful Bill Act that exclude large-spending orphan-only drugs from the Medicare Drug Price Negotiation Program, and restore Medicare's authority to negotiate the prices of high-cost, blockbuster drugs.
- On October 20, U.S. Senators Susan Collins (R-ME) and Jeanne Shaheen (D-NH) reintroduced the Ensuring Timely Access to Generics Act (S. 3014), bipartisan legislation designed to help lower prescription drug costs by promoting greater competition in the generic drug market through FDA oversight of the citizen petition process.
- On October 10, Senators John Cornyn (R-TX), Jacky Rosen (D-NV), Thom Tillis (R-NC), and Peter Welch (D-VT) introduced the Shared Savings with Seniors Act of 2025 (S. 2973) that would require full rebate pass-through at the point of sale for medications treating certain chronic illnesses.

Hearings

- On November 18, the Senate Aging Committee held a bipartisan hearing focused on strengthening the domestic pharmaceutical supply chain and reducing U.S. dependence on foreign active pharmaceutical ingredient (API) manufacturing. Witnesses included leaders from USAntibiotics, Civica Rx, PHLOW-USA, and Oxford Pharmaceuticals, who discussed initiatives to expand domestic drug production capacity, improve supply chain transparency, and build public trust in the quality and safety of medicines made in the United States.
- On October 29, the Senate Health, Education, Labor, and Pensions (HELP) Committee held a hearing examining the balance between U.S. biotechnology innovation, global competitiveness, and drug pricing pressures. Lawmakers explored how to maintain incentives for breakthrough innovation while addressing affordability challenges for patients and payers.
- On October 23, the Senate Health, Education, Labor, and Pensions (HELP) Committee held a hearing to review the growth and operations of the 340B Drug Pricing Program. Discussion centered on oversight, financial accountability, patient benefit, and provider practices. Several senators signaled support for program reforms, including clearer patient eligibility standards and greater transparency in how 340B savings are used.

State update

Across the country, states continue to advance PBM-related reforms. In 2025, over 300 PBM bills were enacted, focusing on utilization management, pharmacy reimbursement, and rebate pass-through. As of November 21, there are seven state legislatures in session and a number of PBM-related bills still active.

Emerging issues

This year, several new policy trends have emerged across the states. Seven states introduced bills to define or regulate group purchasing organizations (GPOs) or rebate aggregators. Nine states proposed measures to ban or limit vertical integration between PBMs, pharmacies, or insurance carriers — though only Arkansas enacted such a law, which is now facing a legal challenge. Eleven states introduced legislation to "delink" PBM compensation from drug prices, replacing it with a flat fee structure; only Colorado and California enacted such provisions. More recently, states have begun discussing proposals that would require PBMs to establish public and private portals displaying per-person drug costs and permit third parties to access an individual's drug benefit information with consent.

Recently enacted state legislation

On October 11, Governor Newsom signed into law the omnibus PBM legislation (SB 41). The law establishes a fiduciary duty to self-funded plans, mandates rebate pass-through, bans spread pricing, and includes provisions on delinking, any willing pharmacy, and non-discrimination toward non-affiliated pharmacies. SB 41 closely mirrors SB 966.

Pending state activity

Ohio

Ohio remains one of the few states still in active legislative session, with two PBM-related bills pending. HB 229 includes provisions on PBM licensure, reporting, and transparency. HB 192 would limit PBM pharmacy accreditation standards, allow pharmacies to file complaints with the Superintendent of Insurance, and require pharmacy reimbursement at acquisition cost plus an "adequate dispensing fee" determined by the Superintendent. An amendment to HB 192 would also require PBMs to create public and private portals displaying per-person drug costs and permit third-party access to individual drug benefit information with consent.

New Jersey

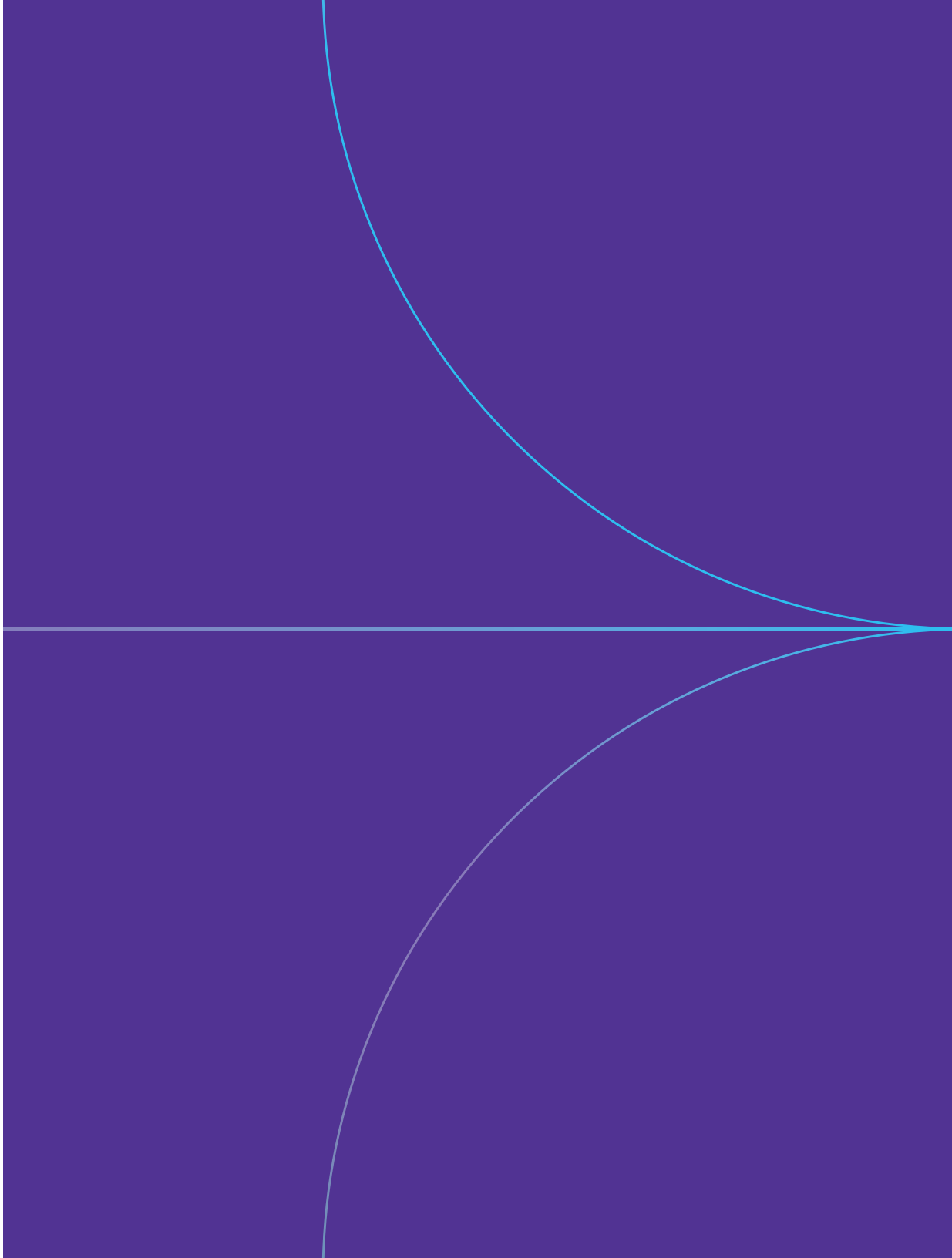
In New Jersey, omnibus PBM legislation (AB 4953) remains active, containing provisions on PBM delinking, PBM fiduciary mandate, pharmacy network restrictions, and minimum reimbursement requirements. Two related bills — S4717, prohibiting PBM ownership of pharmacies, and S4969, prohibiting carrier ownership of PBMs — were introduced in July but have shown little momentum. While consideration of these bills remains possible, it is unlikely that any will advance this year.

Other state activity

California announced that it will begin selling state-branded insulin through its CalRx program on January 1, 2026, in partnership with Civica, offering insulin pens at $11 each.

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 continue to evolve, this summary captures many of the issues that are currently in review.



The information in this report is current as of December 2, 2025.

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