Q3 2025 State and Federal Regulatory and Legislative Activity Update

carelon Rx

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 May 22, 2025, and August 21, 2025.

Federal update

Medicare

Preliminary 2026 Medicare Part D Bid information and revised Premium Stabilization Demonstration parameters

On July 28, 2025, the Centers for Medicare & Medicaid Services (CMS) released preliminary technical information for Medicare Part D plans for Contract Year (CY) 2026 including a National Average Monthly Bid Amount (NAMBA) of $239.27, an increase from $179.45 in 2025. The direct subsidy will be $200.28, an increase from $142.67 in 2025.

CMS also announced it is continuing the voluntary Part D Premium Stabilization Demonstration (demonstration) originally implemented in 2025 but with less generous premium stabilization for CY 2026.

As with the 2025 demonstration, standalone prescription drug plans (PDPs) including Employer Group Waiver Plan (EGWP) PDPs are eligible to participate but Medicare Advantage Prescription Drug Plans (MAPDs) are not. For the first time, CMS notably rejected some standalone PDP bids due to significant year-over-year premium increases.

CMS will release final Part D premiums at the individual plan level in September in the 2026 Medicare Advantage and Part D Landscape, following Part D sponsor decisions to participate in the demonstration.

CY 2026 Medicare PFS proposed rule

On July 14, 2025, CMS released the CY 2026 Medicare Physician Fee Schedule (PFS) proposed rule. Comments on the rule are due to CMS on September 12, 2025. Specific to drugs, CMS proposes to:

- Calculate the manufacturer's average sales price (ASP), CMS is proposing new guidance regarding pricing concessions, including definitions of bona fide service fees (BFSFs).
- Clarify that units of selected drugs sold at the maximum fair price (MFP) under the Medicare Drug Price Negotiation Program must be included in average selling price (ASP) calculations.
- Establish a claims-based methodology to remove 340B units from Part D rebate calculations starting on January 1st and creating a Medicare Part D Claims Data 340B Repository.

CY 2026 OPPS proposed rule

On July 15, 2025, CMS released the CY 2026 Hospital Outpatient Prospective Payment System (OPPS) proposed rule. Comments on the rule are due to CMS on September 15, 2025. Specific to drugs, CMS proposes to:

- Expand site neutral payment to drug administration services furnished by excepted off-campus provider-based outpatient departments (with an exemption for sole community hospitals).
- Revise the annual reduction to the OPPS conversion factor for non-drug items and services from 0.5% to 2%.

Medicaid

CGT Access Model

On July 15, 2025, CMS announced that 33 states, plus the District of Columbia and Puerto Rico, will participate in the Cell and Gene Therapy (CGT) Access Model, which is designed to test whether a CMS-led approach to administering outcomes-based agreements for sickle cell gene therapies improves Medicaid beneficiaries' health outcomes and reduces costs to state Medicaid programs.

- The states participating in the model include Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Illinois, Kansas, Kentucky, Louisiana, Maine, Maryland, Michigan, Mississippi, Missouri, New Jersey, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, and Wisconsin.
- States may launch the model at any point before January 2026 and must coordinate with managed care organizations (MCOs) to ensure alignment with model requirements. States have flexibility in how they choose to implement and manage the model in partnership with MCOs.

Commercial market

RFI on Drug Transparency

On May 22, 2025, the Tri-Agencies issued a request for information (RFI) on the Transparency in Coverage final rule's requirements related to the prescription drug machine readable file (MRF). The RFI solicits feedback on how best to implement the still-pending requirement for group health plans to publicly post MRFs detailing prescription drug pricing and the data elements that should be posted.

General drug update

Executive Order on Strategic Active Pharmaceutical Ingredients Reserve

On August 13, 2025, President Trump signed an executive order directing the Office of the Assistant Secretary for Preparedness and Response (ASPR) to develop a list of approximately 26 critical drugs vital to national health and security, and for the Strategic Active Pharmaceutical Ingredients Reserve (SAPIR) to be filled with the ingredients to make those drugs. The goal is to reduce dependence on foreign suppliers, prevent shortages, and ensure the U.S. can produce essential medicines during global supply disruption.

"Most Favored Nation" drug prices

On July 31, 2025, the Administration announced that President Trump sent letters to leading manufacturers — including AbbVie, Amgen, AstraZeneca, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly, EMD Serono, Genentech, Gilead, GSK, Johnson & Johnson, Merck, Novartis, Novo Nordisk, Pfizer, Regeneron, and Sanofi — outlining required actions to lower U.S. prescription drug prices and align with MFN prices. These steps include:

- Requiring manufacturers to provide MFN prices to all Medicaid patients.
- Requiring manufacturers to commit to not offering other developed nations better prices for new drugs.
- Providing manufacturers with an avenue to sell drugs directly to patients at MFN prices.
- Using trade policy to raise drug prices internationally provided that derived revenues are reinvested into lowering prices in the U.S.

The letters warn that if manufacturers fail to act, the Administration will use all available "tools" to address abusive drug pricing practices.

European Union trade deal

On July 27, 2025, the U.S. signed a trade agreement with the European Union that includes a provisional 15% flat tariff on most imports from Europe, including prescription drugs, pending the outcome of the U.S. Department of Commerce's national security investigation into pharmaceutical imports. It is unclear whether the tariff also applies to generic drugs.

FTC and DOJ joint listening sessions on drug pricing

The Department of Justice (DOJ) and Federal Trade Commission (FTC) held three joint public listening sessions on June 30, July 1, and August 4, 2025, to investigate anticompetitive practices in the pharmaceutical industry. The sessions, mandated by executive order, brought together experts to discuss a wide range of conduct, including "pay-for-delay" patent settlements, product hopping, exclusive supply agreements, and the effect of PBMs.

FTC Commissioner

On July 17, 2025, a federal judge ruled that President Trump's removal of U.S. Federal Trade Commission (FTC) Commissioner Rebecca Slaughter earlier this year was unlawful.

- With Slaughter's reinstatement, the FTC now includes one Democratic Commissioner and three Republican Commissioners.
- Commissioner Slaughter has been a vocal proponent of increased scrutiny of pharmacy benefit managers (PBMs).
- The Trump Administration is expected to appeal the decision, potentially taking the case to the U.S. Supreme Court.

New False Claims Working Group

On July 2, 2025, the DOJ and U.S. Department of Health and Human Services (HHS) announced the formation of a False Claims Act Working Group to combat healthcare fraud. The Working Group includes senior leadership from HHS legal offices, CMS, and the DOJ's Civil Division. HHS intends to make referrals to the DOJ across a handful of priority areas, including drug and device rebates, formulary placement, and kickbacks.

FDA National Priority Voucher program

On June 17, 2025, the U.S. Food and Drug Administration (FDA) announced the Commissioner's National Priority Voucher (CNPV) program designed to accelerate the review of therapies addressing critical national health priorities. The eligibility criteria

include “increasing affordability,” which “could include a company that lowers the U.S. price of a drug or drugs consistent with Most Favored Nation pricing or reduces other downstream medical utilization to lower overall healthcare costs.”

Vaccine update

HHS Task Force on Safer Childhood Vaccines

On August 14, 2025, HHS announced it is reinstating the Task Force on Safer Childhood Vaccines — a federal panel created by Congress but disbanded in 1998 — intended to strengthen the safety, quality, and oversight of vaccines administered to children. The Task Force is represented by senior leadership from the National Institutes of Health (NIH), the U.S. Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC). HHS will submit its first formal report to Congress within two years, with updates occurring every two years thereafter.

Vaccine Committee Work Groups

On July 31, 2025, the U.S. Centers for Disease Control and Prevention (CDC) told external physician groups, public health professionals and infectious disease experts that they are no longer permitted to serve on the Advisory Committee on Immunization Practices’ (ACIP) work groups.

- The CDC cited a need to shield work group activities from potential bias rooted in group-specific constituencies or population interests.
- These groups will still retain access to open ACIP plenary meetings but are excluded from closed technical deliberations and drafting sessions where expert reviews occur.

ACIP recommendation to remove thimerosal from influenza vaccines

On July 23, 2025, HHS Secretary Robert F. Kennedy, Jr. approved the Centers for Disease Control and Prevention’s (CDC’s) Advisory Committee on Immunization Practices (ACIP) recommendation to remove the mercury-based preservative thimerosal from all influenza vaccines. Vaccine manufacturers confirmed they can replace mercury-containing vials without disrupting vaccine supplies.

ACIP members

On June 9, 2025, HHS Secretary Robert F. Kennedy Jr. dismissed all 17 members of ACIP, the body responsible for recommending vaccine use in the U.S. He cited concerns about conflicts of interest and promised a "clean sweep" to restore public trust and bring in "unbiased science."

On June 11, 2025, Secretary Robert F. Kennedy Jr. appointed eight new members to ACIP. These individuals include a mix of scientists and physicians, some of whom are reported to harbor vaccine skepticism.

The 340B program

HRSA launches voluntary 340B Rebate Model Pilot program

On July 13, 2025, the Health Resources and Services Administration (HRSA) announced a voluntary 340B Rebate Model Pilot Program for drugs on the CMS Medicare Drug Price Negotiation Selected Drug List for 2026. Manufacturers with standing negotiation agreements for 2026 must apply by September 15, 2025, and the pilot will go into effect on January 1, 2026.

Under the model, covered entities will purchase designated drugs at full price and submit claims data within 45 days of dispensing. Manufacturers then must issue rebate payments within 10 days of receiving the data. Since 2024, several manufacturers have pushed to replace upfront discounts with retroactive rebates. HRSA clarified that such rebate models require pre-approval under the existing 340B statute. In May 2025, a federal district court affirmed HRSA's authority to require pre-approval after a series of legal challenges. This pilot represents the first HRSA sanctioned shift away from the upfront discount structure to a post-purchase rebate mechanism. The outcomes from this pilot may shape future policy reforms to the 340B program.

Congressional update

The Remedy Act

On July 31, 2025, Senators Dick Durbin (D-IL) and Bill Cassidy, M.D. (R-LA) reintroduced the Reforming Evergreening and Manipulation that Extends Drug Years (REMEDY) Act (S. 2620) that targets the practice where brand-name drug manufacturers file numerous minor or secondary patents to artificially extend their market exclusivity and delay generic competition.

The ETHIC Act

On July 15, 2025, Senators Peter Welch (D-VT), Josh Hawley (R-MO), and Amy Klobuchar (D-MN) reintroduced the Eliminating Thickets to Improve Competition (ETHIC) Act (S. 2276) that would streamline patent litigation by limiting the number of patents per patent thicket a pharmaceutical company can assert in litigation.

The Fair Pharmacies for Federal Employees Act

On July 15, 2025, Representatives Raja Krishnamoorthi (D-IL) and Diana Harshbarger (R-TN) introduced the Fair Pharmacies for Federal Employees Act (H.R. 4409) that would prohibit the Office of Personnel Management (OPM) from contracting with entities in the Federal Employee Health Benefits Program (FEHBP) that both manage prescription drug benefits and own or control a pharmacy.

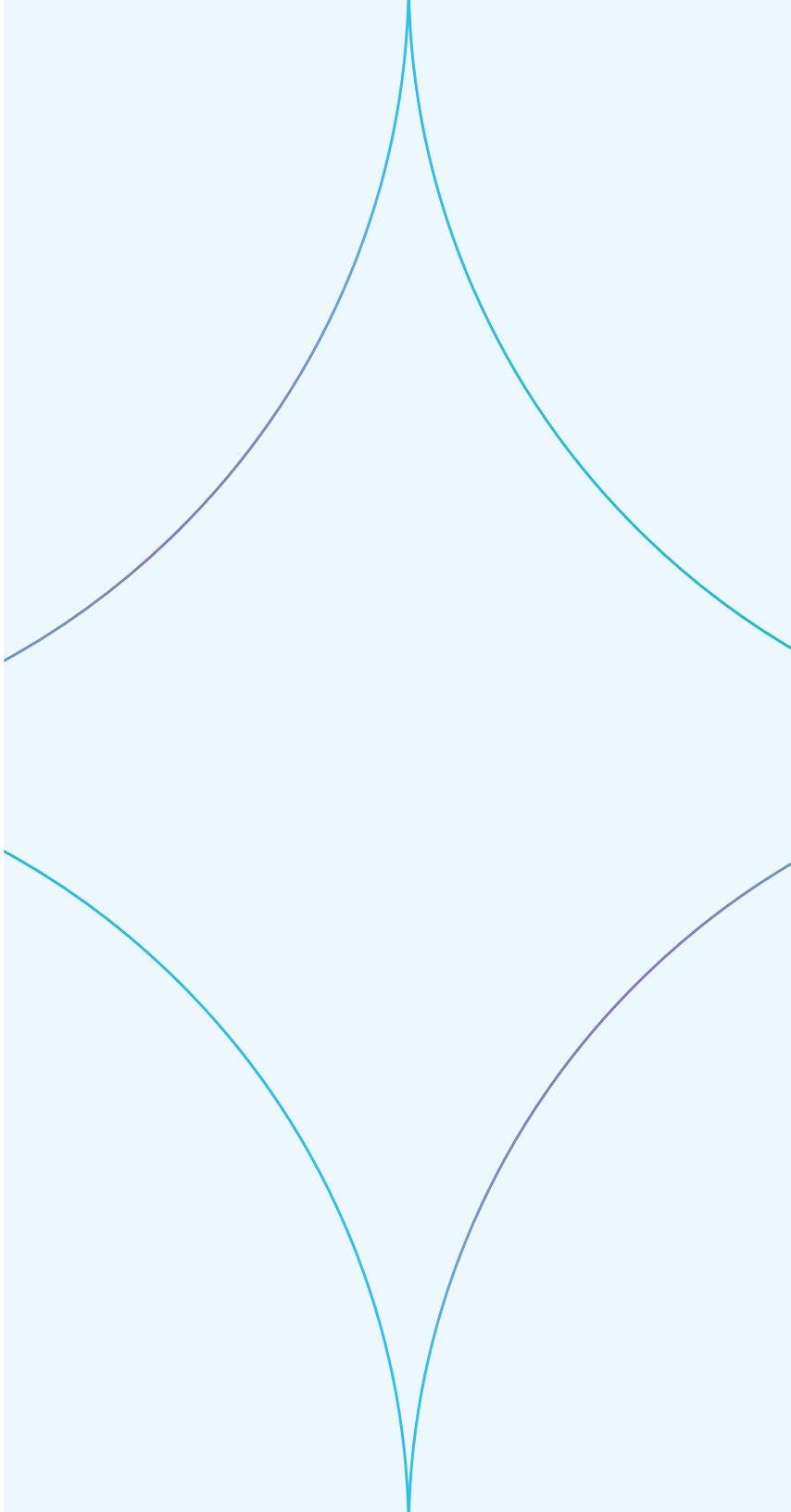
PBM Reform Act

On July 10, 2025, Representative Earl L. "Buddy" Carter (R-GA) introduced the PBM Reform Act of 2025 (H.R. 4317) that would ban spread pricing arrangements in Medicaid, delink PBM compensation from the cost of medications, and require additional PBM reporting to commercial plans sponsors.

One Big Beautiful Bill Act

On July 4, 2025, the President signed the One Big Beautiful Bill Act (H.R. 1) containing over $1 trillion in healthcare spending cuts, mostly from Medicaid. Specific to drugs, the enacted legislation expands the exceptions for orphan drugs under the Medicare Drug Price Negotiation Program by:

- Extending exemptions to orphan drugs with multiple rare disease uses, not just those treating a single condition.
- Starting the clock for negotiation eligibility only after a drug gains approval for a non-orphan use, delaying when it becomes subject to price negotiation.



Emerging issues

This year has seen the advent of several new issues:

- Seven states introduced legislation to attempt to define or regulate GPOs or rebate aggregators.
- Nine states introduced legislation to ban or disrupt vertical integration between a PBM and a pharmacy and/or an insurance carrier, but only Arkansas enacted such a measure (now subject to legal challenge).
- Eleven states introdtuced legislation to “delink” PBM compensation from drug prices, instead limiting remuneration to a flat fee. Only Colorado enacted such legislation that is slated to go into effect January 1, 2027.

Pending state legislation

California

At the end of June 2025, PBM licensure, data reporting requirements, and fiduciary duty were enacted in the state’s budget “trailer bill,” aligning with Governor Newsom’s preference for data-driven oversight. However, an omnibus PBM bill (S.B. 41) is still pending and includes a ban on spread pricing, 100% rebate pass-through, “any willing pharmacy,” delinking, and fiduciary duty. It excludes mandated pharmacy reimbursement and exempts Taft-Hartley but not non-union self-funded plans. Having cleared all policy committees, S.B. 41 could reach the Governor by August 30, 2025, with a September 12, 2025, deadline for enrollment. Similar legislation (S.B. 966) was vetoed by Governor Newsom at the end of last year.

New Jersey

The General Assembly is in recess and will not resume activity until after election day. An omnibus PBM regulation bill (A.B. 4953) remains active and includes provisions on delinking, PBM fiduciary duty, pharmacy network restrictions and minimum pharmacy reimbursement. A bill (S. 4717) to prohibit PBM ownership of a pharmacy and a bill (S. 4969) to prohibit carrier ownership of a PBM were both introduced in July 2025. While it is possible for any of these bills to be considered during the lame duck session, given political realities, it seems unlikely that any of these measures will advance this year.

Other state updates

Louisiana

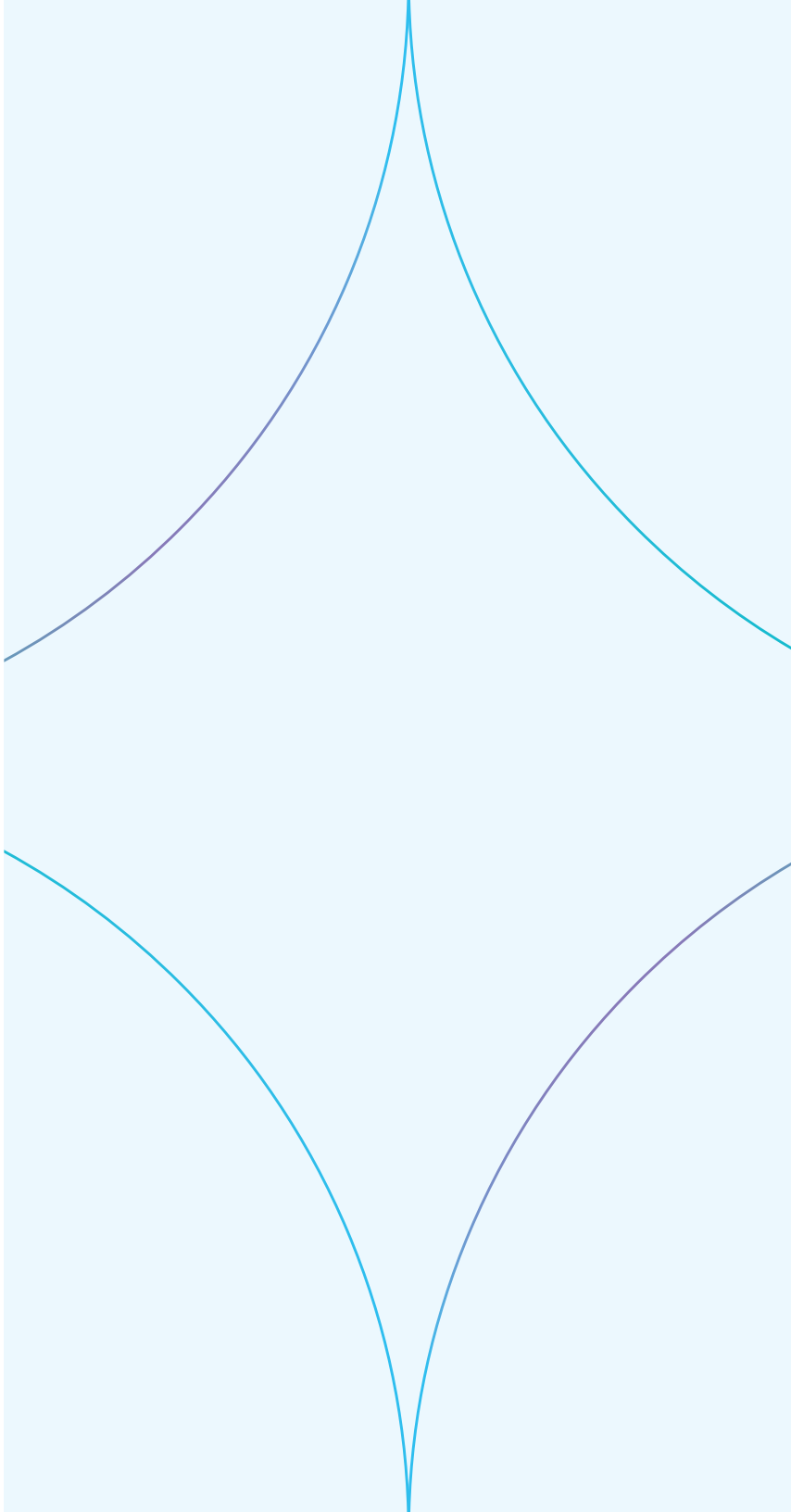
During the 2025 state legislative session, omnibus PBM legislation (H.B. 264) was signed into law and includes 100% rebate pass-through; prohibitions on spread and "effective rate" pricing; prohibitions on affiliate steering; mandated reimbursement for local pharmacies and additional transparency requirements. Despite the passage of this legislation, at the very end of the legislative session, an amendment was inserted into a bill pertaining to pharmacy technicians to prohibit PBM ownership of pharmacies in the state but was not adopted. Governor Landry subsequently convened a press conference to announce his interest in this issue and signaled that he is assembling a panel of outside experts to examine state statutes to determine if executive authority exists to ban vertical integration.

Ohio

The Ohio Legislature completed its State Budget plan in late June. The Governor vetoed all PBM provisions included in the budget bill including language on retail pharmacy audits, prohibition on retaliation, payment parity between independent pharmacies and pharmacies owned by PBMs and a requirement that PBMs pay "Actual Acquisition Cost" to retail pharmacies. In his veto message, Governor DeWine urged the legislature to pass a standalone PBM reform which may be deliberated this fall when the legislature returns.

Tennessee

On June 21, 2025, State Senator Bobby Harshbarger (R) announced his intention to introduce a bill in the 2026 session that would bar PBMs from owning or operating retail pharmacies in Tennessee.



Enacted state legislation under legal challenge

Arkansas

On July 28, 2025, a federal judge granted a preliminary injunction blocking the enforcement of Arkansas Act 624 of 2025, which sought to restrict PBMs from owning or operating retail, mail-order, or specialty pharmacies as of January 1, 2026. The court concluded that the statute "likely violates" the Dormant Commerce Clause of the U.S. Constitution by discriminating against out-of-state businesses. Additionally, the judge found that the law is "likely preempted" by the TRICARE program's express federal preemption clause, which overrides conflicting state regulations.

Caremark, Express Scripts, and OptumRx each filed legal challenges to the statute, and the Pharmaceutical Care Management Association (PCMA) filed a separate suit on behalf of its member organizations. The court consolidated the four actions into a single proceeding. This ruling effectively suspends implementation of Act 624 pending a final determination on its legality. The outcome of this case may have broader implications for states interested in pursuing similar PBM restrictions.

Iowa

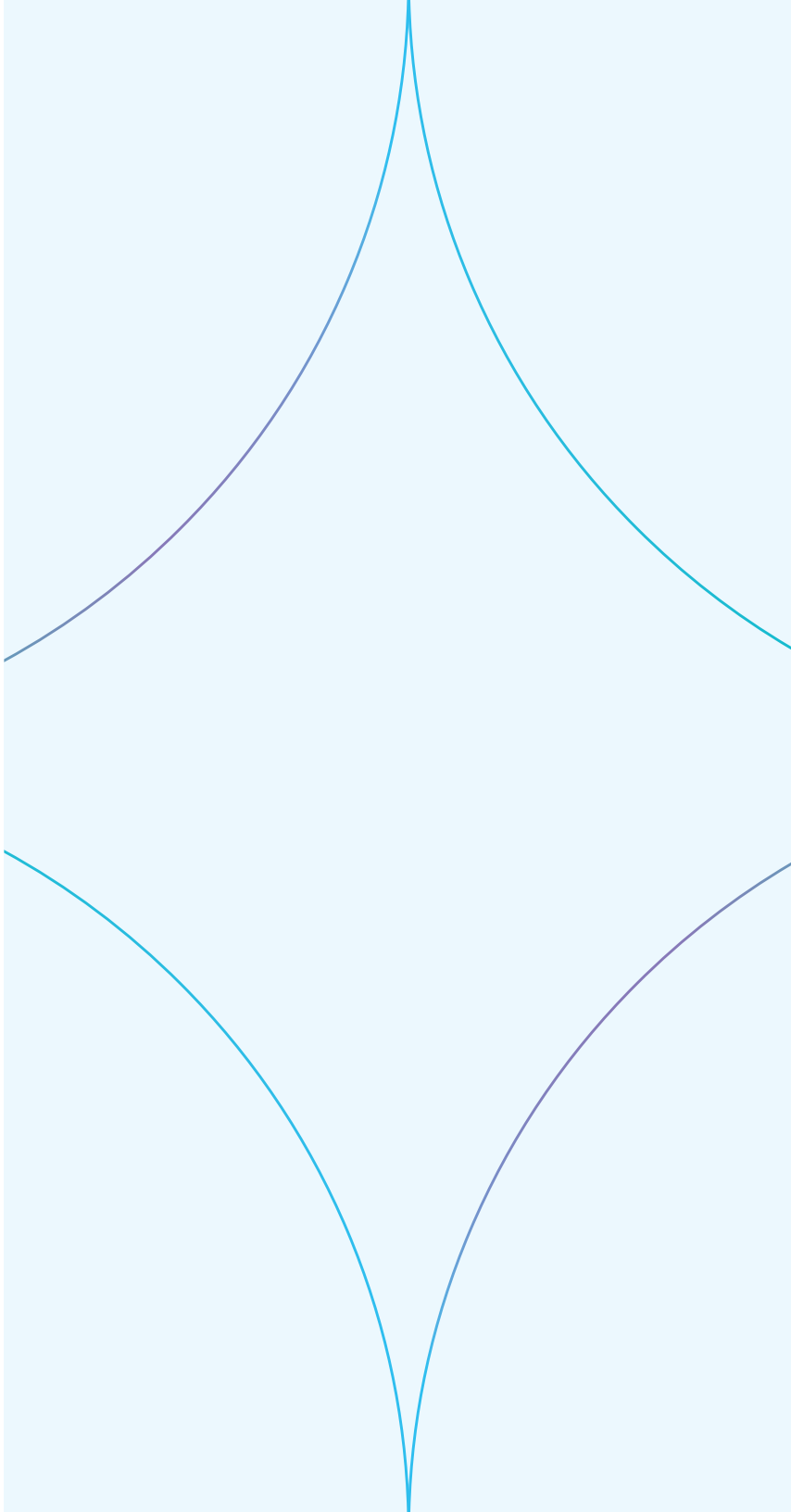
On June 23, 2025, the Iowa Association of Business and Industry and others sued to block S.F. 383, alleging violations of ERISA and the First Amendment. A federal court issued a temporary restraining order on June 30, 2025, and on July 21, 2025, granted a preliminary injunction, finding key provisions preempted by the Employee Retirement Income Security Act of 1974 (ERISA) and others unconstitutional under the First Amendment. The blocked provisions include restrictions on steering, provider access mandates, mail-order limits, cost-sharing rules, contract overrides, and certain speech and data disclosure requirements. Related inseverable provisions were also enjoined. However, aspects of S.F. 383 governing pharmacy payment standards, PBM reporting, limited rebate pass-through, dispute processes, and non-ERISA-related pharmacy guidance were allowed to stand.

Oklahoma

On June 30, 2025, the U.S. Supreme Court declined Oklahoma's petition for certiorari in *Pharmaceutical Care Management Association v. Mulready*, leaving in place the Tenth Circuit's ruling that key provisions of Oklahoma's PBM law are preempted by ERISA. The court found that network adequacy standards, a ban on cost-sharing incentives, an "any willing pharmacy" mandate, and prohibition on excluding pharmacies/pharmacists on probation were preempted. While this decision technically applies only to states within the Tenth Circuit (CO, KS, NM, OK, UT, WY), it signals the Supreme Court's position on these specific provisions.

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 25, 2025.