Q2 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 February 7, 2025, and May 21, 2025.

Federal regulatory activity

Commercial market

On April 22, 2025, the U.S. Supreme Court heard oral arguments in *Kennedy v. Braidwood* (formerly Braidwood v. Becerra), a lawsuit involving the constitutionality of the U.S. Preventive Services Task Force, and by extension, the scope of the Affordable Care Act's (ACA's) preventive services coverage mandate. The case also raises important questions regarding the U.S. Department of Health and Human Services (HHS) Secretary's authority to oversee the Task Force and implement its recommendations. A decision is anticipated later this summer.

General drug update

COVID-19 vaccines

On May 20, 2025, the U.S. Food and Drug Administration (FDA) announced it will require full clinical trials for updated COVID-19 vaccines intended for healthy individuals aged 6 months to 64 years, while continuing to allow access for adults 65 and older and those with high-risk conditions under the current approval process.

"Most-Favored Nation" Executive Order

On May 12, 2025, President Trump signed an Executive Order (EO) aiming to align drug prices in the U.S. with other developed countries. The EO directs the HHS Secretary to communicate "Most-Favored Nation (MFN)" price targets to drug manufacturers within the next 30 days to ensure the U.S. "gets the best deal." If drug manufacturers do not meet the proposed payment terms voluntarily, the EO directs:

- HHS to impose MFN pricing by the rulemaking process and take other "aggressive measures to significantly reduce the cost of prescription drugs."
- Congress to consider drug importation from other countries.
- The FTC to enforce action against anti-competitive practices.

The EO also directs the HHS Secretary to create a direct-to-consumer (DTC) drug purchasing option for U.S. patients to buy direct from manufacturers at the MFN prices.

The EO directs the Secretary of Commerce to take action to ensure other countries are not engaged in any act, policy, or practice that drives the U.S. to pay more than other countries.

Following the EO, on May 20, 2025, HHS clarified that manufacturers are expected to align U.S. prices for all brand-name drugs without generic or biosimilar competition across all markets to the lowest price available in select countries. These countries include Germany, Canada, the U.K., and others with at least 60% of U.S. Gross Domestic Product (GDP) per capita.

Domestic production of critical medicines EO

On May 5, 2025, President Trump signed an EO aimed at reducing the regulatory barriers related to the domestic production of the medicines. The EO orders the Secretary of HHS and the Administrator of the Environmental Protection Agency (EPA) to review existing regulations and guidance pertaining to the development of domestic pharmaceutical manufacturing, eliminate duplicative or unnecessary requirements, and maximize the timeliness and predictability of agency review.

Lowering drug prices EO

On April 15, 2025, the President signed an EO titled "Lowering Drug Prices by Once Again Putting Americans First." Key provisions of the EO include:

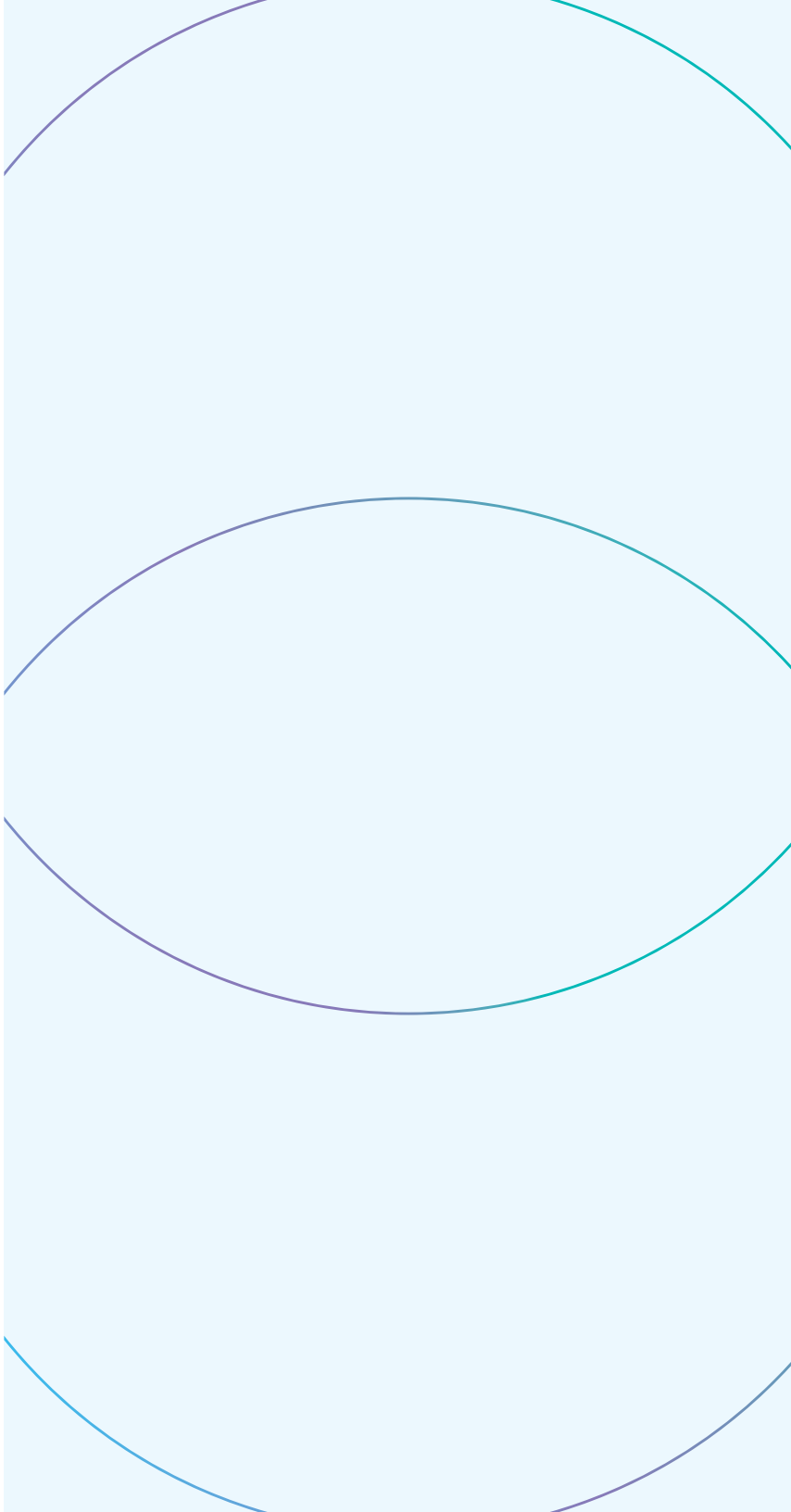
- Calls for recommendations on how to stabilize and reduce Part D premiums (within 180 days) and directs the Secretary of HHS to work with Congress to increase the time since launch when small molecule drugs are eligible for negotiation to align with biologics.
- Directs the Secretary to implement a payment model to obtain better value for high-cost drugs in Medicare (within one year).
- Directs the Secretary to survey hospitals for their drug acquisition costs to develop Medicare payment adjustments to align with acquisition costs (within 180 days).
- Calls for recommendations to ensure manufacturers pay accurate Medicaid rebates and to promote innovation in Medicaid payment methods (within 180 days).
- Calls for actions to ensure future grants to Community Health Centers (CHCs) are contingent on them making insulin and epinephrine available at 340B prices to certain individuals with low incomes (within 90 days).
- Calls for recommendations on a more competitive, efficient, transparent, and resilient pharmaceutical value chain that delivers lower drug prices (within 90 days).
- Calls for report options to accelerate approval of generics, biosimilars, as well as improvement to the over-the-counter conversion process (within 180 days).
- Directs the FDA to streamline the existing state importation program (within 90 days).
- Directs the Secretary of Labor to propose ERISA regulations to improve employer fiduciary transparency into pharmacy benefit manager (PBM) compensation (within 180 days).
- Calls for the Department of Justice to issue a report with recommendations to reduce anti-competitive behavior from drug manufacturers (within 180 days).

Pharmaceutical tariffs

On April 16, 2025, the Administration announced a Section 232 National Security Investigation evaluating whether reliance on imported pharmaceuticals and ingredients compromises national security. The investigation encompasses finished drugs, active pharmaceutical ingredients (APIs), and critical inputs. The study is seen as a precursor to tariffs on prescription drugs.

In vitro fertilization (IVF) EO

On February 19, 2025, the President signed an EO directing various agencies to develop policy recommendations on how to protect IVF access and will prioritize policies that reduce the cost of IVF. The EO also highlights the low rates of coverage of IVF treatments, including low rates of employer coverage for IVF.



Congressional activity

U.S. Senate

Prescription drug advertisements

On May 16, 2025, Senators Jeanne Shaheen (D-NH) and Josh Hawley (R-MO) introduced the No Handouts for Drug Advertisements Act (S. 1785) that would prohibit pharmaceutical companies from claiming tax deductions for expenses on drug advertisements to consumers.

Senate hearing on pharmacy benefit managers

On May 13, 2025, the Senate Judiciary Committee held a hearing titled "Pharmacy Benefit Managers Power Play: Examining Competition Issues in the Prescription Drug Supply Chain." Hearing witnesses included representatives from Navitus Health Solutions, Northwestern Medicine, the American Pharmacists Association, the Pharmaceutical Care Management Association, and the University of Southern California.

International reference pricing

On May 5, 2025, Senators Josh Hawley (R-MO) and Peter Welch (D-VT) reintroduced the Fair Prescription Drug Prices for Americans Act (S. 1587). The act seeks to address the high cost of prescription medications in the United States by aligning domestic drug prices with those in other developed nations.

340B

On April 24, 2025, Senator Bill Cassidy (R-LA) released a report on how covered entities use and generate revenue from the 340B Drug Pricing Program. Senator Cassidy also outlined potential reforms needed to improve the program to better serve patients, including:

- Require covered entities to provide detailed annual reporting on how 340B revenue is used to ensure direct savings for patients.
- Investigate the types of financial benefits contract pharmacies receive for administering the 340B Program.
- Require transparency and data reporting for entities in the 340B Program.
- Provide clear guidelines to ensure that manufacturer discounts benefit 340B-eligible patients, including examining legislative changes to the definition of eligible patient and contract pharmacies' use of the inventory replenishment model.

Anti-competitive manufacturer practices

On April 3, 2025, the Senate Judiciary Committee passed six bills to boost competition in the pharmaceutical industry and improve access to more affordable prescription drugs by voice vote. Bills include limits on "pay-for-delay," "product hopping," and "patent thickets," among other provisions.

U.S. House of Representatives

Budget reconciliation

On May 12, 2025, the House Energy & Commerce and House Ways & Means Committees released their budget reconciliation drafts for consideration that includes several drug pricing provisions such as banning PBM spread pricing in Medicaid, requiring PBM reporting to Part D plan sponsors, restricting PBM compensation to fixed fees in Medicare Part D, and requiring pharmacies to report their drug acquisition costs to CMS. The bill did not include any commercial PBM-related provisions. On May 22, 2025, the House of Representatives passed the legislation by a narrow 215-214 margin. The bill will now be considered by the U.S. Senate.

"Most-Favored Nation"

On May 12, 2025, Representative Jefferson Van Drew (R-NJ) introduced the Fair Prescription Drug Prices for Americans Act (S. 1587) that would codify President Trump's recently signed Most-Favored Nation Executive Order and align the cost of prescription medications in the United States with those in other developed nations.

Drug importation

On May 5, 2025, Representative Jan Schakowsky (D-IL) introduced the Affordable and Safe Prescription Drug Importation Act (H.R. 3162) that would allow individuals, wholesalers, and pharmacies to import drugs from Canada.

Drug advertisement

On April 24, 2025, Representative Greg Murphy (R-NC) introduced the No Handouts for Drug Advertisements Act (H.R. 3010) that would amend the Internal Revenue Code of 1986 to deny the deduction for advertising and promoting expenses for certain drugs.

State legislative activity

As of May 21, 2025, state legislatures have adjourned. Approximately 886 PBM-related bills remain active. Key themes include:

- Delinking PBM compensation — 8 states
- Potential applicability to ERISA plans — 15 states
- Pharmacy reimbursement mandates — 32 states
- Any willing pharmacy (AWP) — 8 states
- Pharmacy steering — 25 states
- Formulary utilization management restrictions — 48 states
- Mandating fiduciary duty on PBMs — 16 states
- Spread ban in the Medicaid and/or commercial markets or requiring disclosure of spread to either the state or plan sponsor — 15 states

**Number of states is approximate given the number of state legislatures that have recently adjourned or are scheduled to do so.*

Emerging state issues

- Regulation of group purchasing organizations (GPOs)/rebate aggregators — 7 states
- Restrictions on vertical integration, including bans on PBM/pharmacy ownership and required merger reviews — 11 states

Enacted state legislation

Arkansas

H.B. 1150 was signed by Governor Sarah Huckabee Sanders on April 16, 2025, and prohibits a PBM from holding a permit for the retail sale of drugs or medicine in the state, effectively prohibiting a PBM from owning a retail, mail-order, or specialty pharmacy.

Alabama

S.B. 252 was signed by Governor Kay Ivey on April 15, 2025. The enacted legislation requires 100% of all rebates to be passed through to the plan sponsor; prohibits PBMs from charging pharmacies fees unrelated to audits, reimbursing independent pharmacies below Medicaid rates, or retroactively reducing reimbursement amounts. The law takes effect immediately, with pharmacy reimbursement rate provisions effective October 1, 2025.

Indiana

S.B. 140 was signed by Governor Mike Braun on May 6, 2025. The enacted bill allows large employers to choose their own PBM by prohibiting third party administrators (TPAs) from requiring use of a specific one. It sets pharmacy reimbursement rates, permits pharmacists to share lower-cost options with patients, and directs a state study on consolidating PBM services for Medicaid and the state employee plan.

S.B. 3 was also signed by Governor Mike Braun on April 16, 2025. This enacted bill requires TPAs and PBMs to act in the best interest of the plan sponsor. It defines fiduciary duty to include acting with loyalty and care, fully disclosing all fees and costs, avoiding conflicts of interest, and maintaining transparency in all financial and contract-related matters, including prescription drug benefits. The law is effective July 1, 2025.

Virginia

S.B. 875 was signed by Governor Glenn Youngkin on May 5, 2025, and directs the Department of Medical Assistance Services (DMAS) to contract with a single third-party administrator by July 1, 2026, to manage all Medicaid pharmacy benefits. The contract must establish fiduciary duty, mandate pass-through pricing, adopt DMAS-negotiated formularies and reimbursement terms, ensure full pricing and rebate transparency, and ban spread pricing in Medicaid.

State legislation pending Governor's action

Iowa

S.F. 383 passed the House and Senate and awaits action by the Governor. The bill mandates specific reimbursement and dispensing fees for independent and Hy-Vee pharmacies, enforces AWP requirements, bans co-pay accumulators and preferred pharmacy networks, prohibits reimbursing non-affiliated pharmacies less than affiliates, requires full rebate pass-through to employers, eliminates spread pricing, and bans mandatory or incentivized mail-order use. Provisions must appear in pharmacy contracts after July 1, 2025, and take effect January 1, 2026.

Colorado

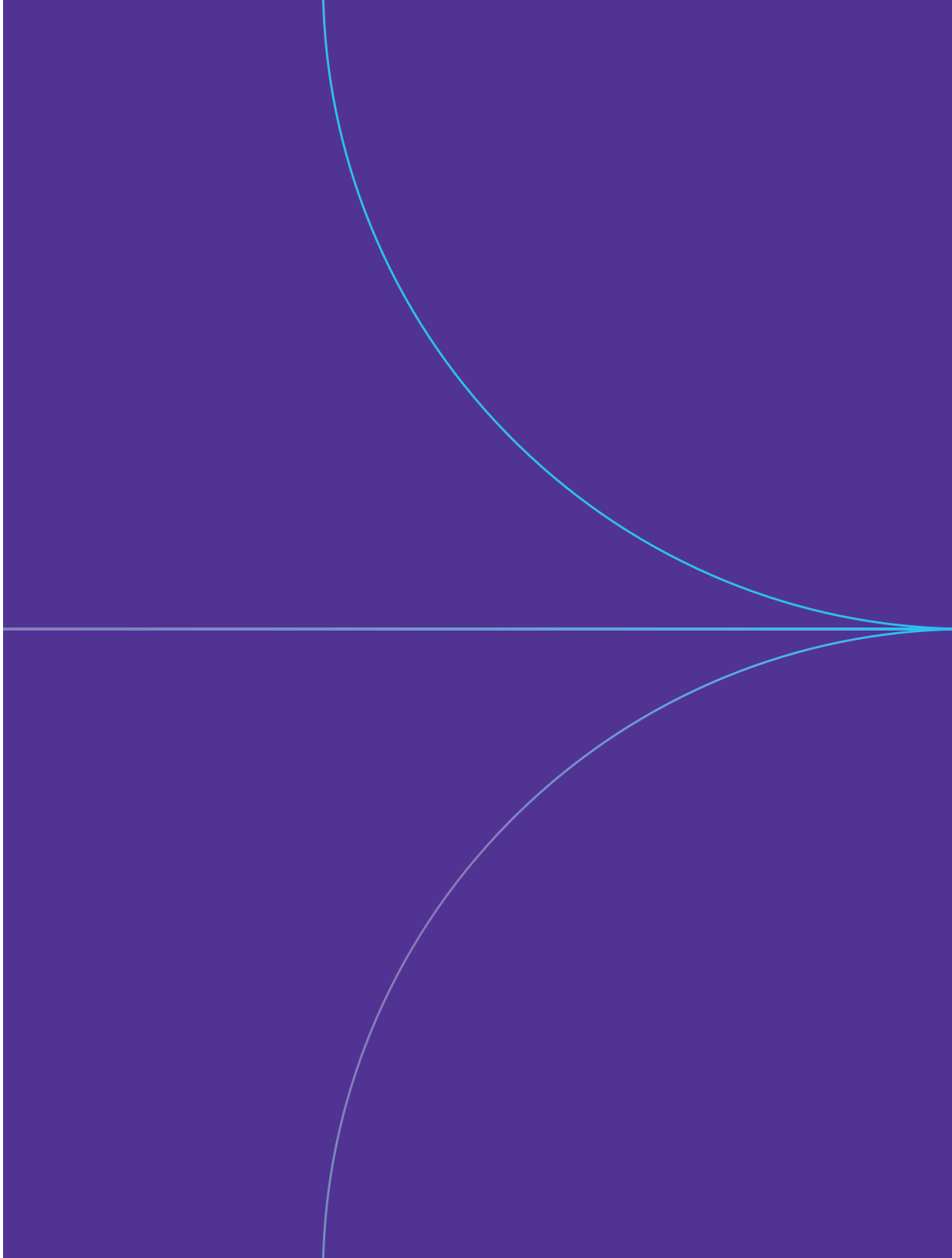
SH.B. 1094 passed both chambers and awaits the Governor's decision by June 7, 2025. The bill includes key provisions including exemptions for ERISA plans and limits PBM compensation to flat fees per prescription. It prohibits formularies that favor higher-cost drugs unless they offer a lower net cost, mandates cost-based pharmacy reimbursements, and requires PBMs to disclose pricing and income data. It also calls for PBMs to return any inadvertently collected income to health plans. The law would take effect January 1, 2027.

Texas

S.B. 1236 passed both chambers and awaits the Governor's action. The bill mandates that PBM contracts be governed by the Texas Insurance Code, limits pharmacy audit recoveries to nominal dispensing fees when the correct drug and dosage are dispensed and requires PBMs and plan issuers to give pharmacies secure online access to network contracts and amendments.

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 May 28, 2025.

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