

Q1 2026 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 December 19, 2025, and February 20, 2026.

Federal regulatory update

Medicare

Medicare Drug Price Negotiation Program

On January 27, the Centers for Medicare & Medicaid Services (CMS) announced the selection of 15 high-cost drugs for the third cycle of the Medicare Drug Price Negotiation Program (initial price applicability year 2028), marking the first inclusion of Medicare Part B drugs. CMS also selected one previously negotiated drug for its first renegotiation. Negotiations will occur in 2026, with negotiated prices taking effect January 1, 2028.

Medicare Advance Notice

On January 26, CMS released the Advance Notice for CY 2027 Medicare Advantage (MA) and Part D payment policies. Key updates include:

- **Inflation Reduction Act implementation:** Considering ongoing Part D benefit redesign under the Inflation Reduction Act (IRA), CMS proposes updates to the Part D Prescription Drug Hierarchical Condition Category (RxHCC) risk adjustment model to reflect the revised benefit structure in historical spending data.
- **Separate model segments for Medicare Advantage prescription drug plans (MA-PD) and standalone prescription drug plans (PDP):** CMS proposes creating distinct continuing enrollee risk adjustment model segments for beneficiaries enrolled in integrated Medicare Advantage Prescription Drug Plans and those enrolled in standalone Prescription Drug Plans.

Comments were due on February 25.

Better Approaches to Lifestyle and Nutrition for Comprehensive hEalth (BALANCE) Model

On December 23, 2025, CMS released a Notice of Intent (NOI) for plan sponsors and states, along with a manufacturer request for applications (RFA), for the Better Approaches to Lifestyle and Nutrition for Comprehensive hEalth (BALANCE) Model. The model is designed to expand access to certain glucagon-like peptide-1 (GLP-1) medications and related lifestyle interventions in Medicare and Medicaid.

- CMS would negotiate pricing and coverage terms with manufacturers on behalf of Part D sponsors and state Medicaid agencies.
- State Medicaid coverage could begin May 2026; the Part D component would launch January 2027.
- An initial demonstration operated outside of the Medicare Part D benefit is expected to launch as early as July 2026 and serve as a bridge to the BALANCE Model.
- Participation depends on manufacturer, state, and plan engagement.
- Manufacturers would establish eligibility criteria (e.g., prior authorization).
- Eligible beneficiaries would receive manufacturer-funded lifestyle support at no cost.

Medicare Most-Favored-Nation drug payment models

On December 19, 2025, CMS issued two Proposed Rules to launch two new models testing alternative approaches to Medicare Part B and Part D inflation rebates, aiming to lower drug prices in Medicare:

- Global Benchmark for Efficient Drug Pricing (GLOBE) Model, a mandatory five-year model which tests alternative payment methods for calculating Part B inflation rebates for certain separately payable Part B drugs and biological products. Model would launch October 1, 2026, and continue through 2031 with rebate invoicing and reconciliation continuing into 2033.
- Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model, a mandatory five-year model which tests alternative payment methods for calculating inflation rebates for certain Part D drugs and biological products. Model would launch on January 1, 2027, and continue through 2031 with rebate invoicing and reconciliation continuing into 2033.
- Comments for both proposed rules were due on February 23.

340B Drug Program

340B rebate pilot

After withdrawing its 340B rebate pilot program following a court challenge, the Health Resources and Services Administration (HRSA) has issued a request for Information (RFI) to guide next steps on potential rebate models under the 340B Program.

The agency is seeking public input on whether it should implement a rebate model and, if so, how best to operationalize it. The agency will use this input to determine whether a revised 340B rebate pilot is in the public interest and, if appropriate, how to implement it consistent with the 340B statute. Comments are due March 19, 2026.

Commercial market

Pharmacy Benefit Manager Fee Disclosure Proposed Rule

On July 29, 2025, the Department of Labor (DOL) issued a proposed rule that would require providers of pharmacy benefit manager (PBM) services and affiliated providers of brokerage and consulting services to disclose information about their compensation to fiduciaries of self-insured group health plans subject to the Employee Retirement Income Security Act (ERISA). Comments on the rule are due March 31.

General updates

Tariffs

On February 20, the U.S. Supreme Court ruled 6 to 3 that President Donald Trump did not have authority under the International Emergency Economic Powers Act to impose broad tariffs on imports from most countries. The decision invalidates those global “reciprocal” tariffs, which had applied duties of 10–50% across many types of goods. This ruling only applies to tariffs issued under that emergency law. A separate national security trade law — Section 232 of the Trade Expansion Act — allows tariffs if imports are found to threaten U.S. national security. The Administration has launched a Section 232 review of pharmaceutical imports, including finished drugs and key ingredients. That review is ongoing, and no pharmaceutical tariffs have been imposed under this authority.

In response to the Court ruling, on February 20, the President used a different legal authority under the Trade Act of 1974 to impose a temporary tariff on select imports. Certain goods, including pharmaceuticals and pharmaceutical ingredients, are exempt based on economic and policy considerations.

TrumpRx launch

On February 5, the White House launched TrumpRx, a website facilitating access to manufacturer direct-to-consumer (DTC) pricing platforms.

- Initially includes 40 brand-name drugs from five manufacturers participating in Most-Favored-Nation (MFN) pricing arrangements.
- Does not accept insurance; patients must agree not to seek reimbursement.
- Requires a valid prescription.
- Additional manufacturers and products are expected to be added.

Drug supply chain proposed rule

On January 26, CMS issued a proposed rule seeking feedback on potential approaches to strengthen the American-made supply chain for personal protective equipment and essential medicines, including the creation of a new “Secure American Medical Supplies” designation for hospitals committed to American-made purchasing, and streamlined payment approaches to help offset the resource costs of domestic procurement. Comments are due March 30.

Federal Anti-Kickback Statute RFI and guidance related to DTC programs

On January 27, the Department of Health and Human Services Office of Inspector General issued:

- An RFI seeking input on potential updates to Anti-Kickback Statute safe harbors related to DTC drug programs (comments due March 30).
- A Special Advisory Bulletin outlining safeguards for DTC drug programs, including independent prescribing, exclusion from federal claims submission, no out-of-pocket accumulation, full-plan-year availability, and exclusion of controlled substances.

White House releases healthcare affordability framework

On January 15, the White House released a healthcare affordability and transparency framework requiring congressional action. Proposals include:

- Codifying Most-Favored-Nation pricing arrangements.
- Expanding over-the-counter access to certain pharmaceutical products.
- Enhancing insurer and provider transparency.
- Prohibiting certain pharmacy benefit manager payments to brokers.

Congressional update

Drug Supply Chain Hearing

On February 11, the U.S. House of Representatives Energy and Commerce Committee Health Subcommittee held a hearing on prescription drug supply chain costs and market dynamics, featuring testimony from pharmaceutical manufacturers, pharmacy benefit managers, distributors, pharmacists, and employers.

Anti-Vertical Integration Legislation

Senators Elizabeth Warren and Josh Hawley introduced the bipartisan Break Up Big Medicine Act, targeting consolidation and vertical integration across health insurers, pharmacy benefit managers, medical providers, management services organizations, pharmacies, and prescription drug or medical device wholesalers.

The Consolidated Appropriations Act, 2026

On February 3, the Consolidated Appropriations Act, 2026 (CAA) was signed into law and establishes new national standards for pharmacy benefit managers in commercial employer plans and Medicare. Key drug-specific provisions include:

Commercial Provisions (effective 30 months after enactment)

- **Transparency:** Requires semi-annual reporting to group health plans and issuers detailing prescription drug spending, utilization, rebates, fees, and pharmacy network arrangements; beneficiaries may request summary information.
- **Rebate Pass-Through:** Requires 100% pass-through of manufacturer rebates, fees, and discounts to plans governed by the Employee Retirement Income Security Act of 1974, excluding bona fide service fees.
- **Contract Access and Audit Rights:** Grants plan sponsors access to rebate contracts and audit authority.

Medicare Part D provisions

- **Delinking Compensation (Effective 2028):** Limits pharmacy benefit manager compensation to flat, fair-market-value bona fide service fees and prohibits remuneration tied to drug price, rebates, or volume.
- **Annual Reporting (Effective 2028):** Requires reporting on spending, utilization, cost-sharing structures, access to generics and biosimilars, affiliate relationships, broker compensation, and manufacturer rebate conditions.
- **Any Willing Pharmacy (Effective 2029):** Requires plan sponsors to admit pharmacies meeting “reasonable and relevant” contract standards established by the Secretary of Health and Human Services.
- **Plan Reporting Requirements:** Requires reporting of pharmacy incentive payments (beginning 2027) and affiliated retail pharmacies (beginning 2028).
- **Low-Income Cost Sharing (Effective 2028):** Establishes zero-dollar cost sharing for generic drugs for certain low-income beneficiaries.
- **Government Accountability Office and Medicare Payment Advisory Commission Studies:** Directs evaluation of compensation and payment structures in the Part D supply chain.

Other drug provisions

- Requires disclosure of inactive ingredient information to facilitate generic drug approvals.
- Closes orphan drug exclusivity loopholes that limit therapeutic competition.

State activity update

State legislative activity

As of February 17, 549 PBM-related bills have been introduced across 45 states, in addition to approximately 650 bills carried over from the 2025 legislative sessions.

Legislation continues to focus on core PBM business practices, including restrictions on vertical integration and forced pharmacy arrangements; delinking or limiting PBM compensation to flat fees; spread pricing bans; rebate pass-through requirements (including point-of-sale pass-through); and mandated pharmacy reimbursement standards.

There is also a growing volume of bills addressing coverage mandates and limiting utilization management (UM) for specific disease states, including metastatic breast cancer, mental illness, dementia, and related conditions. Additional proposals would impose fiduciary duties on PBMs, define “specialty drug,” and restrict formulary management practices.

Emerging issues

A notable new trend this year is legislation requiring plans to apply cash-pay prescription drug transactions toward enrollee deductibles and cost-sharing limits. Bills introduced in Kentucky and West Virginia define “cash pay” broadly to include drugs purchased using discount cards, manufacturer assistance programs, direct-to-consumer (DTC) pricing arrangements, and in some cases pharmacy-discounted cash prices.

State activity

Virginia

PBM reform legislation (HB830/SB669) is advancing through the Virginia General Assembly as part of Governor Spanberger's healthcare affordability package. The bill would require PBMs to pass through 100% of rebates to plan sponsors or to consumers at the point of sale and to offer a delinked, fee-based compensation model upon request by a plan sponsor. The legislation would also expand PBM reporting requirements and mandate a study examining PBM steering to affiliated pharmacies.

Tennessee

Legislation has been introduced in Tennessee (SB 2040) that would prohibit "direct or indirect" PBM ownership of retail, mail-order, and specialty pharmacies, regardless of ownership structure. The bill includes limited carve-out language for certain hospital-affiliated pharmacies, expands oversight authority for the Tennessee Board of Pharmacy, and would require approval from the Attorney General for certain pharmacy transactions or sales.

Similar legislation has been introduced in Arizona (SB 1545) and Oklahoma (HB 3538). Comparable bills in New Jersey, New York, and Pennsylvania were carried over from the 2025 legislative sessions and remain pending.

West Virginia

House Bill 5430 and House Bill 907 have been introduced and received an initial hearing in the House Health Committee. The legislation would prohibit spread pricing and ban the use of a group purchasing organization (GPO) "for the purpose of avoiding PBM regulatory requirements."

A separate bill, House Bill 5109, would expand the definition of "pharmacy benefit manager" to include additional entities that provide PBM services or arrange for the procurement of such services.

Kentucky

House Bill 512 would broaden the definition of "rebates" and require that between 80 and 85 percent of rebates be passed through at the point of sale (pharmacy counter), with the remainder passed through to the plan sponsor. The bill is currently under active consideration.

Other state updates

Omnibus PBM regulatory bills have been introduced in Utah and Kansas, including provisions to prohibit spread pricing.

Delinking legislation, which would limit PBM compensation to a fee-based model, is pending in New Hampshire and New Jersey.

Legislation establishing minimum pharmacy reimbursement requirements has been introduced in Illinois, Kansas, and South Carolina.

Litigation and enforcement

Arkansas

AHIP and the Arkansas Chamber of Commerce have filed amicus briefs in support of the Pharmaceutical Care Management Association's (PCMA's) legal challenge to Arkansas' prohibition on PBMs holding pharmacy licenses. Their participation reflects broader industry opposition to the law and bolsters arguments against state-mandated divestiture requirements.

Florida

Florida regulators have initiated audits of PBMs under the state's 2023 law, requesting claims-level data that includes personally identifiable information (PII). This enforcement posture raises significant operational, legal, and patient privacy concerns associated with state transparency and reporting requirements.

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 March 2, 2026.

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