Q1 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 December 1, 2024, and February 7, 2025.

Federal regulatory activity

Commercial market

Proposed rules on coverage of over-the-counter contraceptives

On January 15, 2025, the Biden Administration withdrew its proposed rule that would have required coverage of certain over-the-counter (OTC) items, including contraceptives, without a prescription and without cost-sharing requirements.

Notice of Benefit and Payment Parameters final rule

On January 13, 2025, the Centers for Medicare & Medicaid Services (CMS) released the final 2026 Notice of Benefit and Payment Parameters (NBPP) rule that includes payment parameters and provisions related to the HHS-operated risk adjustment and risk adjustment data validation (HHS-RADV) programs for the individual and small group markets. In the proposed version of the rule, CMS indicated it intended to issue future rulemaking to address the definition of "cost-sharing," which would impact the treatment of drug manufacturer support (i.e. copay coupons) to the annual limitation on cost-sharing. However, this issue was not mentioned in the final rule.

General drug update

Telemedicine prescribing of controlled substances

On January 17, 2025, the Drug Enforcement Administration (DEA) and HHS jointly published two final rules addressing the prescription of controlled substances via telemedicine in limited contexts: prescription of buprenorphine and prescriptions by Department of Veterans Affairs (VA) practitioners to VA patients. The same day, the DEA also published a proposed rule that seeks to establish a "special registration" framework that would broadly permit the prescription of controlled substances via telemedicine without an in-person evaluation.

FTC interim report on PBMs

On January 14, 2025, the Federal Trade Commission (FTC) unanimously voted to release its second interim report on pharmacy benefit managers (PBMs), which builds on its first report and focuses on reimbursement of specialty generic drugs by the three largest PBMs: CVS Caremark, Express Scripts, and OptumRx.

FDA draft guidance on developing obesity and weight management drugs

On January 7, 2025, the U.S. Food and Drug Administration (FDA) released draft guidance that "provides recommendations to industry regarding the development of drugs and biological products regulated within the Center for Drug Evaluation and Research intended for reduction and long-term maintenance of body weight in patients with obesity or overweight," revising and replacing draft guidance released in 2007. Comments are due to the FDA by April 8, 2025.

Prescription drug pricing report to Congress

On December 4, 2024, the Assistant Secretary for Planning and Evaluation (ASPE) released the first report to Congress analyzing the data submitted by issuers under Section 204 of the 2021 Consolidated Appropriations Act (CAA) Prescription Drug Data Collection (RxDC) program. The report highlights the value of prescription drug rebates, showing that rebates reduced employer and individual market plan drug spending by over 20%, and reduced Medicare Part D and Medicaid drug spending by 31% and 53%, respectively.

Congressional activity

Senate

Prescription drug advertisements

On February 7, 2025, Senator Angus King (I-ME) introduced the Responsibility in Drug Advertising Act (S 4785), which would prohibit direct-to-consumer (DTC) advertising of a new drug in the first three years after the drug receives FDA approval.

On January 23, 2025, Senators Chuck Grassley (R-IA) and Dick Durbin (D-IL) reintroduced the DTC Act of 2025 (S 229), which would require price disclosures on prescription drug advertisements.

Bill limiting ownership of PBMs and pharmacies

On December 11, 2024, Senators Elizabeth Warren (D-MA) and Josh Hawley (R-MO), along with Representatives Diana Harshbarger (R-TN) and Jake Auchincloss (D-MA) introduced the Patients Before Monopolies Act (S 5503), which would prohibit a parent company of a PBM or an insurer from owning a pharmacy business and require these entities to divest their pharmacy businesses within three years.

House of Representatives

21st Century Cures initiative

On December 21, 2024, Representative Diana DeGette (D-CO) and former Representative Larry Bucshon (R-IN) released a white paper on potential next steps for Cures 2.1 and the 21st Century Cures initiative that aims to create an environment that enables the rapid and appropriate deployment of innovative technologies to improve health outcomes; build a health care infrastructure that enables information sharing, continuous evidence gathering, and implementation of new knowledge; and foster innovations that improve public health, promote patient-centric care, reduce the burden of chronic disease, and conserve valuable resources.

State legislative activity

- As of February 4, 2025, over 700 PBM-related bills have been introduced across 44 states.
- "Delinking" legislation that would limit PBM compensation to a flat dollar amount is currently pending in six states.
- Categories of introduced PBM bills with potential for significant impact to business include:
  - 21 bills in 13 states include language with potential to be applicable to the Employee Retirement Income Security Act of 1974 (ERISA)
  - 21 bills in 11 states would impose a fiduciary responsibility on PBMs
  - 20 bills in 10 states would require any pharmacy to be considered in-network if it accepts terms and conditions
  - 56 bills in 20 states would include pharmacy reimbursement mandates
  - 35 bills in 14 states would prohibit reimbursement differentiation on affiliate vs. non-affiliate pharmacies or prohibit the practice of pharmacy steering
  - 23 bills in 14 states would either prohibit spread (in the Medicaid and/or commercial markets) or require disclosure of spread to either the state or plan sponsor

Other common themes in the introduced legislation include limits on PBM's utilization management tools, coverage mandates, transparency and reporting requirements, and cost-sharing mandates.

Emerging state issues

- **Pharmacy ownership restrictions:** Three states introduced legislation designed to place restrictions on pharmacy ownership. Arkansas HB 1150 would prohibit any PBM from obtaining a permit for the retail sale of drugs or medicine in the state while Oregon HB 2252 would require PBMs to demonstrate that they are not owned by or affiliated with an insurer to conduct business in the state. These two bills appear to be based on federal legislation introduced at the end of 2024. In addition, South Dakota HB 1016 would require all pharmacies operating in the state to be owned by a licensed pharmacist.
- **Patient assistance/alternative funding programs:** In Oregon, HB 3082 and SB 447 were introduced to require manufacturers to disclose information pertaining to patient assistance programs. In New Jersey, A 4015 and S 2886 were introduced to require all pharmacies to display notices disclosing availability of patient assistance programs for insulin.
- **Pharmacy deserts:** In Hawaii, HB 223 was introduced to establish a special fund to which all pharmacies would contribute to provide financial support for pharmacies in underserved and rural areas. In Massachusetts, HD 896 and SD 718 were introduced to direct the state to conduct a study assessing existing pharmacy deserts and measure the impact of barriers to pharmacy access on patient outcomes.

Other state highlights

New Mexico

On February 6, 2025, New Mexico's "delinking" bill, SB 62, was removed from the Senate Tax, Business, & Transportation Committee's agenda after the Fiscal Impact Report showed an impact of almost $170 million to the state's retiree and public-school insurance benefit plans.

Virginia

On January 21, 2025, HB 2774 and SB 1078 were defeated in Virginia. These bills would have restricted PBM compensation to fixed fees, required point-of-sale rebates, and mandated a PBM fiduciary duty.

Arkansas

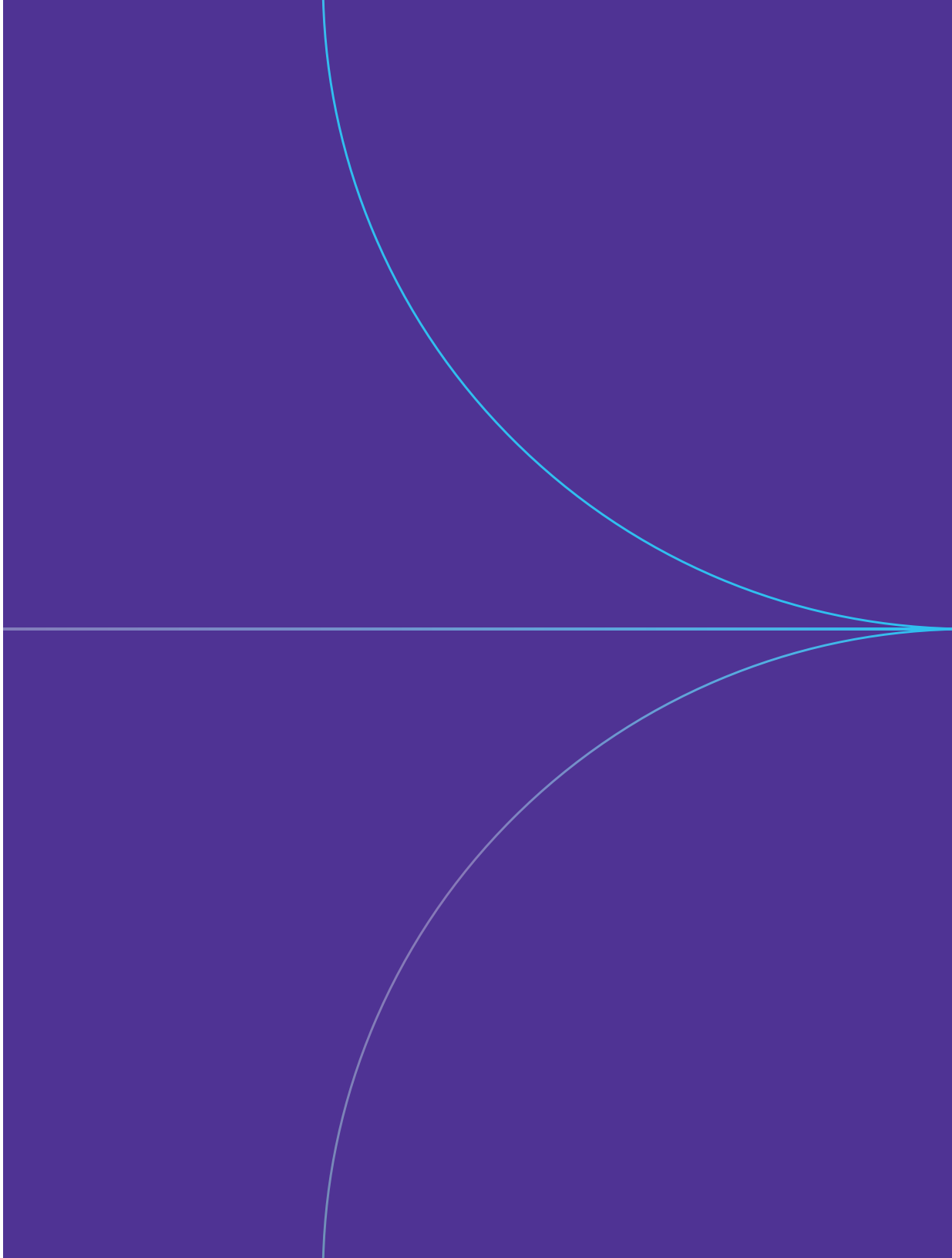
On January 16, 2025, HB 1150 was introduced to prohibit a healthcare payor or PBM from holding an Arkansas state pharmacy permit. This legislation, which is being advanced by the Arkansas Pharmacists Association, would impact specialty and mail order pharmacies and would apply to state employee plans.

California

On December 3, 2024, SB 41 was pre-filed in advance of the start of the 2025 legislative session. The bill is a reintroduction of omnibus anti-PBM legislation (SB 966) from last year that includes provisions on delinking (that would restrict PBM compensation to only fixed fees), spread pricing prohibitions, as well as pharmacy anti-steering and fiduciary duty provisions. Governor Newsom vetoed SB 966 at the end of 2024 based on his belief that the bill would not address the issue of high drug costs. In early January 2025, Governor Newsom delivered his budget address in which he asserted his desire to evaluate key drivers of prescription drug cost growth including the impact of PBMs and to increase transparency across the entire pharmacy supply chain.

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 February 18, 2025.

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