



September 11, 2019

COST CONTAINMENT OF PRESCRIPTION DRUGS—STATE ACTION

The rising cost of prescription drugs in the United States is a source of concern for patients, prescribers, payers, and policymakers.¹ In 2013, per capita spending on prescription drugs was \$858, compared with an average of \$400 for 19 other industrialized nations.² In 2016, total U.S. prescription sales was \$448.2 billion, which was a 5.8 percent increase compared with 2015.³ This memorandum explores the cost of prescription drugs and state efforts to reduce those increasing costs.

Recent State Action

According to the National Conference of State Legislatures (NCSL), in 2018 and 2019, at least 130 new laws were signed in 42 states and Puerto Rico related to prescription drugs.⁴ NCSL keeps track of state legislative activity in its “Statewide Prescription Drug Database, 2015-Present” report.⁵

In addition to legislative action, lawsuits have been filed related to prescription drug pricing. In November 2018, the Kansas Attorney General, along with the attorneys general of 31 other states and the District of Columbia, filed a brief with the U.S. Supreme Court, asking the U.S. Supreme Court to overturn a ruling by the U.S. Court of Appeals for the Eighth Circuit related to the preemption of state pharmacy benefit manager (PBM) laws by the federal government.⁶

Additionally, the Connecticut Attorney General, joined by attorneys general from 43 other states, including Kansas, filed an antitrust complaint on May 10, 2019, in the U.S. District Court for the District of Connecticut.⁷ The complaint alleges Teva Pharmaceuticals, with other companies and individuals described in the complaint as co-conspirators, worked together to

1 Aaron S. Kesselheim, Jerry Avorn, and Ameet Sarpatwari, *The High Cost of Prescription Drugs in the United States*, 316 JAMA 858 (2016).

2 *Id.*

3 Glen T. Schumock et al., *National Trends in Prescription Drug Expenditures and Projections for 2017*, 74 American Journal of Health-System Pharmacy 1158 (2017).

4 NCSL, *Statewide Prescription Drug Database, 2015-Present* (updated as of August 26, 2019), <http://www.ncsl.org/research/health/prescription-drug-statenet-database.aspx>.

5 *Id.*

6 *Rutledge v. Pharmaceutical Care Management Ass’n*, 2018 WL 6179405 (U.S.).

7 *State of Connecticut et al. v. Teva Pharmaceuticals et al.*, Complaint, 2019 WL 2126100 (D. Conn 2019).

artificially inflate and maintain prices and reduce competition in the generic pharmaceutical industry in the United States.⁸

Kansas

Recent Legislative Sessions

In recent legislative sessions, Kansas has enacted bills related to the substitution of biological products and the activities of PBMs.

Substitution of biological products. Senate Sub. for HB 2055, enacted in 2017, amended the Kansas Pharmacy Act to, among other things, permit pharmacists to exercise brand exchange (substitution) of biological products without prior approval from the prescriber, unless certain conditions exist. Under KSA 65-1637, pharmacists are required to notify the patient and prescriber of the substitution of a biological product after the exchange has occurred. The statute also specifies recording requirements for biological product substitutions.

PBMs. SB 103 (2016) created law related to contracts between pharmacies and PBMs. The 2016 legislation is codified at KSA 2018 Supp. 40-3829 and 40-3830. PBMs are prohibited from placing a drug on a maximum allowable cost (MAC) list unless at least two therapeutically equivalent multi-source generic drugs, or at least one generic drug available from at least one manufacturer, are generally available for purchase by network pharmacies from national or regional wholesalers, and the drug is not obsolete (KSA 2018 Supp. 40-3830(a)). Under KSA 2018 Supp. 40-3830, PBMs must provide to each network pharmacy at the beginning of a contract term, and upon request thereafter, the sources utilized to determine the MAC price; provide a process for each network pharmacy provider to readily access the maximum allowable price specific to that provider; review and update each applicable MAC list every seven business days and apply the updates to reimbursements by no later than one business day; and ensure dispensing fees are not included in the calculation of MAC. PBMs are also required to establish an appeal process to permit a network pharmacy to appeal reimbursement for a drug specific to MAC, as specified in KSA 2018 Supp. 40-3830.

SB 351 (2018) created the Kansas Pharmacy Patients Fair Practices Act (Act), which is codified at KSA 2018 Supp. 40-3831. The Act specifies co-payments applied by a health carrier for a prescription drug may not exceed the total submitted charges by the network pharmacy (KSA 2018 Supp. 40-3831(c)(1)). Additionally, a pharmacy or pharmacist has the right to provide a covered person with information regarding the amount of the covered person's cost share for a prescription drug (KSA 2018 Supp. 40-3831(c)(2)). The Act specifies neither a pharmacy nor pharmacist can be proscribed by a PBM from discussing any such information or selling a more affordable alternative to the covered person, if such alternative is available (KSA 2018 Supp. 40-3831(c)(1)). [Note: This is often described as prohibiting PBM "gag clauses" that restrict pharmacists from disclosing prices to consumers.] The Act applies to any contract between a PBM and a pharmacy, pharmacy services administration organization, or group purchasing organization entered or renewed on and after January 1, 2019, but exempts supplemental policies (KSA 2018 Supp. 40-3831(d)(1-2)).

8 *Id.*

State Employee Health Plan

The State Employee Health Plan (SEHP) provides health insurance coverage for state employees, retirees, and their dependents. The SEHP offers medical, dental, vision, prescription drug, and other benefits. In total, about 90,000 state employees and their dependents are enrolled in the SEHP.⁹

The SEHP is overseen by the Kansas State Employees Health Care Commission (HCC), which was created by the 1984 Legislature through enactment of KSA 2018 Supp. 75-6501 *et seq.* The HCC is authorized to “negotiate and enter into contracts with qualified insurers, health maintenance organizations and other contracting parties for the purpose of establishing the state health care benefits program.” The HCC is assisted by a 21-member employee advisory committee. The HCC is responsible for overseeing the SEHP, but the Kansas Department of Health and Environment (KDHE) is responsible for the day-to-day operations of the SEHP. The staff administering the SEHP became part of the Division of Health Care Finance of KDHE beginning July 1, 2011.

The current PBM contract of the SEHP expires December 31, 2019. A request for proposal (RFP) for PBM services of the SEHP was released January 23, 2019, and closed March 14, 2019. The objectives of the bid included maximizing the State’s purchasing power by securing market competitive financial terms while maintaining comprehensive and flexible PBM programs, and providing excellent member service and high quality benefits to eligible employees and their dependents. The RFP requested transparent pricing terms, a managed formulary, and both an open and exclusive specialty pharmacy arrangement (including site of care and drug benefit alignment). The State also expressed interest in considering a carve-out specialty drug program.¹⁰

The State received bids from Blue Cross Blue Shield of Kansas (BCBS), partnering with Prime Therapeutics; CVS Health; Envelope; Navitus Health Solutions; OptumRx; WellDyneRx; and the University of Kansas Health System. The first phase of the RFP analysis eliminated those bidders that did not have the capacity to adequately serve the needs of the State. The SEHP staff then held negotiation meetings with CVS Health, BCBS (Broad with Walgreens or CVS option), BCBS (Broad Plus), OptumRx, and Envelope. Following the meetings, the companies were asked to provide additional information to clarify their bids and their best and final pricing. The SEHP staff recommended a three-year contract be awarded to CVS Health for PBM services.

On June 3, 2019, the HCC met to discuss the PBM contract, among other items. The HCC had a detailed discussion of the PBM contract and negotiations. A vote on the contract was postponed until a later date. On June 28, 2019, the HCC was presented with follow-up information, including that CVS Health was then administering the State’s commercial prescription drug benefits under a transparent pricing arrangement and CVS Health passes through 100.0 percent of rebates the SEHP earns; however, certain products were excluded from the minimum rebate guarantee (e.g., biosimilars), as those products generally do not yield a rebate. The HCC approved a three-year contract with CVS Health for PBM services for plan years 2020-2022.¹¹

9 HCC, *Annual Report: Plan Year 2018*, http://www.kdheks.gov/hcf/sehp/healthcare_commission.html.

10 HCC Meeting Materials for June 3, 2019, <http://www.kdheks.gov/hcf/hcc/MeetingMaterials/HCC060319.htm>.

11 HCC Meeting Materials for June 28, 2019, <http://www.kdheks.gov/hcf/hcc/MeetingMaterials/HCC062819.htm>.

Other State Action—Policy Topics

States have taken various actions related to the cost of prescription drugs. The following is a snapshot of those actions, which include capping the price of insulin, the creation of a drug affordability board, permitting the importation of drugs from Canada, regulation of PBMs, addressing the price of generics, and volume-based purchasing. [Note: See the Appendix beginning on page 8 for a listing of reference materials by topic and state.]

Cost of Insulin

Colorado. In May 2019, Governor Polis signed HB 1216 into law, which caps patient co-payments of insulin at \$100 per 30-day supply of insulin, regardless of the amount or type of insulin required by the patient. The bill also directs the Department of Law to investigate pricing of prescription insulin made available to Colorado consumers to ensure adequate consumer protections in pricing and determine whether additional consumer protections are needed.

Minnesota. In August 2019, health insurance provider Medica announced it was placing a \$25 a month cap on the maximum amount commercial and individual market members will pay for insulin. Starting January 1, 2020, all members of fully insured commercial groups headquartered in Minnesota and individual members in Minnesota will pay no more than \$25 for each 30-day supply of insulin.¹²

Industry action. In March 2019, Eli Lilly announced it would introduce a lower-priced version of Humalog, called Insulin Lispro, available at a list price of \$137.35 for a single vial and \$265.20 for a five-pack of pens.¹³ In April 2019, Cigna and Express Scripts announced the launch of the Patient Assurance Program, which limits the cost of insulin to no more than \$25 for a 30-day supply.¹⁴ In September 2019, Novo Nordisk announced the company will offer a generic version of its most heavily prescribed insulin drug, Novolog, at a 50.0 percent discount compared to its current list price. The company will also introduce a cash card program, beginning in 2020, that patients can use to buy three vials or two packs of pens of the company's analog insulin for a flat cost of \$99.¹⁵

Drug Affordability Board

During the 2019 Legislative Session, several states considered legislation to create prescription drug affordability review boards.¹⁶ These boards would identify certain high-cost

12 Press Release, *Medica Introduces Insulin Cost Relief Program*, Medica (August 6, 2019), <https://www.medica.com/newsroom/press-releases/press-releases/2019/08062019-medica-introduces-insulin-cost-relief-program>.

13 Press Release, *Lilly to Introduce Lower-Priced Insulin*, Eli Lilly (March 4, 2019), <https://investor.lilly.com/news-releases/news-release-details/lilly-introduce-lower-priced-insulin>.

14 Press Release, *Cigna and Express Scripts Introduce Patient Assurance Program to Cap Out of Pocket Costs at \$25 Per 30-day Insulin Prescription*, Cigna (April 3, 2019), <https://www.cigna.com/newsroom/news-releases/2019/cigna-and-express-scripts-introduce-patient-assurance-program-to-cap-out-of-pocket-costs-at-25-per-30-day-insulin-prescription>.

15 Reuters, *Novo Nordisk to Cut Insulin Prices in the U.S.* (September 6, 2019), <https://www.reuters.com/article/us-novo-nordisk-usa/novo-nordisk-to-cut-insulin-prices-in-the-us-idUSKCN1VR1JO>.

drugs and enable states to set allowable rates for those drugs. Maine and Maryland enacted statutes creating these boards in their states.

Maine. In June 2019, LD 1449 was enacted to establish a Drug Affordability Review Board. The Board may consider expanding the purchasing pool for prescription drugs and allow carriers that cover small business and individuals to buy into a public payer drug benefit plan.

Maryland. In May 2019, HB 768 was enacted to establish the Prescription Drug Affordability Board. The Board must make specified determinations, collect data, and identify specified prescription drug products that may cause affordability issues. The Board may conduct a cost review of each drug and, if required, draft a plan of action that includes criteria to set upper payment limits for prescription drugs.

Drug Importation

Current federal law authorizes the Secretary of Health and Human Services (HHS) to allow wholesale importation of prescription drugs from Canada in limited circumstances, if such importation is shown to be both safe and less costly for American consumers.¹⁷ States must have approval of programs by the Secretary of HHS in order to implement drug importation from Canada in the state. Four states have passed legislation authorizing a drug importation plan under current federal law, but none have submitted their plans to HHS for approval. On July 31, 2019, HHS announced that HHS and the U.S. Food and Drug Administration were publishing the Safe Importation Action Plan outlining two potential pathways for the importation of certain drugs.¹⁸

Colorado. In May 2019, Governor Polis signed SB 5 into law, which creates the Colorado Wholesale Importation of Prescription Drugs Act. The bill requires the Department of Health Care Policy and Financing to design a program to import prescription pharmaceutical products from Canada for sale to Colorado consumers. The bill requires Colorado to seek HHS approval by September 1, 2020.

Florida. In June 2019, Governor DeSantis signed HB 19 into law, which requires the Agency for Health Care Administration to establish the Canadian Prescription Drug Importation Program. The bill authorizes a Canadian supplier to export drugs into Florida under certain circumstances and establishes an international export pharmacy permit for participation in the International Prescription Drug Importation Program. The bill requires applications to be filed with HHS by July 1, 2020.

Maine. In June 2019, Governor Mills signed LD 1272 into law, which establishes a Canadian wholesale prescription drug importation plan. The bill requires applications to be filed with HHS no later than May 1, 2020.

16 Center for State Rx Drug Pricing, *Comparison of Bills Creating State Prescription Drug Affordability Review Boards*, NASHP (March 19, 2019), <https://nashp.org/comparison-of-bills-creating-state-prescription-drug-affordability-review-boards/>.

17 21 U.S.C. 384

18 Press Release, *HHS Announces New Action Plan to Lay Foundation for Safe Importation of Certain Prescription Drugs*, HHS (July 31, 2019), <https://www.hhs.gov/about/news/2019/07/31/hhs-new-action-plan-foundation-safe-importation-certain-prescription-drugs.html>.

Vermont. In May 2018, Vermont became the first state in the nation to approve the importation of prescription drugs from Canada with the enactment of S. 175.¹⁹ The bill directed the Agency of Human Services to design a program for wholesale importation of prescription drugs into Vermont from Canada and required the Agency of Human Services to submit a formal request to HHS by July 1, 2019. The 2019 appropriations bill (H. 542), signed by the Governor on June 18, 2019, extended the submission of the plan to HHS by one year, to July 1, 2020.

PBMs

According to NCSL's Statewide Prescription Database (last updated May 20, 2019), in 2019, 18 states enacted 26 bills related to PBMs. Enacted legislative topics include audits (New Mexico, Tennessee, and Virginia), prohibition on gag clauses (Alabama, Minnesota, South Carolina, South Dakota, and Wyoming), prohibition on other conduct (Louisiana, Maryland, Montana, and Nevada), cost sharing and deductibles (Georgia), business practices (Louisiana), relationship with state medical assistance programs (Maryland), contract requirements (Maryland and New Mexico), prior authorization (New Mexico), authorization of an interim study (Nevada), MAC lists (Arizona), regulation or registration by a state agency (Alabama, Iowa, Louisiana, Minnesota, South Carolina, and West Virginia), reporting requirements (Arkansas and West Virginia), and other drug transparency measures (Texas).

Additionally, in late June 2019, Maine enacted a comprehensive package to control the cost of prescription drugs.²⁰ The package includes stricter requirements on PBMs (LD 1504) and updates to its drug transparency program to require more prescriptive data collection and enforcement mechanisms (LD 1162). [Note: The package also included the establishment of a drug affordability review board (LD 1449) and support for the state to pursue a wholesale drug importation program (LD 1272).]

[Note: President Trump signed two bills related to gag clauses in October 2018. The "Patient Right to Know Act" (S. 2554) and the "Know the Lowest Price Act of 2018" (S. 2553). NCSL notes as of May 2019, 33 states have enacted laws prohibiting gag clauses in contracts.²¹]

Massachusetts. The Massachusetts Health Policy Commission published a report June 5, 2019, related to PBM pricing for generic drugs in the Massachusetts Medicaid program and the commercial market.²² The report notes PBM prices for generic drugs were dramatically higher than the drugs' acquisition costs in the Medicaid program and the commercial market.

19 Center for State Rx Drug Pricing, *Vermont First in the Nation to Approve Rx Drug Importation from Canada*, National Academy for State Health Policy (May 2018), <https://nashp.org/vermont-legislature-first-in-the-nation-to-approve-rx-drug-importation-from-canada/>.

20 Sarah Lanford and Maureen Hensley-Quinn, *Maine Forges New Ground and Enacts Comprehensive Drug Package* (July 1, 2019), <https://nashp.org/maine-forges-new-ground-and-enacts-comprehensive-drug-package/>.

21 Colleen Becker, *Status of PBM "Gag Clause" State Laws and Legislation* (May 16, 2019), <http://www.ncsl.org/research/health/pbm-state-legislation.aspx>.

22 Massachusetts Health Policy Commission, *HPC Datapoints, Issue 12: Cracking Open the Black Box of Pharmacy Benefit Managers* (June 5, 2019), <https://www.mass.gov/info-details/hpc-datapoints-issue-12-cracking-open-the-black-box-of-pharmacy-benefit-managers>.

Price-gouging for Essential Generic Drugs

Maryland. In May 2017, HB 631 was enacted to prohibit a manufacturer or wholesale distributor from engaging in price gouging in the sale of an essential off-patent or generic drug. The U.S. Court of Appeals for the Fourth Circuit held the law unconstitutional because it regulated commerce beyond Maryland's state borders.²³ The U.S. Supreme Court declined to hear the appeal in February 2019.²⁴

Volume Purchasing

California. Executive Order (EO) 01-19, issued by Governor Newsom in January 2019, requires certain executive agencies to take actions to lower prescription drug and health care costs in California. EO 01-19 orders the Department of Health Care Services to transition all pharmacy services for the Medicaid program to a fee-for-service benefit by January 2021 and to review all state purchasing initiatives and consider additional options to maximize the State's bargaining power. The Department of General Services must develop a list of prescription drugs that could be prioritized for future bulk purchasing initiatives or reexamined for potential renegotiation with the manufacturer and, based on that list, develop and implement bulk purchasing agreements for high-priority drugs. The Department of General Services is also directed to develop a framework for enabling private purchasers to benefit from State bulk pharmaceutical purchasing.

New Mexico. In 2019, SB 131 was enacted, establishing the Interagency Pharmaceuticals Purchasing Council and providing for the coordinated procurement of pharmaceuticals and pharmaceutical benefits among certain state agencies and other governmental agencies.

²³ *Ass'n for Accessible Medicines v. Frosh*, 887 F.3d 664 (4th Cir. 2018).

²⁴ *Ass'n for Accessible Medicines v. Frosh*, cert. denied, 139 S. Ct. 1168, 203 L. Ed. 2D 197 (2019).

APPENDIX OF STATE LAWS

[*Note:* All legislation is from 2019, unless otherwise noted.]

Cost of insulin: Colorado (HB 1216).

Drug affordability board: Maine (LD 1449) and Maryland (HB 768).

Drug importation: Colorado (SB 5), Florida (HB 19), Maine (LD 1272), and Vermont (2018 S. 175).

PBMs:

Audits: New Mexico (SB 394), Tennessee (HB 786), and Virginia (HB 2561).

Prohibition on gag clauses: Alabama (SB 73), Minnesota (SB 278), South Carolina (SB 359), South Dakota (HB 1137), and Wyoming (HB 63).

Prohibition on other conduct: Louisiana (HB 242), Maine (LD 1504), Maryland (HB 754), Montana (SB 83), and Nevada (AB 141).

Cost sharing and deductibles: Georgia (HB 323).

Business practices: Louisiana (HB 433).

Relationship with state medical assistance programs: Maryland (HB 589).

Contract requirements: Maryland (HB 754) and New Mexico (SB 415).

Prior authorization: New Mexico (SB 188).

Authorization of an interim study: Nevada (SB 276).

MAC lists: Arizona (HB 2285).

Regulation or registration by a state agency: Alabama (SB 73), Iowa (SB 563), Louisiana (SB 41), Maine (LD 1504), Minnesota (SB 278), South Carolina (SB 359), and West Virginia (SB 489).

Reporting requirements: Arkansas (SB 520) and West Virginia (HB 2538).

Other drug transparency measures: Maine (LD 1162) and Texas (HB 2536).

Price-gouging for essential generic drugs: Maryland (2017 HB 631).

Volume purchasing: California (EO 01-19) and New Mexico (SB 131).