Recent Approaches and Innovations in State Prescription Drug Laws

Report #1 - State Enacted Provisions; Outcomes Underway, to Be Determined or Not Yet Tested

During the past two to three years, several states have enacted laws with novel or alternative approaches to state regulation related to prescription drug costs and prices. The laws described below are examples from Arizona, California, Connecticut, Louisiana, Maine, Maryland, Massachusetts, Nevada, New York, Oregon, Tennessee and Vermont. The list does not include pending legislation or laws from earlier years. NCSL’s Prescription Drug Database provides additional details and further examples of non-enacted measures, covering 2015 to 2018.

Drug Cost Transparency

California law (SB 17), enacted Oct. 19, 2017 as Chapter 603. Lead sponsor: Senator Ed Hernandez (D); Passed Senate (28y-10n) and Assembly (66y-9n).

This price transparency law applies to all drugs (brand-name and generic) with a wholesale acquisition cost of at least $40 when the price of these drugs increases more than 16 percent in the prior 12 months or 32 percent in the preceding 24 months. Requires pharmaceutical manufacturers to submit to public and private purchasers (including state agencies, health insurers and pharmacy benefit managers) 90-day advance notification of price increases for prescription drugs currently on the market, including detailed information regarding the reasons and justification for such increases, aggregating and summarizing public information. It also requires justification of launch prices for new drugs. Requires health insurers that file rate information to report specified cost information regarding covered prescription drugs, including generic, brand-name and specialty drugs. Requires reporting the percentage of the insurance premium attributable to prescription drugs.

Vermont laws, 2016 and 2018

Vermont enacted two related state laws, first in 2016, then in 2018, modifying and expanding the earlier law. Review both laws to obtain the full effect of the changes:

- Vermont 2016: (S 216), enacted in June 6, 2016 as Act 165; lead sponsor: Senator Kevin Mullin (R)
  Provides for pharmaceutical cost transparency, requiring the state to annually identify up to 15 state-purchased prescription drugs "on which the State spends significant health care dollars and for which the wholesale acquisition cost has increased by 50 percent or more over the past five years or by 15 percent or more over the past 12 months, creating a substantial public interest in understanding the development of the drugs' pricing."
  The state attorney general "shall require the drug's manufacturer to provide a justification for the increase in the wholesale acquisition cost of the drug" in an understandable and appropriate format. Requires that rules be adopted requiring certain insurers to provide information about the State Health Benefit Exchange plan's drug formularies; also provides for drug dispensing fees, reimbursement, and out-of-pocket drug limits.
Vermont 2018 (S 92); signed May 30, 2018 as Act No. 193; lead sponsor: Sen. Virginia Ginny Lyons (D)

Revises provisions relating to prescription drug price transparency and cost containment. 1) It expands the provisions of Vermont’s 2016 Rx transparency law to require the Department of Vermont Health Access and health insurers with more than 5,000 covered lives to create lists of 10 prescription drugs for which the payer’s net cost has increased by 50 percent or more over the past five years or 15+ percent annually. The Office of the Attorney General will identify 15 drugs for which the drugs' manufacturers must provide a justification for the price increase or increases. Each manufacturer must also provide a separate version of its justification that will be made public.

2) It prohibits pharmacy benefit managers from prohibiting or penalizing a pharmacy or pharmacist for providing information to an insured about a cost-sharing amount for a prescription drug, disclosing to an insured the cash price of a prescription drug, or selling a lower-cost drug to an insured if one is available.

3) It requires prior authorization to refill a prescription with a drug or biological product different than the originally filled prescription; requires electronic notification from the pharmacy to the provider after dispensing biological products. Requires a pharmacist to select the lowest priced drug or interchangeable biological product.

Vermont Attorney General implementation report, February 2018  [Full text, PDF]

Nevada law (SB 539), enacted June 15, 2017 as Chapter 509; Lead sponsor: Senator Michael Roberson (R),

This law has several provisions to contain drug costs. The law requires the state to post a list of all essential anti-diabetes medicines, and the drugs’ makers also must report annually the costs of manufacturing and marketing each product, in addition to other details. Additionally, each year the state will identify products with price increases exceeding the medical consumer price index in the past 12 months or twice the increase in the previous 24 months. Makers of those drugs must report additional information that justifies or explains their price increases. Nevada’s law makes all manufacturer-supplied information public. The law also requires:

- Reporting free goods or compensation provided by each sales representative to Nevada-licensed health care providers.

- Pharmacy benefit managers to report the dollar value of manufacturer drug rebates collected.

- All non-profit patient groups that are active in Nevada to publicly report all sources of financial support. The intent is to make it more transparent when patient groups have financial interests in aligning with and lobbying on behalf of the pharmaceutical industry.


Revises provisions relating to prescription drug price transparency. Requires that the state will annually list the top 10 drugs that represent substantial state spending, when priced at $60 a month or more and with an annual cost increase of 20 percent or more. For these products, the manufacturers will publicly release research and development costs and other such capital expenditures and for specified price changes, will post on the state website justifications for all factors that caused the price increases. Manufacturers with new applications for drug approval also “shall submit” notice of FDA action to the state. Health insurers and PBMs also must submit details on the 25 greatest-cost, frequently-used and rapid cost increase prescription products.


Expands provisions for prescription drug price transparency. Requires the state Health Data Organization to report on the 25 most frequently prescribed drugs and the 25 with highest cost determined by the total amount spent on those drugs and largest price increases. It requires a new plan for data collection from manufacturers, with a yearly report on prescription drug prices published starting in 2019.

Oregon law (H 4005), enacted March 12, 2018. Lead sponsor: Representative Robert Nosse (D)

Requires prescription drug manufacturers to report annually to the Department of Consumer and Business Services the prices of prescription drugs and costs associated with developing and marketing prescription drugs. This includes drugs for which the price was $100 or more for a one-month supply or for a course of treatment lasting less than one month, and there was a net increase of 10 percent or more in the price of these drugs over the course of the previous calendar year. Also requires drug manufacturers to report the reasons behind significant drug price increases, and authorizes the state to impose civil penalties on a manufacturer for failing to comply with reporting requirements. Requires health insurers that offer a prescription drug benefit to report to the department the most frequently
prescribed and higher-priced drugs, including those whose prices have increased dramatically. The law requires insurers to detail the impact of these costs on insurance premium rates.

**Louisiana law (H 436) Enacted as Act No. 220 of 2017, June 14, 2017.** Sponsors: Representatives Kirk Talbot (R); H. Bernard LeBas (D); Major Thibaut (D); Helena Moreno (D); Paul Hollis (R) and Dustin Miller (D).

Requires drug manufacturers to provide transparency of information regarding prescription drug prices. Each manufacturer or pharmaceutical marketer "who engages in any form of prescription drug marketing" to a physician, prescriber or any member of his or her staff must provide to the Louisiana Board of Pharmacy the current wholesale acquisition cost (WAC) of each of the drugs approved by the U.S. Food and Drug Administration and marketed in the state by that manufacturer.

**Prohibiting PBM “Gag Clauses” to Lower Prices to Consumers**

Recently enacted laws in **at least 29 states** block commercial PBM or health insurer contracts that may prohibit pharmacies from informing customers about available alternative pricing for medications, including paying out-of-pocket, or including generics or brand products that may be less costly, or comparatively more suitable for a patient. Many bills also address the "co-pay clawback" situation. Typical state language includes, "A pharmacy or pharmacist shall have the right to provide an insured information regarding the amount of the insured's cost share for a prescription drug. Neither a pharmacy nor a pharmacist shall be penalized by a pharmacy benefits manager for discussing any information described in this section or for selling a lower priced drug to the insured if one is available."

- Read Full NCSL report online | Updated October 2018
  * includes 2004 statute in Minnesota. SEE MAP on last page

**Free Speech for Off-Label Pharmaceutical Use**

**Arizona law (H 2382), enacted March 21, 2017.** Lead sponsor: Representative Lovas (R).

Creates a "Free Speech in Medicine Act." Relates to pharmaceuticals, allowing drug makers to promote and market drugs off label if the information consists of "truthful promotion" of a drug, biological product or device. Prohibits the state or any medical board or subdivision from enforcing any federal or state restriction on manufacturers, health care institutions or a physician from such "truthful promotion." Does not require a health care insurer, other third-party payer or other health plan sponsor to provide coverage for the cost of any off-label use of a drug, biological product or device as a treatment. The law conflicts with current federal law, 21 USC Sec. 331, restricting drug manufacturers from promoting off-label uses.

* Tennessee law (H 2220) 2nd law, with same provisions; enacted and signed May 3, 2018.

**Drug Anti-Price Gouging**

**Maryland law (H 631), enacted May 2017.**

This law prohibits makers of “essential drugs” from raising prices to “unconscionable” levels. The law applies to generic and off-patent drugs on the World Health Organization’s list of “essential medicines”—considered to be the minimum pharmaceutical treatments needed for a basic health care system. Three manufacturers would be affected. Allows the state’s Medicaid agency to inform the attorney general about drugs that cost at least $80 and have a wholesale cost increase of 50 percent or more in 12 months. The attorney general can use the agency information or it can independently identify essential generic and off-patent drugs that undergo an “unconscionable” price increase. An “unconscionable” price increase is defined as an excessive price hike that is not justified by changes in production and for which consumers have no meaningful treatment alternative. If the attorney general does not find an adequate explanation for the price increase, the issue can be referred to the state court, which can decide if penalties should be imposed on a manufacturer. The law specifies three specific remedies that a state court could apply to manufacturers: They can lower the price to an earlier, lower level; compensate all Maryland purchasers and insurance companies that paid the “unconscionable” price for the drugs; or impose civil penalties of up to $10,000 for each violation.
**Drug Co-payment Limits in Health Insurance**

**Nevada law** ([A 381](#)) of 2017, enacted June 1, 2017, as Act No. 281. Lead sponsor: Assembly member Spiegel (D)

Relates to health insurance, prohibiting an insurer from taking certain actions concerning prescription drugs covered by Individual and small group health insurance policies. Restricts increasing co-payments to a higher cost tier from original coverage for a prescription drug pursuant to a formulary with more than one cost tier. The insurer may move the prescription drug from a lower cost tier to a higher cost tier only on Jan. 1, 2018, at the annual start of the policy or when a new generic drug is approved by the FDA and is added to the lower tier list. Does not alter the ability of a pharmacist to substitute a generic or interchangeable biologic when it is available.

**California law: 'Cap the co-pay.'** ([A 1860](#)) of 2018; enacted Sept. 19, 2018. Lead sponsor: Asm. Monique Limon

Extends existing 2014 law until 2024, prohibiting an individual health insurance policy or group health care service plan contract that provides coverage for prescribed, orally administered, anticancer medications (used to kill or slow the growth of cancerous cells) from requiring an enrollee to pay a total amount of copayments and coinsurance that exceeds $250 for a 30-day supply individual prescription. (Previous law was capped at $200 per prescription.)

**Requires Brand Manufacturers to sell an “innovator” drug to a developer of a generic version of that drug**

**Maine law** ([S 432](#)), enacted July 4, 2018

The new law "ensures increased competition in the market for drugs and biological products, which will lower the cost of prescription drugs for Maine residents and for the State." Amends the Maine Pharmacy Act to require that a drug distributed in this state must be made available for sale in this state to a person seeking to develop an application for the approval of the drug under the Federal Food, Drug, and Cosmetic Act or the licensing of a biological product under the federal Public Health Service Act; establishes disciplinary actions for noncompliance. (updated 7/20/2018)

**Prescription Drug Wholesale Importation**

**Vermont Law** ([S 175](#)) passed House (141y-2n) and Senate (29y-0n) May 7, 2018; signed into law May 16, 2018.

Creates a wholesale importation program to purchase high-cost drugs through authorized wholesalers, who will purchase the drugs in Canada and make them available to Vermonters through an existing supply chain that includes local pharmacies. The new law requires Vermont’s Agency for Human Services, in consultation with stakeholders and the federal government, to design and submit an importation proposal to the state legislature on or before Jan. 1, 2019 and further requires the agency to submit its proposal to the federal government on or before July 1, 2019, for final approval. The importation program must be operational within six months of approval of the financing strategy, certification, and federal government sign-off.

- Read Vermont Legislature First to Approve Rx Drug Importation | Is It Safe and Cost-Effective to Import Drugs from Canada? | View an infographic on wholesale importation | posted by NASHP.

**Medicaid Rx Coverage Based on Negotiation and Cost Effectiveness (Includes state executive actions)**

**New York law** ([NY S 2007; Act No. 57 of 2017](#)) Establishes a Medicaid drug cap, 04/20/2017

"The legislature hereby finds and declares that there is a significant public interest for the Medicaid program to manage drug costs in a manner that ensures patient access while providing financial stability for the state and participating providers. Since 2011, the state has taken significant steps to contain costs in the Medicaid program by imposing a statutory limit on annual growth. Drug expenditures, however, continually outpace other cost components... Therefore, the department will "establish a Medicaid drug cap as a separate component within the Medicaid global cap as part of a focused and sustained effort to balance the growth of drug expenditures with the growth of total Medicaid expenditures."
Provides for the Medicaid state Drug Utilization Review Board (DUR) to follow "a recommendation for a target supplemental Medicaid rebate to be paid by the manufacturer of the drug to the department and the target amount of the rebate." If the state is unsuccessful in entering into a satisfactory rebate agreement, non-cooperating manufacturers will be required to file a detailed financial report including "actual cost of developing, manufacturing, producing... administrative, marketing, and advertising costs, including but not limited to prescriber detailing, copayment discount programs, and direct-to-consumer marketing, pricing used outside the U.S. and other specific statistics. Provides for budget implementation.

**Oklahoma** Value-Based Contracting approved. On June 27, 2018 CMS approved a state plan amendment to "allow the state to negotiate supplemental rebate agreements involving value-base purchasing agreements with drug manufacturers that could produce extra rebates for the state if clinical outcomes are not achieved." This is the first-in-the-nation approval of this approach. (CMS release, 6/27/2018).

- NCSL held three meeting sessions in 2017 discussing value-based purchasing and contracting - see descriptions online.
- Oklahoma’s second contract, signed in September, is with the pharmaceutical company Melinta for a drug used primarily to treat bacterial skin infections. The state Medicaid program had required prior authorization before paying for the drug. A report on Oklahoma posted 9/25/18 by NASHP noted that under the new value-based contract, prior authorization will no longer be required. “In return for having the drug listed as a first-line treatment, Melinta ensures that oritavancin will not result in a net increase in costs. While other drugs used to treat bacterial skin infections may require hospitalization for administration, oritavancin does not. While its purchase price is higher, oritavancin is not expected to cost the state Medicaid program more because it is expected to eliminate costly hospitalizations required by other drug options.” However, under the value-based contract, if the state does incur higher costs— despite the avoided hospitalizations — Melinta will be required to cover those costs through additional rebates to the state.

**Louisiana** has the most recent publicly-initiated Medicaid purchasing idea, with a new subscription-based payment model for Hepatitis C (State agency description) unveiled August 7, 2018. In this plan “the state would pay a drug manufacturer or manufacturers for unlimited access to the treatment for the individuals in Louisiana who are enrolled in Medicaid or in Louisiana’s correctional system. The payment to the manufacturer would be equal to or less than what the state is currently spending to provide the antiviral medication to these populations.” The Department seeks comments from the public, healthcare professionals, pharmaceutical companies, and others on a plan that will bring us much closer to the goal of Hepatitis C elimination for vulnerable populations. Through a Request for Information, the Louisiana Department of Health is asking for public input on the creation of a subscription-based payment model for Hepatitis C medication. Under this payment model, the state would pay a drug manufacturer or manufacturers for unlimited access to the treatment for the individuals in Louisiana who are enrolled in Medicaid or in Louisiana’s correctional system. The payment to the manufacturer would be equal to or less than what the state is currently spending to provide the antiviral medication to these populations. “A successful subscription-based model would create an incentive for us to find and treat as many people as possible. For the drug manufacturer, this model would guarantee a fixed purchase price for a contracted period of time and would allow the drug manufacturer to expand their product reach into populations that otherwise would not have received treatment,” said Dr. Rebekah Gee, secretary of the Louisiana Department of Health. Their next step is evaluating public comments, due by August 24, 2018.

**Massachusetts**, by agency executive action, requested a Section 1115 Medicaid waiver that would allow the state to choose which prescription drugs to cover based on the majority of beneficiaries’ needs and which medicines prove to be the most cost effective. The state wants the power to negotiate discounts for the drugs it purchases and to exclude drugs with limited treatment value. According to the most recent data, Medicaid spending on prescription drugs increased about 25 percent in 2014 and nearly 14 percent in 2015. The Department of Health and Human Services declined to approve the plan, June 27, but state officials were examining variations and amendments.

- As States Try To Rein In Drug Spending, Feds Slap Down One Bold Medicaid Move. - Analysis by KHN and NPR, Sep. 21, 2018.

CMS denied a proposal from Massachusetts "that was seen as the boldest attempt yet to control Medicaid drug spending. Massachusetts planned to exclude expensive drugs that weren’t proven to work better than existing
alternatives. The state said Medicaid drug spending had doubled in five years. Massachusetts wanted to negotiate prices for about 1 percent of the highest-priced drugs and stop covering some of them. CMS rejected the proposal without much explanation, beyond saying Massachusetts couldn’t do what it wanted and continue to receive the deep discounts drugmakers are required by law to give state Medicaid programs.” The state does not plan to refile at this time.

- “A Setback For Massachusetts In States’ Drive To Contain Medicaid Drug Spending”- Analysis and commentary by NPR. “Massachusetts planned to exclude expensive drugs that weren’t proven to work better than existing alternatives. The state said Medicaid drug spending had doubled in five years. Massachusetts wanted to negotiate prices for about 1 percent of the highest-priced drugs and stop covering some of them. CMS rejected the proposal without much explanation beyond saying Massachusetts couldn’t do what it wanted and continue to receive the deep discounts drugmakers are required by law to give state Medicaid programs.” - September 12, 2018.

- States want control over drug prices. Will feds give it to them? - by Governing Magazine, 5/7/2018 - "In an attempt to lower health-care costs, Massachusetts is seeking to exclude certain drugs from its Medicaid program."

**Legal Analyses for State Drug Laws**

Legal Resources for Drug Cost Containment Legal Challenges of Rx Drug Laws Passed in 2017 Will Shape States’ Future Cost Containment Legislation: Analysis of 2018 cases with links to individual cases, posted 2018 by the National Academy for State Health Policy.

**Opposing Views:** The Pharmaceutical Research and Manufacturers of America (PhRMA) argues that state legislation (like California’s SB 17) “attempts to dictate national health care policy related to drug prices in violation of the United States Constitution, singles out drug manufacturers as the sole determinant of drug costs despite the significant role many other entities play in the costs patients pay, and will cause market distortions such as drug stockpiling and reduced competition.” They note that the mandatory transparency bills don’t fully consider the costs of drug development and post-market surveillance, and the value and savings drugs bring to society. “None of these bills get at the affordability question for patients. It’s a huge oversight.”

**Rx Ballot Questions- Rejected in 4 states by judges and voters**

A South Dakota judge blocked a ballot measure intended to limit how much state agencies could pay for prescription drugs. In July 2018 the circuit court judge ruled in favor of a group opposing the measure, which had challenged the validity of the signatures used to get the initiative on the ballot. The measure would have prevented the state from paying more than the VA pays for drugs. It’s the second time this year a court fight has kept a drug pricing initiative off the ballot — a nearly identical measure didn’t make the ballot in the District of Columbia — and similar initiatives have failed in Ohio and California in 2016.

**Federal: The Trump Administration Plan - May 2018**

The Trump administration announced on May 11 a “Blueprint to Lower Prices and Reduce Out-of-Pocket Costs.” The plan included more than 25 strategies grouped into four categories: improved competition, better negotiation, incentives to lower list prices and lower out-of-pocket costs. (Read NCSL’s analysis, posted July 2, 2018)

Mr. Trump said his administration will begin work immediately, describing it this way: "Everyone involved in the broken system -- the drug makers, insurance companies, distributors, pharmacy benefit managers, and many others -- contribute to the problem," Mr. Trump said. "Government has also been part of the problem because previous leaders turned a blind eye to this incredible abuse. But under this administration, we are putting American patients first. ... I've instructed Secretary Azar to begin moving forward on reforms that will bring soaring drug prices back down to Earth."

The blueprint strongly favors value-based pricing, with the Department of Health and Human Services calling value-based transformation of the entire health care system a top priority. The same week the 21st state enacted a no gag-clause law, President Donald Trump said “Our plan will end the dishonest double dealing that allows the middleman to pocket rebates and discounts that should be passed on to consumers and patients. Our plan bans the pharmacist gag rule which punishes pharmacists for telling patients how to save money. This is a total rip off, and we are ending it." This federal executive action aims to affect Medicare transactions and may expand to include Medicaid; however, state regulators have primary jurisdiction over much of the commercial and private market coverage.
Also see NCSL report: “Recently Enacted State Laws Affecting Pharmaceutical Costs, Pricing and Payment, 2015-2017” - Use the link to the PDF edition for printing, searching or sharing (32 pages)

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