

Recent Approaches in State Prescription Drug Laws

State Enacted Provisions; Outcomes to Be Determined or Not Yet Tested

Memo compiled 4/10/2018 -advance edition for discussion Richard Cauchi, NCSL Health program

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 single state examples, from Arizona, California, Louisiana, Maryland, Massachusetts, Nevada, Oregon and Vermont. The list does not include pending legislation or laws from earlier years. NCSL's <u>Prescription Drug database</u> provides additional details and further examples of non-enacted measures, covering 2015-2018.

Drug cost transparency –

California law (SB 17), enacted in 2017.

This price transparency law applies to <u>all drugs (brand-name and generic)</u> 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—to the extent that the information is otherwise public. 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 drugs, brand name drugs, and specialty drugs. Requires reporting the percentage of the insurance premium attributable to prescription drugs.

Vermont law (S 216), enacted in June 2016 as Act 165) Lead sponsor: Sen Mullin (R)

Provides for pharmaceutical cost transparency, requiring the state to do an annual identification of <u>up to 15 state purchased prescription drugs</u> "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 a 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, provides further for drug dispensing fees, reimbursement, a related report and out-of-pocket drug limits.

Vermont A.G. Implementation report, Feb 2018 (10 pages): https://legislature.vermont.gov/assets/Legislative-Reports/2018-2-23-AGO-Pharma-Cost-Transparency-Report-for-2017.pdf

Nevada law (SB 539), enacted in 2017, has several provisions to contain drug costs. The law requires the state to post a list of all <u>essential antidiabetes</u> 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 of pharmaceutical sales representatives and the free goods or compensation provided by each sales representative to Nevada-licensed providers; • Pharmacy benefit managers to report the dollar value of manufacturer drug rebates collected; and • 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 publicly transparent when patient groups have financial interests in aligning with and lobbying on behalf of the pharmaceutical industry.

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

Requires prescription drug manufacturers to report annually information to Department of Consumer and Business Services regarding prices of prescription drugs and costs associated with developing and marketing prescription drugs for which: (a) The price was \$100 or more for a one-month supply or for a course of treatment lasting less than one month; and (b) There was a net increase of 10 percent or more in the price of the prescription drug described in paragraph (a) of this subsection 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 prescription drug benefit to report to 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 of 2017) Enacted - Act No. 220, 6/14/2017. Lead sponsor: Talbot (R) Additional Authors: LeBas (D); Thibaut (D); Moreno (D); Hollis (R); Miller D. (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 in Louisiana to provide to the Louisiana Board of Pharmacy the current wholesale acquisition cost (WAC) information for each of the U.S. FDA approved drugs marketed in the state by that manufacturer.

Free Speech for Off-Label Pharmaceutical Use

Arizona law (H 2382) enacted March 21, 2017. Lead sponsor: Rep. 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." Provides that this section does not require a health care insurer, other third-party payor 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 manufacturer promotion of off-label uses.

Drug anti-price-gouging

Maryland law (SB 631) enacted May 2017.

This law prohibits makers of "essential drugs" from raising prices to "unconscionable" levels. The law <u>applies to generic and off-patent drugs</u> 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. The Maryland law 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: 1) Lower the price to an earlier, lower level; 2) Compensate all Maryland purchasers and insurance companies that paid the "unconscionable" price for the drugs; or 3) Impose civil penalties of up to \$10,000 for each violation.

Prescription Drugs Covered by Health Insurance

Nevada law (A 381) of 2017; Enacted 6/1/2017 as Act No. 281. Lead sponsor: Assemblymember Spiegel (D)

Relates to health insurance, prohibiting an insurer from taking certain actions concerning prescription drugs covered by Individual and small group policies of health insurance. 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 or 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.

Prohibiting PBM "Gag Clauses", to Lower Prices to Consumers

See separate NCSL report, featuring recent enacted laws in 14 states. - http://www.ncsl.org/research/health/pbm-state-legislation.aspx

Executive Order:

Medicaid Rx Coverage Based on Negotiation and Cost Effectiveness

Massachusetts, by agency executive action, requested a Section 1115 Medicaid waiver that would allow them to choose which prescription drugs the states cover based on the majority of beneficiaries needs as well as which medicines prove to be the most cost effective. It 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. If the Department of Health and Human Services approves the Bay State's plan, it is speculated that others may take similar action.

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