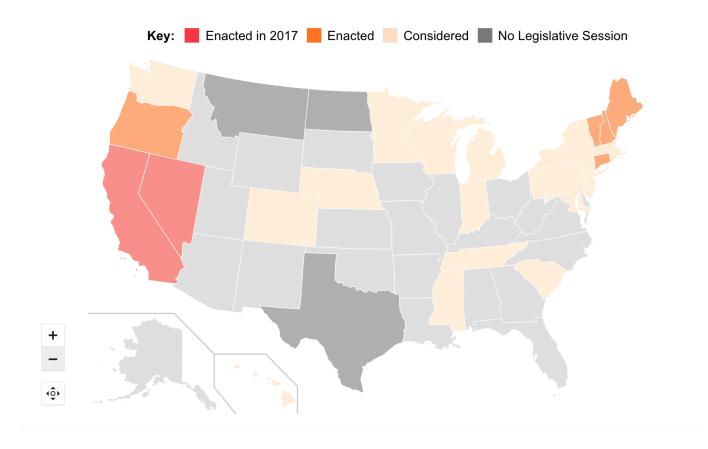
Spotlight on 2018 State Drug Legislation: Part 5 — Pricing Transparency Laws

*Update: This post was written before the end of the 2018 legislative session. For the most recent count of states that passed these legislation, see the <u>Spotlight on 2018 State Drug Legislation Summary: The Year in Review</u> or download our <u>Summary Chart</u>.

Building on the momentum from 2017's passage of two laws to increase transparency in drug prices, California's SB 17 and Nevada's SB 539, in 2018, 22 states considered and 5 states passed legislation to require more transparency of drug pricing (see map and tables below). While transparency laws that simply require reporting of drug prices to the public may seem less effective than many of the other laws passed in 2018 to address pharmaceutical prices, they represent an important step to increasing competition in the pharmaceutical market and may have a fundamental place in the toolbox of state action to control rising drug costs.

Drug Pricing Transparency

Pharmaceutical price transparency legislation requires disclosures from drug manufacturers and insurers to help lawmakers and the public better understand how drugs are priced and how those prices affect insurance premiums. For more information, see the Source Blog post Spotlight on 2018 State Drug Legislation: Part 5 – Pricing Transparency Laws.



What the Drug Pricing Transparency Laws Require

In 2018, each state that considered drug pricing legislation to increase transparency introduced different proposals (see Table 1 for details). Some states (Colorado, Michigan, Nebraska, New York, Rhode Island, and Washington) even considered multiple bills to increase transparency for drug prices. Five states, Connecticut, Maine, New Hampshire, Oregon, and Vermont successfully passed laws to improve drug pricing transparency. Of these five states, New Hampshire and Maine passed laws to establish commissions to study the price of prescriptions, including the role of drug pricing in overall health expenditures in the state, and make recommendations to the state about what legislation would be most effective in that state. Earlier versions of Maine's L.D. 1406 had additional provisions that required disclosures from drug manufacturers including the

cost of research and production of the drug, the list price of the drug and the "true net typical price" for the drug, but those provisions were removed in the final version.

The other three states, Connecticut, Oregon, and Vermont, passed laws in 2018 that are similar to California's SB 17, passed in 2017. All of the laws require disclosures from both insurers and manufacturers about how drugs are priced, increases in list prices, and the effect of pharmaceutical spending on premium increases. All four laws (CA's SB 17, CT's HB 5384, OR's HB 4005, and VT's S 92) require insurers to report information about prescription coverage for their large group plans including: 1) the 25 most frequently prescribed drugs, 2) the 25 most costly drugs by total plan spending, 3) the 25 drugs with the highest year-over-year increase in cost by total plan spending, and 4) the portion of premiums or premium increases attributable to outpatient prescription drugs. While these reports do not directly target the cost of drugs, they generate important information for lawmakers seeking to address rising pharmaceutical expenditures. Lawmakers often struggle to assess the likely effectiveness of legislative actions to address the cost of a few exceptionally expensive drugs, rising prices for all drugs (or a particular class of drugs), or disproportionate price increases for a few drugs with no therapeutic alternative (e.g. Daraprim). The disclosures from insurers required by these laws will give lawmakers needed information about what new solutions to prioritize and allow them to assess the effectiveness of any future laws or programs that target drug prices.

In addition to disclosures by insurers, all four laws require manufacturers to disclose price information (see this table from the National Academy of State Health Policy, NASHP, for a detailed comparison of the disclosures required by manufacturers). Connecticut and Vermont require a state official

to identify a short list of drugs (ten drugs in Connecticut and fifteen in Vermont) for which manufacturers must submit additional information, including an explanation of any factors that caused an increase in price.

Of all the drug pricing transparency laws passed in 2018, Oregon's law, HB 4005, is the most comprehensive. Like SB 17 in California, Oregon's law requires drug manufacturers to file reports for: 1) any new drug with a list price above the threshold for a specialty drug under Medicare (currently \$670 for a course of treatment or 30-day supply) or 2) any existing drug with a price increase above a threshold.[1] In the report, Oregon requires manufacturers to include information about the costs to research, develop, manufacture, market, and distribute the drug and the factors that contributed to the price increase. Manufacturers must also report the total sales revenue for the drug and the manufacturer's profit attributable to the drug for the previous year. Additionally, the manufacturer must report the ten highest prices paid for the drug in the previous year in any country other than the United States. Unlike California's SB 17, however, Oregon's law does not require advance notice of anticipated price increases.[2] Nonetheless, Oregon requires more information from manufacturers than California does, so the two states have emerged at the forefront of state efforts to improve transparency for prescription drugs.

Finally, in addition to the disclosures required from insurers and manufacturers, Connecticut's drug transparency law, $\frac{HB}{5384}$, also requires pharmacy benefit managers (PBMs) to disclose to the state Insurance Commissioner aggregated dollar amounts of all rebates for outpatient prescription drugs and the portion of those rebates received by health carriers. Other states, including Louisiana ($\frac{SB}{283}$) and New York ($\frac{A}{10026}$) $\frac{10026}{58384}$), also considered similar laws requiring transparency of net prices and rebates paid by PBMs. These laws will be examined in more detail

in an upcoming Spotlight on 2018 State Drug Legislation post focusing on legislative efforts that target PBMs and other middlemen in the pharmaceutical supply chain.

Effects of Drug Pricing Transparency Laws

Nearly all of the bills and laws to improve drug pricing transparency, including those in California and Oregon, require disclosure of the wholesale acquisition cost (WAC) and tie reporting requirements to increases in the WAC. The WAC is the manufacturer's list price, defined in federal law, as the price charged to wholesalers or direct purchasers in the United States, not including rebates or other discounts.[3] Because it does not include rebates, the WAC may have little correlation with the price actually paid by insurers. As a result, manufacturers may attempt to negotiate lower rebates to raise profits for a drug without increasing the WAC so that they do not trigger state reporting requirements. Finally, these laws do nothing to prevent, and thereby may encourage, cost-shifting among drugs produced by the same manufacturer. Specifically, a drug manufacturer may choose to raise the WAC for all the drugs it produces at a level just below the threshold for reporting instead of increasing the price of a single drug. As a result, while these laws attempt to increase transparency, they may have the unintended consequence of permitting manufacturers and PBMs to hide much of the true cost information in contracts that remain confidential. A meaningful next step for lawmakers seeking to improve transparency in the pharmaceutical market, therefore, would be to consider legislation that gives the state and the public more information about the net reimbursement rates paid by insurers.

Nonetheless, in the first year after California's law went into

effect, at least four manufacturers canceled or reduced previously announced price hikes on at least 10 drugs, including the psoriasis drug Cosentyx manufactured by Novartis.[4] While experts debate whether the decision to forgo price increases should be attributed to transparency laws, California's drug price transparency law allowed payer and the public to know about the planned but abandoned price increases. Furthermore, in an evolving landscape of judicial interpretation of when federal laws preempt state action in pharmaceutical pricing, these transparency laws represent a baseline to establish a state's ability to act. For more details on how the Pharmaceutical Research and Manufacturers of America (PhRMA), the trade group representing biopharmaceutical companies, has California's attempts to increase transparency, see our <u>article</u> in Health Affairs[5] or The Source litigation roundup blog. If the U.S. District Court for the Eastern District of California rules on whether the dormant commerce clause preempts SB-17, it may have a profound impact on defining a state's ability to pass meaningful legislation to address rising drug prices. As a result, these laws represent an important weapon in the arsenal of state lawmakers seeking to address rising drug prices both as a yardstick to measure the effects of any other actions and as a way to define the legal framework within which a state must operate to avoid preemption by federal law.

Table 1: Pharmaceutical Pricing Transparency Laws Enacted in 2018

State	Bill	Description
-------	------	-------------

Connecticut	<u>HB</u> 5384	PRESCRIPTION DRUG COSTS: Concerns prescription drug costs, imposes additional disclosure and reporting requirements on pharmacy benefits managers, health carriers, pharmaceutical manufacturers concerning prescription drug rebates and the cost of prescription drugs. Requires the insurance commissioner to post this
Maine	<u>LD</u> 1406	information to the department's website. AN ACT TO PROMOTE PRESCRIPTION DRUG PRICE TRANSPARENCY: AN ACT TO PROMOTE PRESCRIPTION DRUG PRICE TRANSPARENCY: requires the Maine Health Data Organization to compile a list of the 25 most frequently prescribed drugs in the State, the 25 costliest drugs as determined by the total amount spent on those drugs in the State, and the 25 drugs with the highest year- over-year cost increases as determined by the total amount spent on those drugs in the State. The Maine Health Data Organization shall also develop a plan to collect data from manufacturers related to the cost and pricing of prescription drugs in order to provide transparency in and accountability for prescription drug pricing.
New Hampshire	HB 1418	TRANSPARENCY AND COST CONTROL OF PHARMACEUTICAL DRUG PRICES: This bill requires the commissioner of the department of health and human services, in consultation with the insurance commissioner, to develop a list of certain critical prescription drugs for purposes of cost control and transparency. Under this bill, the commissioner shall make an annual report on prescription drugs and their role in overall health care spending in the New Hampshire.

Oregon <u>Z</u>	HB 4005	RELATING TO THE PRICE OF PRESCRIPTION DRUGS: Requires prescription drug manufacturer 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.
-----------------	------------	---

Vermont S 92 Would require pharmacists to dispense the lowest priced generic or interchangeable product. Would require an insurer to annually file a summary of proposed rates, including an analysis of the impact of drug cost on premium increases. Separately, would require insurers of different sizes to report on a specified number of most frequently prescribed drugs by average wholesale price for each drug, by the total spend, and by higher year on year price increases. Would require a subset of manufacturers to provide cost justification to the Attorney General, who will provide the report from the information received from manufacturers. Green Mountain Care Board shall post the report on its website, Requires manufacturers notice to the Attorney General of new drug launches priced at more than \$670 and supply information about marketing and sales volume and other information to the Attorney General. Would require pharmacy benefit manager transparency as well. Prevents pharmacy benefit manager or other entity paying pharmacy claims from (1) imposing a higher copayment for a prescription drug than the copayment applicable to the type of drug purchased under the insured's health plan; (2) imposing a higher co-payment for a prescription drug than the maximum allowable cost for the drug; or (3) requiring a pharmacy to pass through any portion of the insured's co-payment to the pharmacy benefit manager or other payer; (4) prohibiting or penalizing a pharmacy or pharmacist for providing information to an insured regarding

the insured's cost-sharing amount for a prescription drug.

Table 2: Pharmaceutical Pricing Transparency Laws Considered in 2018

State	Bill	Description
Colorado	HB 1009	DIABETES DRUG PRICING TRANSPARENCY ACT 2018: Require drug manufacturers to submit reports to the state board of health for diabetes products when the price increases relative to the increase in the medical component of the consumer price index. Information to be reported includes market analysis, research, production and marketing costs among other information. There are financial penalties for failure to comply.
	HB 1260	PRESCRIPTION DRUG PRICE TRANSPARENCY: requires health insurers, starting in 2019, to submit to the commissioner of insurance (commissioner), as part of the health care cost reporting requirement, information regarding prescription drugs covered under their health insurance plans that were dispensed in the preceding calendar year; and prescription drug manufacturers, on or after July 1, 2018, to notify state purchasers, health insurers, and pharmacy benefit management firms when the manufacturer increases the price of certain prescription drugs by more than 10% or when the manufacturer introduces a new specialty drug in the commercial market.
Hawaii	HB 2668_	RELATING TO PRESCRIPTION DRUGS: Requires the Department of Health to compile, analyze, and report certain information on essential prescription drugs marketed in the State for the treatment of diabetes, requires certain entities to provide information that justifies cost increases in drug products.
Indiana	HB 1345	PRESCRIPTION DRUG PRICING STUDY. Urges the legislative council to assign to the interim study committee on public health, behavioral health, and human services the task of studying issues related to prescription drug price transparency by drug manufacturers in Indiana.

Maryland	SB 201	PRESCRIPTION DRUG MANUFACTURERS — SALES TO WHOLESALE DISTRIBUTOR: Requiring a prescription drug or device manufacturer to submit certain average sales prices to the Maryland Department of Health for each calendar quarter within 30 days after the end of the quarter; requiring the Department to make the average sales price submitted by a manufacturer available on the Department's website not later than 10 days after it receives the average sales prices; prohibiting the manufacturer from denying a wholesale distributor the right to purchase prescription drugs or devices if the wholesale distributor agrees to pay the manufacturer's average sales price for the prescription drug or device
Massachusetts	S 1163/H 491	AN ACT RELATIVE TO TRANSPARENCY AND ACCESS IN HEALTHCARE: requires that each drug manufacturer that has experience a wholesale acquisition cost increase of 15% or more to file a report of the total costs paid for research and development in the prescription drug's therapeutic category; estimated costs incurred relating to research and development of new products, processes or services, including the costs of research and development of new products or services that were acquired or obtained via a license; research and development costs as a percentage of revenue; estimated total annual revenues for prescription drugs sold in North America; and if the manufacturer sells or markets in the commonwealth four or more prescription drugs covered or purchased by MassHealth pursuant to chapter 118E, total rebates, discounts or other price concessions paid to the commonwealth for such drugs in the aggregate and without disclosure of any information that is likely to compromise its financial, competitive or proprietary nature.

H 620 (replaced b H 4605)	AN ACT RELATING TO HEALTH CARE COST TRANSPARENCY: The connector shall ensure that the following information about each health benefit plan offered for sale to consumers in the commonwealth shall be available to consumers in a clear and understandable form for use in comparing plans, plan coverage, and plan premiums: (a) The ability to determine whether specific types of specialists are in network and to determine whether a named physician, hospital or other health care provider is in network; (b) Any exclusions from coverage and any restrictions on use or quantity of covered items and services in each category of benefits; (c) A description of how medications will specifically be included in or excluded from the deductible, including a description of out-of-pocket costs that may not apply to the deductible for a medication; (d) The specific dollar amount of any co-pay or percentage coinsurance for each item or service; (e) The ability to determine whether a specific drug is available on formulary, the applicable cost-sharing requirement, whether a specific drug is covered when furnished by a physician or clinic, and any clinical prerequisites or authorization requirements for coverage of a drug; (f) The process for a patient to obtain reversal of a health plan decision where an item or service prescribed or ordered by the treating physician has been denied; and (g) An explanation of the amount of coverage for out of network providers or non-covered services, and any rights of appeal that exist when out of network providers or non-covered services are medically necessary.
H 3223/ S 627; replaced b H 4605)	AN ACT TO PROMOTE PRICE TRANSPARENCY IN PRESCRIPTION DRUG PRICES: The Health Policy Commission, in collaboration with the Center for Health Information and Analysis, shall identify annually up to 15 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, or is a new drug whose price may have a significant impact on the cost benchmark. For each prescription drug identified pursuant to subsection (b) of this section, the Office of the Attorney General shall require the drug's manufacturer to provide a justification for the increase in the wholesale acquisition cost of the drug.

	H 1228 (accompanied by study order H 4625)	AN ACT TO PROMOTE TO TRANSPARENCY AND COST CONTROL OF PHARMACEUTICAL DRUG PRICES: Under this bill, the Health Policy Commission develop a list of critical prescription drugs for which there is a substantial public interest in understanding the development of its pricing. For each prescription drug that the commission places on the critical prescription drug list pursuant to subsection (a), the commission shall require the manufacturers of said prescription drug to report the following information to the commission: i. Total cost of production, and approximate cost of production per dose; ii. Research and development costs of the drug, including: a. research and development costs paid with public funds, including any amount from federal, state, or other governmental programs or any form of subsidies, grants, or other support; b. after-tax research and development costs paid by the manufacturer; c. research and development costs consisting of payments to predecessor entities; d. research and development costs paid by third parties; and e. the costs to acquire the intellectual property rights to a drug, including costs for the purchase of patents, licensing, or acquisition of any corporate entity owning any rights to the drug while in development.
Michigan	<u>SB 825</u>	ANNUAL REPORT ON THE COSTS ASSOCIATED WITH PRESCRIPTION DRUGS: Beginning January 1, 2019, a manufacturer of a prescription drug that is made available in this state and that has a wholesale acquisition cost of \$40.00 or more per course of therapy shall file an annual report with the department of insurance and financial services on the costs associated with the prescription drug for the preceding calendar year. A report filed under this subsection must be filed before May 1 of each year in a form and manner prescribed by the department of insurance and financial services.
	SB 899 / HB 5691	INCREASE OF WHOLESALE ACQUISITION COST OF PRESCRIPTION DRUG: Beginning October 1, 2018, a manufacturer of a prescription drug that has a wholesale acquisition cost that is more than \$40.00 for a course of treatment and that is made available in this state shall, within 60 days of the effective date of the increased cost, notify a qualified purchaser if the manufacturer is increasing the wholesale acquisition cost of the prescription drug by 12% or more during any 24-month period.

Minnesota	SF 2671 / HF 3538	QUALIFYING PRESCRIPTION DRUG COST DISCLOSURE AND REPORT REQUIREMENTS: Each manufacturer of a prescription drug, made available in Minnesota, that has a wholesale acquisition cost of \$10,000 or more annually or per course of treatment, shall file a report with the commissioner as provided in this subdivision on the costs for each qualifying drug.
Mississippi	<u>HB 784</u>	This bill requires the Attorney General to compile certain lists of prescription drugs that are essential for treating diabetes and compile the wholesale acquisition cost of each drug on the list. This bill would require drug manufacturers and pharmacy benefit managers to provide certain information to the Attorney General regarding those drugs, the cost of the drugs, the received rebates by pharmacy benefit managers and requires the Attorney General to compile a report based on that information.
Nebraska	LB 862	PRESCRIPTION DRUG COST TRANSPARENCY ACT: This Act is intended to promote transparency of the cost of manufacturing prescription pharmaceuticals. The Act would require that a manufacturer of a prescription drug notify certain parties such as insurance companies and health providers in the event that a cost increase on prescription drugs with a wholesale cost of forty dollars for one course of therapy is to increase more than sixteen percent in a prescribed period of time. LB 862 also assigns reporting requirements and publishing of such cost increases by the Department of Administrative Services.
New Hampshire	HB 1529	PRESCRIPTION DRUG REBATE AMOUNTS: This bill requires the insurance commissioner to select 25 prescription drugs and requires insurance carriers and pharmacy benefit managers to annually disclose the amount rebated from drug manufacturers offering rebate programs during the prior year. Under this bill, the commissioner shall analyze the information and include it in the annual report required under RSA 420-G:14-a.

New Jersey	<u>A 583</u> / <u>S</u> <u>983</u>	PRESCRIPTION DRUG REVIEW COMMISSION: The commission shall develop a list of critical prescription drugs made available in New Jersey for which there is a substantial public interest in understanding the development of pricing for the drugs. For each prescription drug that the commission places on the critical prescription drug list, the commission shall require the manufacturer to report the total cost of production, approximate cost of production per dose, and research and development costs of the drug.
New York	<u>S_4986</u>	Enacts the pharmaceutical cost transparency act requiring prescription drug manufacturers to file a report disclosing certain financial information pertaining to prescription drugs which have a wholesale acquisition cost of \$10,000 or more annually or per course of treatment.
	A 2939	PRESCRIPTION DRUG COST TRANSPARENCY: Requires drug manufacturers selling medications in NY with a WAC of \$1,000 for a 30 day supply and for which the price has increased 3x in a 3 month period would be required to file a report within the state.

Pennsylvania	<u>SB 637</u>	This bill would establish the "Pharmaceutical Transparency Commission." It would require pharmaceutical manufacturers to report annually to the commission for each of the following: the total costs derived in the production of the prescription including: research and development costs and separately , the total research and development costs paid by any predecessor in the development of the drugs, the total costs of clinical trials and other regulatory costs paid by predecessors, the total costs paid for materials, manufacturing, and administration attributable for the drug, the total costs paid by any entity other than manufacturer or predecessor for research and development, any other costs to acquire the drug, including costs for the purchase of patents, licensing or acquisition of any corporate entity, the total marketing and advertising costs, a cumulative annual history of average wholesale price and weighted average cost increases, the total profit attributable to the drug, a description of the manufacturer's patient prescription assistance program, total profit and a percentage of company profit derived from the sale of each medication. Provides that pharmacy benefit manger or insurer contracts with pharmacies may not contain a provision that prohibits pharmacists from disclosing information to a customer that would reduce the customer's out-of-pocket costs for prescription drugs.
Rhode Island	H 7004	RELATING TO BUSINESSES AND PROFESSIONS — PHARMACEUTICAL COST TRANSPARENCY. This act would direct the state board of pharmacy, in collaboration with the department of health, to annually identify up to fifteen (15) prescription drugs on which the state spends significant health care dollars due to increases in costs. This list would be provided to the attorney general's office, and the Attorney General's office would require the drug's manufacturers to submit relevant information and documentation to justify these cost increases. The act would also direct the department of health to use the same dispensing fee in its reimbursement formula for 340B prescription drugs as it uses to pay for non-340B prescription drugs under the Medicaid, program, and to provide information to the general assembly and the governor about these programs. The act would also establish an advisory commission on out-of-pocket prescription drug costs who would study these costs and make reports and recommendations to the governor and the general assembly.

	<u>S 2532A</u>	Regulates prescription drug marketing by manufacturers using strategies offering various discounts to disguise costs of high-priced drugs versus lower costs alternatives and makes discounts available to individuals without health insurance. This act would regulate the marketing of prescription drug manufacturers using direct-to-consumer marketing strategies including coupons, discount cards and similar offers to disguise the true costs of high-priced drugs as opposed to lower cost alternatives and making these discounts available to individuals without health insurance.
South Carolina	H 4490	Requires manufacturers of diabetes prescription drugs to provide certain cost information to the Department of Health and Environmental Control and requires certain nonprofit organizations that receive funding from these manufacturers to compile reports addressing the funding received and make the information publicly available. It also requires the Department to post reported information on its publicly accessible website. This bill would amend section 38-17-16 relating to mandated insurance coverage for the treatment of diabetes, so as to require certain health insurance policies to provide notice in certificate of coverage during open enrollments periods of available prescription drugs to treat diabetes and the use of formularies.
Tennessee	HB 2465 / SB 2412	This bill requires the state comptroller to study and make recommendations for increasing transparency in the purchasing of prescription drugs through the group insurance plan for state employees.
Washington	SB 5586	PRESCRIPTION DRUG COST TRANSPARENCY: Requires the office of financial management to use a competitive procurement process to select a data organization to collect, verify, and summarize the prescription drug pricing data provided by issuers and manufacturers. Requires an issuer to submit certain prescription drug cost and utilization data to the data organization for the previous calendar year.

PRESCRIPTION DRUG COST TRANSPARENCY: Requires the state to collect, verify, and summarize prescription drug pricing data provided by health insurance issuers and manufacturers. A manufacturer with a drug that increases more than 10% or \$10,000 in a year must report for such drug, the time on the market, the generic or brand name status, pricing history in the US the previous five years, total financial assistance given by the manufacturer through assistance programs, rebates, and coupons, and an economic justification of the qualifying price increase SB 5401 / HB for the covered drug. Any qualifying price increase for a 1541 covered drug must be announced 60 days before the change. Separately, each health insurance plan issuer must identify overall spending on prescription drugs and by the 25 most frequently prescribed drugs, the 25 costliest prescription drugs, with the information by the state Medicaid program, public employees' benefits board programs, and the individual, small group, and large group markets. All data submitted must be collected by a stateapproved data organization and made publicly available on the office's web site, with reports due starting Nov. 1, 2017. Fines may be up to \$1000 per day for non-compliance.

^[1] Oregon's threshold is a cumulative 10% price increase in the last calendar year; California's threshold is a cumulative 16%

over the current and previous two calendar years.

[2] HB 2387, introduced in Oregon in 2017, would have required 60-day advance notice of pharmaceutical price increases above a threshold, but it failed to pass.

[3] 42 U.S.C. § 1395w-3a(c)(6)(B).

[4]

https://www.bloomberg.com/news/articles/2018-07-10/drugmakers-cancel-price-hikes-as-california-law-takes-effect

[5] Gudiksen KL, Brown TT, Whaley CM, King JS. California's Drug Transparency Law: Navigating The Boundaries Of State Authority On Drug Pricing. Health Affairs (Project Hope). 2018;37(9):1503-8. Available from: https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.0424.