

OREGON LEGISLATIVE ASSEMBLY IOINT TASK FORCE ON FAIR PRICING OF PRESCRIPTION DRUGS

Background: The National Conference of State Legislatures (NCSL) reports that since 2015, states have introduced over 3,500 "pieces of legislation" relating to pharmaceutical policy in the United States.¹

According to NCSL and the National Academy for State Health Policy:

- In 2015, 1,210 bills and resolutions were filed and listed across all 50 states, D.C. and Puerto Rico. Of these, 266 laws were signed or enacted in 48 states, D.C. and Puerto Rico; seven states also adopted non-statutory resolutions.
- In 2016, 1,250 bills and resolutions filed, including new legislation and measures carried over from 2015. Of these, approximately 220 laws have been signed in 44 states and D.C. Bills signed in December may be tagged as 2017.
- In 2017, 170 laws were passed in 43 states and D.C., among over a 1,000 sessionfiled bills and resolutions.
- In 2018, state legislatures introduced over 150 bills to address prescription drug costs with approximately 20 states enacting 37 bills as of July 2018.²

Legislation has spanned a range of policy topics related to prescription drugs that includes but is not limited to (see page 17 for brief descriptions of the terms below):

- Access to prescription drugs
- Biologics and biosimilars
- Clinical trials and right to try
- Compounding pharmacy regulation
- Cost sharing and deductibles for consumers
- Coverage of prescription drugs by insurers
- Drug importation from Canada
- Utilization and costs of prescription drugs in state Medicaid programs

- Price increases and rate-setting
- Pricing and payment in the drug supply chain
- Regulation of pharmacy benefit managers (PBMs)
- Prescription drug safety and errors
- Specialty pharmaceuticals
- Transparency
- Utilization management

¹ National Conference of State Legislatures. Statewide Prescription Drug Database | 2015 - Present.

² National Academy for State Health Policy. <u>Twenty States Passed 37 Bills to Curb Rising Rx Drug Costs in the Short 2018 Legislative Session</u>, July 2018.

OTHER STATES' PRESCRIPTION DRUG LEGISLATIVE PROPOSALS (2015-2018) - DISCUSSION DOCUMENT

Other States' Legislation & Oregon Proposed Cost Factors: Legislative Policy and Research Office (LPRO) staff reviewed proposed and enacted legislation with a focus on measures aimed at transparency and promoting "cost-effective" solutions for payers and consumers as described in House Bill 4005³ and as requested by Governor Brown in written correspondence on April 16, 2018.⁴

The table below outlines approximately 40 bills designed to impact market participants involved in the pharmaceutical supply chain and pharmaceutical expenditures. The list of bills is not exhaustive. Rather, the table is merely to offer examples of policy options considered in other states and to foster discussion among the Task Force in its effort to report on cost-effective and enforceable solutions for pharmaceutical products and develop a transparency strategy.

In Table 1, for each market participant involved in the supply chain, a set of bills with descriptions are listed including a preliminary indication if the proposed (or enacted) legislation may impact transparency specific to the proposed cost factors under consideration by the Task Force. For individual market participants, there is a second sub-section that provides additional placeholder rows for developing transparency strategies.

The table is intended to serve as a discussion tool on August 21st.

Market Participant	Page in Document
Manufacturers (Brand, Generic, Biopharmaceutical)	Page 3
Wholesale Distributors	Page 4
Pharmacy Benefit Managers	Page 5
Insurers	Page 7
Pharmacies (Independent and Retail)	Page 9
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Consumers	<u>Page 15</u>

⁴ Governor Brown. <u>Letter to Members of the Task Force on Fair Pricing of Prescription Drugs</u>, April 2018.

³ House Bill 4005 (2018 Legislative Session).

Table 1: State Prescription Drug Legislative Proposals (2015-2018)

	Policy Concepts	State(s) *Indicates enacted as state law	Brief Bill Description	Potential Transparency for Proposed Cost Factor(s)	Other Market Participants
	Manufacturers				
1	Prohibits price gouging and establish annual reporting requirement for all state funded expenditures on prescription drugs	Maine LC 1605	Prohibit price gouging in the sale of essential off-patent or generic drugs by requiring the Maine Health Data Organization to annually identify prescription drugs on which the State spends significant amounts of money and for which the manufacturer's list price for the drug has increased by 50% or more over the past 5 years or 15% or more over the past 12 months.	List price, discounts, rebates	
2	Potentially increase transparency of money flow for prescription drugs	New Jersey S 2769	Prohibit drug manufacturer from offering any rebate, voucher, or other reduction of an individual's out-of-pocket expenses for any prescription drug or biological product if a lower cost product is available that is designated therapeutically equivalent by the FDA.	Discounts, rebates, list price	
	Manufacturers: Potential	Transparency Strate	gies for Proposed Cost Factors		
	 Discounts Fees Incentive programs (kickbacks) Insurance benefit design List price Rebates 		[placeholder for policy strategy discussion]		

	Policy Concepts	State(s) *Indicates enacted as state law	Brief Bill Description	Potential Transparency for Proposed Cost Factor(s)	Other Market Participants
'	Wholesale Distributor				
1	Creates drug importation program from Canada	Colorado <u>CS 80</u> , Vermont <u>S 175</u> , and West Virginia <u>H 4294</u>	Permits the state to establish a program to import pharmaceuticals from Canada for resale to residents. Vermont & West Virginia primarily focused on higher cost drugs.	List price, discounts, rebates	
2	Prohibits price gouging by wholesalers; authorizes state to obtain drug pricing information	Minnesota SF 2841/HF 3131	Prohibits certain price increases for essential off-patent or generic drugs by wholesale drug distributors (and manufacturers) unless the price increase is directly attributable to additional costs. Establishes civil penalties for violations. Authorizes the attorney general to obtain drug pricing information from wholesalers (and manufacturers).	Discounts, rebates, list price	
ı	Wholesale Distributor: P	otential Transparency	Strategies for Proposed Cost Factors		
	 Discounts Fees Incentive programs (kickbacks) Insurance benefit design List price Rebates 		[placeholder for policy strategy discussion]		

	Policy Concepts	State(s) *Indicates enacted as state law	Brief Bill Description	Potential Transparency for Proposed Cost Factor(s)	Other Market Participants
	Pharmacy Benefit Man	agers (PBMs)		,	
1	Require PBMs to report rebates, discounts, or price concessions, and additional information	Massachusetts H 491 & S 1163	Require each PBM under contract with a covered entity to report to the covered entity and to the Commissioner information including (i) rebates, discounts, or price concessions that were negotiated by the PBM; and (ii) the net difference between what the covered entity paid to the PBM and what the PBM paid retail or mail order pharmacies.	Discounts, rebates, list price, fees	
2	Require PBMs to disclose rebates and discounts from manufacturers	Nebraska LB 324; California AB 29	Require PBMs to disclose to their clients the rebates and discounts received from manufacturers as well as the PBM's pricing methodology. Provides the Director of Insurance the power to revoke the Certification of Authority of a PBM for violations.	Discounts, rebates, list price, fees	
3	Ban the use of pharmacist gag clauses by PBMs, creates transparency for consumers/pharmacists	Georgia HB 276/SB 103, Maine LD 6, North Carolina H 466 & S 384	Ban PBM practice that prohibits a pharmacist or pharmacy from providing an insured patient information regarding the amount of the patient's prescription drug cost share and the clinical efficacy of a lower priced alternative drug if one is available. Neither pharmacy nor pharmacist shall be penalized for sharing information or for selling a more affordable alternative if one is available.	List price, rebates, discounts, fees, insurance benefit design	

	Policy Concepts	State(s) *Indicates enacted as state law	Brief Bill Description	Potential Transparency for Proposed Cost Factor(s)	Other Market Participants
4	Require PBMs to report on prices and costs of prescription drugs	Montana HB 326	Require PBMs that sell a drug whose WAC increases by more than twice the increase in the consumer price index from the previous year to provide to the Attorney General all relevant information necessary to justify the increase. The Attorney General would provide a Report to the legislature which would be posted on the Department of Justice website.	List price, rebates, discounts, fees	
	PBMs: Potential Transpa	rency Strategies for F	Proposed Cost Factors		
	 Discounts Fees Incentive programs (k Insurance benefit desi List price Rebates 		[placeholder for policy strategy discussion]		

	Policy Concepts	State(s) *Indicates enacted as state law	Brief Bill Description	Potential Transparency for Proposed Cost Factor(s)	Other Market Participants
In	surers				
1	Consumer affordability by limiting out-of-pocket costs for prescription drugs	New York SB 2541	Prohibits insurers [and PBMs] from charging patient out of pocket costs that exceed the payors' cost of the drug net of manufacturer.	Rebates, list prices, fees	
2	Consumer affordability by reducing out-of- pocket costs for prescription drugs	Texas <u>HB</u> 2360 & <u>SB 1076</u>	Prevents a health issuer that covers prescription drugs from requiring an enrollee to make a payment for a prescription drug at the point of sale in an amount greater than the lesser of: (1) the applicable copayment; (2) the allowable claim amount for the prescription drug; or (3) the amount an individual would pay for the drug if purchasing the drug without using a health benefit plan or any other source of drug benefits or discounts.	Rebates, list prices, fees, discounts	
3	Consumer transparency requirements for insurers	Massachusetts H 491 & S 1163	Require insurance carriers that cover prescription drugs to disclose to enrollees and potential enrollees, all covered drugs and any cost-sharing imposed on such drugs.	Insurance benefit design	

Policy Concepts	State(s) *Indicates enacted as state law	Brief Bill Description	Potential Transparency for Proposed Cost Factor(s)	Other Market Participants
Discounts Fees Incentive programs (k Insurance benefit desi List price Rebates	ickbacks)	[placeholder for policy strategy discussion]		

	Policy Concepts	State(s) *Indicates enacted as state law	Brief Bill Description	Potential Transparency for Proposed Cost Factor(s)	Other Market Participants
PI	narmacies (Independer	nt and Retail)		I	
1	Allows pharmacists to dispense lower cost medications	Arizona HB 1204; Connecticut HB 7118; Maryland HB 1273; Minnesota* HF 712, SF 1184; New York* AB 7509; Vermont S 92; West Virginia SB 406; Wyoming* SF 121	Allow a pharmacist who receives a prescription for a brand name drug product or biologic product to dispense a lower cost generically therapeutically equivalent drug product or interchangeable biological product. Requires the pharmacist to notify the patient and the prescriber within a specified time-period (e.g., 5 days of the substitution).	List price, rebates, discounts	
2	Increases transparency to allow pharmacists to substitute medications that have lowest cost	Maryland H <u>1273</u>	Requires the State Board of Pharmacy to maintain on its web site a link to specified lists of biological products appropriate for substitution under specified circumstances.	• List price,	
3	Consumer affordability by requiring pharmacists to charge specific prices	New Hampshire SB 238	Require pharmacies to charge an enrollee/insured person the pharmacy's usual and customary price or the contracted co-payment (whichever is less), thereby preventing consumers from paying copayments fees in excess of the cost of the prescription.	Rebates, list price, fees	

Policy Concepts	State(s) *Indicates enacted as state law	Brief Bill Description	Potential Transparency for Proposed Cost Factor(s)	Other Market Participants
Discounts Fees Incentive programs (k Insurance benefit des List price Rebates	kickbacks)	[placeholder for policy strategy discussion]		

	Policy Concepts	State(s) *Indicates enacted as state law	Brief Bill Description	Potential Transparency for Proposed Cost Factor(s)	Other Market Participants
	Providers				
1	Provider compensation by manufacturers	California SB 790	Prohibit a drug manufacturer from offering or giving compensation for services provided by investigators, health care professionals, or health care entities for a bona fide clinical trial, research project, or patient care.	Incentive programs	
2	Provider marketing and utilization by requiring manufacturers to disclose pricing information.	Louisiana * HB 436 (2017)	Requires each drug manufacturer or pharmaceutical marketer who engages in any form of prescription drug marketing to a prescriber, his or her designee, or any member of his or her staff in Louisiana to provide to the Louisiana Board of Pharmacy the current WAC information for each of the U.S. FDA approved drugs marketed in the state by that manufacturer.	• List price	
Pro	viders: Potential Transp	arency Strategies for	Proposed Cost Factors		
	 Discounts Fees Incentive programs (kickbacks) Insurance benefit design List price Rebates 		[placeholder for policy strategy discussion]		

	Policy Concepts	State(s) *Indicates enacted as state law	Brief Bill Description	Potential Transparency for Proposed Cost Factor(s)	Other Market Participants
	Public Agencies				
1	Consumer transparency by publicly reporting costs of retail prices for generic and brand medications.	Florida * HB 589	Requires the State to collect data on the retail prices charged by pharmacies for the 300 most frequently prescribed drugs within the state; to be updated monthly. When a generic is available the price data would be reported for both the generic and the equivalent brand name drug and made available on the agency's internet website for each pharmacy to use.	List price, rebates, discounts,	
2	Establishes prescription drug reporting in Medicaid	Indiana H 1150	Requires the State to identify any prescription drug under the Medicaid program for which the annual wholesale cost or the per course cost of treatment of the drug is at least \$10,000, and directs the State to notify the manufacturer that the manufacturer is required to prepare a report on the drug to the drug utilization review board.	List price, rebates, discounts	
3	Authorizes State to purchase directly from manufacture and caps prices	Massachusetts H 2983	Authorizes that the Group Insurance Commission and the Office of Medicaid to enter into agreements with manufacturer of drugs for purchase of prescribed pharmaceuticals at the same of lowest price paid for the same drug by the U.S. Department of Veterans Affairs.	List price, discounts, rebates,	

Policy Concepts	State(s) *Indicates enacted as state law	Brief Bill Description	Potential Transparency for Proposed Cost Factor(s)	Other Market Participants
Discounts Fees Incentive programs (k Insurance benefit desi List price Rebates	ickbacks)	[placeholder for policy strategy discussion]		

	Policy Concepts	State(s) *Indicates enacted as state law	Brief Bill Description	Potential Transparency for Proposed Cost Factor(s)	Other Market Participants				
(Coordinated Care Organizations (CCOs) [Medicaid Managed Care]								
1	Establishes standardization with formulary within Medicaid program (preferred drug list)	Illinois H 2358	Requires managed care organizations under contract with the State to follow a standard prescription drug formulary established in administrative rule, requires the State to adopt any rules necessary to implement the law.	Insurance benefit design					
2	Expands network of pharmacies for Medicaid consumers	New Jersey A 4043	Requires all managed care organizations to permit all pharmacies in the state to dispense prescriptions for all covered medications.	Insurance benefit design, fees					
CC	CCOs: Potential Transparency Strategies for Proposed Cost Factors								
	 Discounts Fees Incentive programs (kickbacks) Insurance benefit design List price Rebates 	[placeholder for policy strategy discussion]	[placeholder for policy strategy discussion]						

	Policy Concepts	State(s) *Indicates enacted as state law	Brief Bill Description	Potential Transparency for Proposed Cost Factor(s)	Other Market Participants					
(Consumer									
1	Consumer transparency by publicly releasing drug pricing information.	Louisiana A 236*	Commits the Louisiana Board of Pharmacy to develop a website containing specified prescription drug pricing information to be made available to Louisiana prescribers.	• List price						
2	Consumer transparency providing retail price of medications.	New York AB 8046/SB 6629	Require a pharmacy that receives an electronic prescription to provide the retail price of the prescription directly to the patient.	List price, rebates, fees						
3	Consumer transparency requiring manufacturers to disclose price in advertising.	Oregon SB 792	Require manufactures advertising for any drug sold in the state include the WAC price. There would be civil penalties up to \$5,000 for violations	• List price						
4	Consumer notification requiring PBMs to provide explanations of benefits for Rx claims.	Vermont S 57	Require PBMs to mail an explanation of benefits to the beneficiary for each pharmacy claim for a prescription drug covered including information on (1) the cost of the prescription drug being charged to the health plan; (2) the co-payment amount paid by the beneficiary; (3) fees and other charges deducted from the cost of the drug; (4) the amount retained by the PBM; and (5) the final payment to the pharmacy.	Discounts, fees, rebates						

	Policy Concepts	State(s) *Indicates enacted as state law	Brief Bill Description	Potential Transparency for Proposed Cost Factor(s)	Other Market Participants			
5	Consumer affordability limiting the retail price paid by consumers.	West Virginia SB 507	Prohibits pharmacists and PBMs from selling drugs to consumer at a retail price that is in excess of the price(s) the entity paid to acquire the drug. Savings must be passed along to the consumer at the point of sate in the case of an uninsured individual.	List price, discounts, rebates, fees				
Cor	Consumers: Potential Transparency Strategies for Proposed Cost Factors							
	 Discounts Fees Incentive programs (kickbacks) Insurance benefit design List price Rebates 		[placeholder for policy strategy discussion]					

Information obtained from NASHP State Prescription Drug <u>Legislative Tracker</u> 2017, accessed on July 26th, 2018 and the National Conference of State Legislatures, accessed on July 27th via NCSL's 50 state prescription drug <u>database</u> 2015-present.

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NCSL Guide to Prescription Drugs Policy

Access: state policies that affect the way in which patients obtain prescription drugs, including their availability through public or private health facilities or medicine outlets and pharmacies.

Biologics and biosimilars: notice or restrictions on substitution or interchangeability of biosimilars for brand name or first-approved biologics, also other measures that facilitate or limit biologic medications, or address coverage or costs. Note that measures on "Right to Try" are listed separately as "Rx Clinical Trials and Right to Try" in the check box choices above. NCSL has a separate Biologics online report that describes the fast-changing history of this issue.

Clinical trials and right to try-Rx drugs: state policies to facilitate, mandate or restrict pharmaceutical experimental use by patients, including clinical trials, "compassionate use," "expanded access" and "right to try" legislation.

Compounding pharmacy regulation: state policies to define and regulate sterile and non-sterile compounding pharmacies, including coordination with recent FDA/federal law; will allow a keyword search for 503B outsourcing facilities and other sub-topics.

Cost sharing and deductibles: consumer-related pricing policies such as tiers, co-payments, deductibles, out-of-pocket limits (OOP), discount coupons, insurance reference prices and price disclosure.

Coverage by insurers: requirements and restrictions affecting commercial and ACA exchange or marketplace-related insurance. Also includes mandates, parity or essential health benefit bills specific to prescription drugs.

Medicaid use and coverage: Medicaid use of coverage and cost strategies, including preferred drug lists (PDLs), supplemental rebates, utilization review, prior authorization, Pharmacy and Therapeutics committees and related policies.

Regulation of PBMs: state policies affecting transparency of PBMs, maximum allowable cost (MAC) lists and PBM/provider disclosure. Also, includes measures to reform audit standards and certain contractual provisions between pharmacies and PBMs, including 'clawbacks', prohibiting gag-clauses that restrict pharmacists and 'price-gouging.'

Pricing and Payment: state required or authorized manufacturer rebates, discounts, generic and brand name drug choice, carve-outs, transparency and reimbursement formulas. Also includes regulation of formularies.

Prescription drug safety and errors: State policies requiring safe and secure storage and sales of prescription products, including state-FDA compliance and coordination; also, mail-order, Internet and non-compliant marketing and patient confidentiality.

Specialty Pharmaceuticals: complex or costly medications, such as injectable and infusion products and many biologic products used for conditions such as cancer, organ transplants, epilepsy, Hepatitis-C.

Utilization management: use of commercial insurance and retail formularies, preferred drug lists (PDLs), prior authorization, utilization review.