NASHP Center for State Rx Drug Pricing

Comparison of State Transparency Laws: What They Require and What Enforcement Action States Can – or Can't – Take

As of June 4, 2018, six states have passed prescription drug pricing transparency laws that require drug makers to report the reasons behind dramatic price increases. These transparency laws are good first steps, however Maryland's anti-price-gouging law – currently under legal review – takes the next step. It identifies price increases that are "unconscionable" and takes legal action against those drug makers. ***This chart compares manufacturer reporting requirements in transparency legislation against NASHP's model transparency legislation and Maryland's more aggressive anti-price-gouging law.***

		NASHP Model Transparency Legislation	Vermont (S 92)	Maine (LD 1406)	Connecticut (HB 5384)	Nevada (SB 539)	Oregon (HB 4005)	California (SB 17)	Maryland (Price Gouging) (MD 631)
1a) Manufacturer Reporting Requirements for Price Increases	**Law pertains to:**	All prescription drugs	Fifteen drugs with price increases listed by the State and health insurance plans as sources of significant spending (generic and brand name drugs)	Prescription drugs	Not more than 10 outpatient prescription drugs that are a substantial cost to the state or critical to public health identified in list compiled by Office of Health Strategy	Essential diabetes medicines	All prescription drugs that cost more than $100/month or per course of treatment	All prescription drugs that cost less $40/month or per course of treatment	Off-patent or generic drugs that cost more than $80/month or per course of treatment
	Price increases triggering reporting requirements:	**Brand Drugs:** More than 10% or more than $10,000 over 12 months **Generic Drugs**: More than 25% or more than $300 over 12 months	Drugs to be included in the list of 15 drugs will have wholesale acquisition cost increases of 50% or more in past 5 years; or 15% or	Maine Health Data Organization will develop a plan to collect data from manufacturers related to the cost and pricing of prescription drugs	Drug will not be part of list of 10 drugs unless wholesale acquisition cost (less rebates) increased by at least 20% in immediately	Medical care component of the Consumer Price Index (CPI-M), in prior calendar year; or twice	Increase greater than 10% in prior calendar year	More than 16%, including the proposed and cumulative increases that occurred within the previous two calendar years	"Unconscionable" price increase, including a 50% increase in generic drugs in prior 12 months

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			more in previous calendar year		preceding calendar year or 50% during preceding 3 years, and was not less than $60 for a 30-day supply or course of treatment of lasting less than 30 days	CPI-M in prior 2 calendar years			
	Manufacturer data due:	30 days prior to price increase	Upon request of attorney general		Upon request from executive director of Office of Health Strategy	Annually	60 days prior to price increase; quarterly thereafter	60 days prior to increase	Upon request of the attorney general
1b) Data Required by Manufacturers on Price Increases	**Price**					Wholesale acquisition cost (WAC) WAC price over the previous 5 years WAC at launch	Wholesale acquisition cost (WAC) WAC price over the previous 5 years Price increase as % of drug's price 10 highest prices paid for drug outside of the United States Time on market	Wholesale acquisition cost (WAC) Price increase as % of wholesale acquisition cost Patent expiry date Time on market Price at launch	Unspecified, as determined by the attorney general

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							Price at launch Price increase by calendar year since launch	Price increase by calendar year since launch	
	Effectiveness	Whether drug is more effective than predicted					Whether drug is more effective than predicted	Whether drug is more effective than predicted	Whether there is an improvement in public health as a result of drug
	Company Pricing Considerations	All company pricing considerations including: • Life cycle management • Market competition and context	Each factor that caused the net cost increase; the percentage of the total cost increase attributable to each factor; and an explanation of the role of each factor in contributing to the cost increase		All factors that caused the increase in the wholesale acquisition cost in a written, narrative description suitable for public release		Financial and non-financial factors in price increase	Financial and other factors in increase decision	
	Use of Public Funds						Use of public funding for research and development		
	Production Costs				Aggregate company level research and development costs and other such capital expenditures that	Production costs Administrative costs including marketing and advertising	Manufacturing costs Marketing costs Distribution costs		Production costs Increase in production costs over time

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					the executive director deems relevant		Ongoing research		
	Sales Information						Sale revenue in prior calendar year	United States sales volume in prior calendar year	
	Profit Information					Profit since launch	Profit in prior calendar year		
	Rebate/PBM Information	Rebates to Pharmacy Benefit Managers (PBM) Other price concessions				Amount of rebates to PBM	Amount of rebates to PBM PBM rebates by insurance market segment		
	Patient Assistance Programs & Coupons	Description of each patient assistance program (due annually) per product and total market value of the program				Patient assistance program use and cost data Costs associated with coupons	Patient assistance program use and cost data Data on coupon program		
	Other						Any information the manufacturer wants to submit		Any information the manufacturer wants to submit
2a) Manufacturer Reporting Requirements for	**Law pertains to:**	New products with prices of: **Brand**: $30,000 **Generic**: $3000	Prescription drugs whose wholesale acquisition costs exceeds the threshold set for a				New products with prices of: $670	New products with prices of: $670	

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New Drug Prices			specialty drug under the Medicare Part D program						
	Manufacturer data due:	30 days prior to launch	30 days following notification to attorney general; notification to attorney general required within 3 calendar days after launch				Within 30 days after launch	Within 3 days after market launch Follow up detailed information is due 30 days following launch	
2b) Data Required by Manufacturers on New Drug Prices	**Drug Information**		Date of acquisition and acquisition cost (if any) FDA drug approval designation (e.g. breakthrough therapy) Expected utilization		Sponsors of a new drug application or biologics license application must notify the Office of Health Strategy within 60 days after the receipt of an action date from the FDA. For drugs that may have a significant impact on state expenditures, additional information must be supplied: disease for which drug is indicated, route of administration, trial comparators, estimated year of		Acquisition cost (if any) FDA drug approval designation (e.g., breakthrough therapy) Expected utilization	Acquisition cost (if any) FDA drug approval designation (e.g., breakthrough therapy) Expected utilization	

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					market entry, designation as orphan drug, fast track product or breakthrough therapy, accelerated approval or priority review.				
	Marketing Plan		Marketing plan				Marketing plan	Marketing plan	
	Company Pricing Considerations	All company pricing considerations including Life cycle management Market competition and context	Pricing plan				Pricing methodology	Pricing plan Launch price	
	Use of Public Funds						Use of public funding for research and development		

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3) Enforcement		$10,000/day for failure to report	$1,000/day for failure to report		No more than $7,500 per violation	$5,000 /day for failure to report	Up to $10,000/day for failure to report complete and accurate data	$1,000/day for each drug the manufacturer fails to report	The attorney general can refer the case to the state's highest court, which can impose the following remedies on companies found to have price-gouged: -Require the company to provide pricing documents; -Stop (enjoin) the price increase; -Restore to any consumer and third-party payer, payments or spending resulting from the price increase; -Require manufacturers to make the drug available to participants in the state health plan or program for a period of up to one year at the pre-increase price; -Impose a civil penalty of up to $10,000 for each violation.

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4) Data that 340B Hospitals must submit	**Data is due**	**Annually**							
	Hospital must submit	Report per unit profit margin on each 340B drug dispensed multiplied by number of units dispensed.							