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

Several states have passed prescription drug pricing transparency laws that require drug makers to report the reasons behind dramatic price increases. These laws are good first steps that require companies to explain their price increases. Maryland's law – under review by the courts -- takes the next step. It identifies price increases that are "unconscionable" and takes legal action against those drug makers. This chart compares transparency legislation in four states against NASHP's model transparency legislation and Maryland's more aggressive anti-price-gouging law.

		NASHP Model Transparency Legislation	Vermont (S 216)	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	15 drugs representing significant state spending identified in annual state-compiled list	Essential diabetes medicines	All prescription drugs that cost more than $100/month or per course of treatment	All prescription drugs that cost more than $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 $10,000 over 12 months **Generic Drugs**: More than 25% or $300 over 12 months	Wholesale acquisition cost increases greater than 50% in past 5 years; or 15% in last 12 months	Medical care component of the Consumer Price Index (CPI-M), in prior calendar year; or twice CPI-M in prior 2 calendar years	Increase greater than 10% in prior calendar year	More than 16% in previous 12 months or 32% in previous 24 months	"Unconscionable" price increases, including a 50% increase in generic drugs in prior 12 months

	Manufacturer data due:	30 days prior to price increase	Upon request of the attorney general	Annually	60 days prior to price increase; quarterly thereafter	60 days prior to increase	Upon request of the attorney general
		NASHP Model Transparency Legislation	**Vermont (S 216)**	**Nevada (SB 539)**	**Oregon (HB 4005)**	**California (SB 17)**	**Maryland (Price-Gouging) (MD 631)**
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 Price at launch Price increase by calendar year since launch	Wholesale acquisition cost (WAC) Price increase as % of wholesale acquisition cost Patent expiry date Time on market Price at launch Price increase by calendar year since launch	Unspecified, as determined by the attorney general
	Effectiveness	Whether drug is more effective than thought			Whether drug is more effective than thought	Whether drug is more effective than thought	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			Financial and non-financial factors in price increase	Financial and other factors in increase decision	
		NASHP Model Transparency Legislation	**Vermont (S 216)**	**Nevada (SB 539)**	**Oregon (HB 4005)**	**California (SB 17)**	**Maryland (Price-Gouging) (MD 631)**
	Use of Public Funds				Use of public funding for research and development		
	Production Costs			Production costs Administrative costs including marketing and advertising	Manufacturing costs Marketing costs Distribution costs Ongoing research		Production costs Increase in production costs over time
	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/Pharmacy Benefit Manager (PBM) Information	Rebates to PBM Other price concessions		Amount of rebates to PBM	Amount of rebates to PBM PBM rebates by insurance market segment		
	Patient Assistance	Description of each patient assistance		Patient assistance program use and cost	Patient assistance program use and cost		

	Programs & Coupons	program (due annually) per product and total market value of the program		data. Costs associated with coupons	data. Data on coupon program		
		NASHP Model Transparency Legislation	**Vermont (S 216)**	**Nevada (SB 539)**	**Oregon (HB 4005)**	**California (SB 17)**	**Maryland (Price-Gouging) (MD 631)**
	Other		All factors contributing to increase (i.e. not specified); percentages attributed to each factor; explanation of the role of each factor		Any information the manufacturer wants to submit		Any information the manufacturer wants to submit
2a) Manufacturer Reporting Requirements for New Drug Prices	**Law pertains to:**	New products with prices of: **Brand**: $30,000 **Generic**: $3,000			New products with prices of $670	New products with prices of $670	
	Manufacturer data due:	30 days prior to 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**				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	
	Marketing Plan				Marketing plan	Marketing plan	
	Company Pricing Considerations	All company pricing considerations including			Pricing methodology	Pricing plan	

		Life cycle management Market competition and context				Launch price	
		NASHP Model Transparency Legislation	**Vermont (S 216)**	**Nevada (SB 539)**	**Oregon (HB 4005)**	**California (SB 17)**	**Maryland (Price-Gouging) (MD 631)**
	Use of Public Funds				Use of public funding for research and development		
3) Enforcement		$10,000 per day for failure to report	$10,000 per violation for failure to report	$5,000 per day for failure to report	Up to $10,000 per day for failure to report complete and accurate data	$1,000 per 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; and -Impose a civil penalty of up to $10,000 for each violation.

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.					