# Health Research Institute Regulatory Spotlight

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## States take aim at high drug prices

Amid the national debate on drug prices, states are taking up bills and ballot initiatives requiring that pharmaceutical companies justify the cost of their products.

Since January 2015, 13 bills have been introduced in states such as California and Massachusetts requiring companies to disclose the cost to research, develop, produce and market many of their drugs. Some of the bills also require companies to report information such as profit, price history, taxpayer assistance, patient assistance, and prices charged to foreign governments. Vermont is the only state to have passed drug price transparency thus far, though 11 of the remaining 12 bills – all except Oregon's – remain under active consideration.

Not all drugs would be affected in every state. The majority of the bills target specialty drugs, for which spending increased 26.5% between 2013 and 2014. Seven of the eleven active bills cover drugs sold to wholesalers at specific price points – \$1,000, \$5,000, \$10,000 or \$50,000 per year or per course of treatment. Four target any drug where there is a "substantial public interest" in pricing transparency, while another – a bill in North Carolina – targets all brand drugs regardless of cost.

Other proposals go further, proposing caps on what drugmakers can charge for their drugs. <u>Ballot initiatives in California</u> and <u>Ohio</u> would limit prices paid by state entities to those paid by the US Department of Veterans Affairs. In addition to its transparency provisions, the <u>bill in Massachusetts</u> also would permit price caps on drugs which "jeopardize" the state's <u>cost growth benchmark</u> rate of 3.6%.

### **Industry implications**

- 1) Auditing drug costs is no easy task: Few, if any, drug manufacturers account for research and development costs on a per-drug basis. It is difficult to attribute research costs to a single, successful drug. Research and development may result in several approvals or dozens of failed compounds. It takes a decade on average to develop a new drug, and just 10% of drugs entering clinical testing are ultimately approved. Most states have not asked companies to provide data on time spent developing drugs. Four state bills require data to be audited by a third party before it can be submitted. If legislation is passed, acceptable accounting models will need to be developed. Auditing costs will be borne by the manufacturer, potentially adding to drug costs.
- **2) Impacts could be widespread:** Most bills permit top-line data to be made public, which could influence drug cost debates around the country. Developers of treatments for rare diseases, biologics and cancer drugs may be most affected due to their comparatively higher sales prices. States considering punishing companies for failing to disclose costs or lower prices by limiting access may prompt <u>litigation</u>. Even if they are successful, state lawmakers' efforts in this area may have a relatively modest impact on healthcare spending. After rebates, drug costs <u>only account for about 5%</u> of state Medicaid spending, and states pay only a fraction of this amount the federal government pays the rest.
- 3) Value is the key to the cost debate: States are likely to use their bully pulpits to pressure companies into lowering prices. Advocacy groups, pharmaceutical benefit managers and hospitals also may use the data for the same purpose. Drug companies should focus on the value their drugs provide. Expensive drugs may provide extensive value. Healthy profit margins incentivize future research and development to treat and cure diseases. Value also may be found in new payment models, such as global budgets allowing states an unlimited supply of a product for residents at a set cost or allowing a state to pay for a drug over time. These models could allow states to better predict and accommodate drug costs and avoid sudden shocks.

### At a glance

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Some state legislators are taking aim at drug costs by proposing new bills calling for price caps or transparency about development costs.

Proposals have been introduced in at least thirteen states so far that would require transparency about drug costs and profits: Calif., Colo., Mass., Min., N.Y., N.C., Ore., Pa., R.I., Tenn., Wash., Va. and Vt. Legilation has passed in Vermont.

Most bills target drugs wholesaling for more than \$10,000 per year.

While transparency proposals seem simple, accounting for the cost of developing a drug is highly complex due to the failure of other products, the time development takes, and the complexities of research.

Ballot initiatives in two states – Ohio and Calif. – would cap drug prices. The initiatives are subject to public vote and may be harder for the pharmaceutical industry to lobby against.

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