Published on *The National Law Review* https://natlawreview.com

State Efforts to Combat Drug Price Increases

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Growth in health care costs has long been a source of political and administrative tension for public health agencies across the country. More and more, health officials, legislators, patient advocacy groups, and third-party payors blame budgetary constraints and patient dissatisfaction and poor outcomes on high prices for once affordable medications. The issue of drug pricing has generated intense interest among federal regulators, the Department of Justice, Congress, and now, state legislatures.

Legislative Responses

As complaints about drug price fluctuations grow louder, legislatures in Massachusetts, New York, California, North Carolina, Pennsylvania, Oregon, Vermont, and Colorado have introduced “drug pricing transparency” bills. The bills, if passed, would require pharmaceutical manufacturers to disclose a variety of confidential, nonpublic drug cost information. Proponents argue that access to such information will enable policymakers to better understand and address the impact of high-cost drugs on health care spending. Opponents take a predictably different view and raise a host of concerns, summarized below.

The California, New York, Colorado, and Oregon bills require disclosure of certain pricing information for any prescription drug above a certain “annual wholesale acquisition cost,” such as total research and development costs (including clinical trials and other regulatory costs) paid by the manufacturer in the development of the drug, the total costs for materials, manufacturing, and administration attributable to the drug, the total marketing and advertising costs for the promotion of the drug to consumers and prescribers, the total profit derived from sales of the drug, and the total amount of financial assistance that the manufacturer has provided through patient prescription assistance programs for the drug.

The Vermont and Massachusetts bills have no threshold dollar amount and further require disclosure

of “prices charged” to purchasers (domestically and abroad) and “[t]rue net typical prices charged to prescription drug benefit managers for distribution.” Mass. Senate Bill No. 1048, § 18(vi); see also Vermont H. 866, § 4635(c)(1)(J) (requiring “typical prices charged to pharmacy benefit managers for distribution in Vermont during the previous year, net of rebates and of other payments from the manufacturer to the pharmacy benefit manager and the pharmacy benefit manager to the manufacturer”).

The Pennsylvania bill goes further. It exempts public or private health plans from covering “a prescription drug with an average wholesale price of five thousand dollars ($5,000) or more annually or per course of treatment . . . if the manufacturer of the prescription drug has not filed a report on the drug as required.” (House Bill No. 1042, § 635.7) Notably, the current draft bill does not define “average wholesale price,” despite more than a decade of litigation over its meaning, including in Pennsylvania.

The Massachusetts bill is the most aggressive. It authorizes the Health Policy Commission, an executive agency created to develop policy to reduce health care costs, to “set the maximum allowable price that the manufacturer can charge for [a] prescription drug that is sold for use in the commonwealth” if “the commission determines that a prescription drug is significantly high” based on “(i) the prescription drug’s medical benefits, (ii) the cost to develop and manufacture the prescription drug, and (iii) the prices charged by the manufacturer in other countries.” (Senate No. 1048, § 19(a) and (b)) Not surprisingly, the “drug price cap” bill has generated a lot of controversy. A hearing on the bill took place on April 11 before the Joint Committee on Health Care Financing. The bill’s fate remains to be seen.

The other proposals faced mixed reactions. The Colorado bill was killed by the House Committee on Health, Insurance & Environment by a 12-1 vote. Following a two-day public hearing in March 2015 attended by a variety of drug industry participants, the Oregon bill was pulled with no future committee meetings or floor sessions scheduled. The California bill likewise died in committee; an amended version was introduced on February 1, 2016 but has been stalled. The North Carolina bill, too, has languished for nearly a year. And most recently, during a U.S. Senate Appropriations budget hearing on April 7, the Director of the National Institutes of Health disagreed that the institute should exercise its federal “march-in” rights to ensure broader access to high-priced brand drugs developed as a result of government-funded research.

The Effects of Forced Price Transparency

The approaches described here raise a number of red flags:

- First, the breadth of reporting required by manufacturers could force companies to publicly disclose protected trade secret or otherwise confidential business information. (Only the Vermont, Massachusetts, and California bills provide any type of protection from public disclosure under state open records laws). Indeed, the Oregon bill had directed the Oregon Health Authority to “publish on a website maintained by the authority [the annual] reports . . . and any information that the authority deems necessary to assist the general public in understanding [the] reports.” (H.B. 3486, § 1(6))

- Second, the proposals have been criticized for oversimplifying the costs to develop and market new medications and for interfering with the market forces driving price negotiations that affect drug purchasing and reimbursement.

- Third, compulsory price transparency may be self-defeating. The New England Journal of Medicine suggests, for example, that more price transparency in health care may lead lower-priced sellers to raise prices to the levels of their higher-priced competitors, reducing price variation but raising the overall price level and, in turn, drug spending levels.

The fate of drug price transparency legislation, while far from certain, is of great interest to state and federal governments, medical services providers, consumers, and virtually all drug industry stakeholders. We will monitor the ebb and flow of any legislation going forward.

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National Law Review, Volume VI, Number 104

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