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2017 Was a Busy Year for State Imposition of Drug Manufacturer Price Disclosure Obligations and 2018 Isn't Looking Much Better

By Merle M. DeLancey Jr.*

State legislatures have been aggressive in taking on drug price increases. The author of this article discusses transparency disclosure requirement laws and what drug manufacturers should do now.

Although several bills were introduced in Congress and President Trump has complained that drug prices are way too high, during 2017, the federal government did not pass any law nor implement any policy requiring drug manufacturers to disclose information concerning price increases. As a result, state legislatures have stepped in to fill this void. Unlike Congress, state legislatures have been much more aggressive in taking on drug price increases.

NEW STATE TRANSPARENCY DISCLOSURE REQUIREMENTS

Vermont was the first state to enact transparency disclosure requirements for drug price increases. In June 2016, Vermont passed legislation that requires drug manufacturers to justify drug price increases when a drug's wholesale acquisition cost ("WAC") has increased by 50 percent or more over the past five years or by 15 percent or more over the past 12 months. A manufacturer must provide all relevant information and documentation to support the WAC increase. If a manufacturer fails to provide a justification, Vermont's Attorney General could seek injunctive relief and civil fines.

In 2017, five states (New York, Maryland, Louisiana, Nevada, and California) enacted a variety of laws requiring drug manufacturers to disclose confidential and proprietary cost information and/or information to justify price increases.

- In April 2017, New York implemented procedures to allow its Medicaid program to request rebates from manufacturers of drugs with high Medicaid utilization. If a manufacturer refuses to provide the requested rebate, among other information, the manufacturer must report cost information for manufacturing, distribution, research and

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development, marketing and advertising, prices, and rebates offered to purchasers.

- In May 2017, Maryland targeted "price gouging" in the sale of an "essential or off-patent generic drug." "Price gouging," defined as an "unconscionable increase," involves a drug whose WAC increased 50 percent or more in a year or a drug price increase that resulted in Maryland's Medicaid program experiencing a 50 percent or more increase in the amount it paid within the prior year. For such drugs, the Maryland Attorney General could require a manufacturer to submit information justifying the price increase.
- In June 2017, Louisiana passed legislation requiring drug manufacturers to provide quarterly reports of its current WAC prices.
- In June 2017, Nevada began requiring drug manufacturers to disclose pricing data for drugs "essential for treating diabetes." The Nevada law provides for different disclosure requirements depending on whether a drug's WAC increased in an amount equal to or greater than the Consumer Price Index ("CPI") during the prior calendar year (List ♯1) or equal to twice or more than CPI during the preceding two years (List ♯2).
    - For List ♯1 drugs, a manufacturer is required to report production costs; administrative costs (including marketing and advertising); profit earned; amount of financial assistance provided through any patient assistance program; cost associated with direct-to-consumer coupons and copayment assistance programs, including the cost to the manufacturer attributable to those programs; the current WAC and WAC increases over the preceding five years, including an explanation for the increase; and pharmacy benefit manager rebates for sales of the drug in Nevada.
    - For drugs on List ♯2, a manufacturer must report the above List ♯1 information plus each factor that contributed to the WAC increase, the percentage of increase attributable to each factor, and the role played by each factor in the WAC increase.
    - Further, all drug manufacturers are required to disclose the sales representatives who market the manufacturer's drugs (not limited to diabetes drugs) in Nevada. The sales representatives are required to provide a list of Nevada customers to whom they provided any type of compensation exceeding $10 per individual or $100 in aggregate. The sales representatives are also required to report the names of Nevada customers provided a free drug

sample.

- The information reported by manufacturers will be publicly available on the Internet.

- In October 2017, California enacted a drug price transparency law that requires manufacturers to notify the state and certain purchasers if the price of a drug, with a wholesale cost greater than $40, increases by more than 16 percent over a two-year period. The disclosure obligation applies to manufacturers whose drugs are purchased or reimbursed by any health insurer licensed in California and pharmacy benefit managers. The law requires drug manufacturers to:
  - Provide purchasers with 60-days advance written notice of an increase meeting the above requirements and explain the rationale for the increase—e.g., change or improvement in the drug;
  - Report price increases, in general, to the California Office of Statewide Health Planning as well as price increases meeting the requirements above. For price increases during the previous two years that meet the requirements above, manufacturers will need to provide, among other information, financial and nonfinancial factors relied on to increase the drug price, the drug's sales volume in the United States for the previous year, and, if applicable, a description of the change or improvement in the drug that necessitated the price increase. The information reported by manufacturers will be publicly available on the Internet; and
  - For newly introduced drugs with a wholesale cost exceeding the Medicare Part D program's specialty drug threshold, within three days after the release of the drug in the commercial market, manufacturers must notify the state. Within 30 days of that notice, a manufacturer must provide the state with a description of the marketing and pricing plans used in the launch of the new drug (domestic and international), the estimated number of patients that may be prescribed the drug, and whether the drug was granted a breakthrough therapy designation or priority review by the FDA prior to final approval.

PENDING LEGISLATION

In addition to states that enacted drug price reporting laws during 2017, legislation was introduced in numerous other states seeking to require drug manufacturers to publicly disclose price increase justifications. Illinois had two bills stalled in committees that would require drug manufacturers to disclose (1)

price increases, 30 days in advance, to certain purchasers and (2) the cost of certain newly approved drugs three days before commercial availability. Maine proposed legislation that would require drug manufacturers to justify price increases for drugs that cost $2,500 or more and rose in price 50 percent or more over the previous five years, or by 15 percent or more over the previous 12 months. Manufacturers would also be required to report drug prices charged purchasers, including other countries. Similar legislative proposals were introduced in Massachusetts, New York, Rhode Island, and Washington. Montana and Pennsylvania proposed to establish drug pricing task forces to study prescription drug prices.

While the pharmaceutical industry lobby has been able to delay many of the proposed drug pricing disclosure and transparency legislative initiatives, it appears that it is only a matter of time until many states follow California's and Nevada's lead and enact some sort of drug pricing transparency obligations. Already in 2018, Massachusetts, Pennsylvania, and Vermont have legislation pending concerning the transparency of drug pricing. At some point, drug manufacturers need to determine whether it is better to comply with a multitude of state drug pricing disclosure obligations or seek a uniform and consistent disclosure requirement through federal legislation.

WHAT SHOULD DRUG MANUFACTURERS DO NOW?

In the meantime, drug manufacturers need to alert and/or establish certain functions to make sure they are complying with current state laws and are prepared in the event other states enact disclosure obligations. These functions include the following:

- Price Setting/Changing Committees—these committees need to be educated in terms of the reporting disclosure triggers, i.e., percentage increases and applicable time periods.
- Compliance Department—this department needs to maintain a list of the states currently requiring price reporting and the deadlines for such reporting. It should also be aware of pending legislation that may trigger reporting obligations.
- Communications Department—because states intend to make the information your company reports regarding price increases (as well as profit and R&D spending) public, this department needs to be kept in the loop so that it is prepared for media inquiries.