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What's Happening with Drug Manufacturer Pricing Disclosure Law?

By Merle M. DeLancey Jr.*

After identifying recent federal efforts that would require drug pricing transparency, this article discusses two state laws enacted recently. Thereafter, the article assesses previously enacted state laws requiring drug manufacturers to disclose pricing and other information to determine whether these reporting requirements have had any effect on drug pricing in the applicable state.

While the introduction of state legislation that would require drug manufacturers to disclose pricing and other information did not slow down in 2018, the number of bills that were made law did slow down. During 2018, 22 state legislatures considered bills seeking to require drug manufacturers to disclose pricing information; however, most of the legislation failed.

There are numerous reasons why state efforts to require drug manufacturers to disclose pricing and other information have slowed and/or failed. As discussed below, some states that enacted so-called "transparency" laws have found that confidentiality and trade secret protections result in such diluted information being disclosed that the pricing information available is of no use. Many states chose to focus transparency and disclosure requirements on other entities in the drug supply chain, *e.g.*, pharmacy benefit managers ("PBMs"), managed care organizations ("MCOs"), and health plans. Perhaps states are realizing that obtaining manufacturers' wholesale acquisition costs ("WACs") or list prices serves no useful purpose because patients do not pay WAC prices and the public reporting of WAC prices, thus far, has done nothing or very little to keep manufacturers from raising prices.

After identifying recent federal efforts that would require drug pricing transparency, this article discusses the two state laws enacted in the latter half of 2018. Thereafter, the article assesses previously enacted state laws requiring drug manufacturers to disclose pricing and other information to determine whether these reporting requirements have had any effect on drug pricing in the applicable state.

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OVERVIEW OF RECENT FEDERAL EFFORTS

More recently, appearances suggest the federal government, and not states, has attempted to take back the reins and implement drug manufacturer pricing disclosure requirements. In May 2018, the administration released its "blueprint" to reduce drug prices. But in the end, there have been few tangible achievements.

The Department of Health and Human Services has requested comments on several proposed regulations to reduce and/or make publicly available drug prices. The proposed regulations include adopting an international reference pricing system for Medicare Part B drugs, a requirement that drug manufacturers include WAC prices in their television advertising, and allowing manufacturers to offer discounts directly to consumers but not MCOs or PBMs. The likelihood that any of these measures will become law is very slim.

During 2018, the one measure passed by the U.S. Congress and in numerous states was the prohibition on pharmacy gag rules. These laws bar health plans or middlemen that manage pharmacy benefits from getting in between pharmacists and their customers. No longer can pharmacists be contractually prohibited from telling consumers when they would save money by not using their insurance plans.

STATE LAWS

Two states—Vermont and New Hampshire—passed laws that arguably touch on requiring pharmaceutical manufacturers to report drug prices.[1]

Vermont

On May 30, 2018, Vermont, one of the few states that previously passed legislation requiring drug manufacturer pricing disclosures, expanded its reporting requirements. Specifically, Vermont Act No. 93 ("S. Bill 92"), expanded Vermont's transparency law by requiring the Department of Vermont Health Access and health insurers with more than 5,000 covered lives to create lists of 10 prescription drugs for which the payer's net cost has increased by 50 percent or more over the past five years or more than 15 percent annually. From those lists, the attorney general ("AG") will identify 15 drugs for which the

[1] On January 7, 2019, California Governor Gavin Newsom signed an Executive Order to "create the nation's biggest single purchaser system for drugs. . . . " While the Executive Order does not mandate manufacturer pricing disclosures, it requires the creation of "a list of prescription drugs that could appropriately be prioritized for future bulk purchasing initiatives or reexamined for potential renegotiation with the manufacturer." Among other things, the drug list will be based on "the price of the drug and the extent to which the drug is subject to competition, such as a sole-source drug without a generic or alternative option."

drugs' manufacturers must provide a justification for the price increases which will be made public. Previously, manufacturer reports were not publicly disclosed. Under the new law, a public version of such reports will be posted online. In the public versions, manufacturers can request to redact proprietary or confidential information, subject to the AG's approval.

Further, the new law requires a drug manufacturer to notify the AG if it intends to introduce a new drug with a WAC that exceeds the $670 threshold set for specialty drugs under Medicare Part D. The notification must be provided three days prior to commercial release of the drug. Thereafter, within 30 days of the three-day notification, the manufacturer must provide additional information to the AG including a description of marketing and pricing plans and, if the drug was acquired from another company, the acquisition date and price of the drug. The AG will make information available on its website, but do so in a manner that does not allow identification of the drug. The law also creates a working group to study drug pricing throughout the supply chain to identify opportunities for savings and for increasing price transparency.

New Hampshire

On July 2, 2018, New Hampshire enacted House Bill 1418, which established a commission to study greater transparency in pharmaceutical costs and drug rebate programs. HB 1418 did nothing more than establish a commission to study drug costs. As required by the law, on November 1, 2018, the Commission to Study Greater Transparency in Pharmaceutical Costs and Drug Rebate Programs submitted its Report. Unsurprisingly, the Commission was unable to complete its work in the less than four months it was allotted. The Commission noted that, among other work, it reviewed the pharmaceutical transparency laws enacted by other states, but, because such laws are relatively new, the Commission stated, "it is too early to tell if these laws will have an effect on transparency or lower costs."

In the end, among other recommendations, the Commission suggested the Legislature consider "[l]egislation similar to other states that requires transparency and disclosure on the part of pharmaceutical manufacturers when increasing wholesale drug costs on drugs already in distribution and publish all disclosure information on the state's website." The Commission also suggested "[l]egislation relating to a manufacturer's introduction of new high-cost prescription drugs." Finally, the Commission recommended legislation that allows consumers to report price gouging, in tandem price raising, or the introduction of new high-cost drugs and enables the AG or the Commission to request certain information from, among others in the pharmaceutical supply chain, drug manufacturers so that an investigation could be conducted.

STATUS OF STATE REQUIREMENTS FOR MANUFACTURER PRICING DISCLOSURES

Given that in 2018 fewer states passed laws requiring manufacturers to disclose prices, we decided to review the status and progress of such state laws previously enacted. Since 2016, 11 states have passed laws requiring drug manufacturers to disclose pricing and/or other pricing-related information. Set forth below is an update on these state disclosure laws:

New York

New York's law requires a manufacturer to disclose certain cost and price information if its drug had high Medicaid utilization *and* the manufacturer refused New York Medicaid's request to provide an additional rebate. To date, New York Medicaid requested and received additional rebates on 30 high-utilization drugs. With one exception, all the companies that were requested to provide an additional rebate agreed. Only one drug manufacturer refused and, to date, it does not appear that New York has requested that the company report cost or pricing information.

Maryland

In April 2018, the U.S. Court of Appeals for the Fourth Circuit struck down Maryland's anti-price gouging law; thus, no manufacturers have been required to report pricing. The U.S. Supreme Court declined to review the Fourth Circuit's decision. As a result, the Fourth Circuit's decision finding the Maryland law unconstitutional stands.

Louisiana

Louisiana requires drug manufacturers to report current WACs to the state's Board of Pharmacy on a quarterly basis. The state is in the process of developing a web portal for such reporting, but in the meantime, manufacturers are to email reports to the Pharmacy Board. Although the Louisiana law requires the Pharmacy Board to make manufacturer reported WACs publicly available, it is unclear when this will happen. The Board's Pharmaceutical Cost Transparency webpage has not been updated since September 2017. At a November 2018 meeting, the Board was considering an agreement with a private contractor for the development of a website.

Oregon

Under Oregon's Prescription Drug Price Transparency Program, by July 1, 2019, manufacturers are required to report detailed information for a drug with a WAC of $100 or more for a one-month supply or for a course of treatment lasting less than one month *and* the drug's WAC increased 10 percent or more during the prior year. In late December 2018, the Oregon Department of

Consumer and Business Services ("DCBS") proposed regulations detailing the information manufacturers are required disclose and the procedures to be followed if a manufacturer claims trade secret status for the applicable information to prevent its public disclosure.

With respect to drugs meeting the criteria above, the proposed regulations would require reports include 17 data elements including the factors that contributed to the price increase, the research and development costs associated with the prescription drug that were paid using public funds, the total sales revenue for and manufacturer's net profit attributable to the prescription drug during the previous calendar year, and the 10 highest prices paid for the prescription drug during the previous calendar year in any country other than the United States.

For newly introduced specialty drugs, the proposed regulations would require a manufacture's report to include a description of the marketing used in introducing the new drug, spending on direct-to-consumer marketing, spending to promote the drug to physicians, the methodology used to establish the price of the new drug, a narrative description and explanation of all major financial and nonfinancial factors that influenced the decision to set the price of the drug at the level it was first set by the reporting manufacturer following its approval for marketing by the U.S. Food and Drug Administration ("FDA"), and the research and development costs associated with the new drug that were paid using public funds.

In addition, if applicable, manufacturers are required to report detailed information regarding any patient assistance programs offered to consumers residing in Oregon.

The proposed regulations require DCBS to make drug manufacturer filings available to the public on its website, but prohibits DCBS from disclosing specific trade secret information. Information conditionally exempt from disclosure as a trade secret may not be disclosed, provided that the public interest does not require disclosure of the information. To claim a trade secret exemption from public disclosure, a manufacturer must clearly mark each line and information element and explain, like a federal reverse-Freedom of Information Act request, among other things, that public disclosure would cause competitive harm to the manufacturer. The proposed regulations then set forth a review and/or appeal process for the manufacturer, DCBS, and ultimately the AG to follow.

The deadline for filing comments on the proposed regulations closed on February 1, 2019.

Connecticut

Connecticut's drug transparency law requires the state Office of Health Strategy to prepare a list of drugs on or before March 1, 2020. The List will include drugs identified as requiring pricing disclosure information (WAC less rebates increased at least 20 percent during the prior year or increased 50 percent during the prior three years, *and* the WAC is greater than $60 for a 30-day supply or course of treatment lasting less than 30 days). For such drugs, manufacturers will be required to submit information consistent with its SEC filings or other public disclosures.

Maine

Maine's law, passed in May 2018, requires the Maine Health Data Organization to develop a plan for collecting drug cost and pricing data from manufacturers and submit the plan, findings, and recommendations for proposed legislation to the Maine Legislature on or before April 1, 2019.

STATES RECEIVING MANUFACTURE PRICE REPORTS

Of the 11 state laws, Vermont, California, and Nevada have received price disclosures from manufacturers and made certain information available to the public and/or applicable state legislatures.

Vermont

In 2016, Vermont passed the first drug transparency law requiring manufacturers to disclose pricing information. Under the law, the state was to identify up to 15 drugs annually for which the WAC increased 50 percent or more over the previous five years or 15 percent or more over the previous year *and* on which the state spends significant money through programs such as Medicaid. Manufacturers of such drugs were required to submit to the Vermont AG, among other information, a justification for the price increases. The AG then creates and submits a report to the legislature. However, the law included broad confidentiality protection for the information submitted by the drug manufacturers. Specifically, the law provides that officials cannot release the company information "in a manner that allows for the identification of an individual drug or manufacturer or that is likely to compromise the financial, competitive, or proprietary nature of the information."

On December 1, 2016, the AG submitted his first report to the legislature, but the report failed to include details about specific drug costs or specific pharmaceutical companies. As a result, the report was of little value. While the drug companies whose drugs met the above criteria submitted information to the AG, because of confidentiality rules included in the law, only the AG's office could review the manufacturers' reports. As a result, legislators were provided a

general summary of the information prepared by the AG. Manufacturers were asked to submit all factors that contributed to price increases, and percentages attributable to each factor, but none of their answers appeared in the report given the legislature. Rather, the report merely summarizes some of the reasons given, such as the industry's need to invest in research and manufacturing.

As a result, in May 2018, Vermont passed the revised manufacturer disclosure law discussed above.

California

In October 2017, California enacted SB 17 which, among other requirements, contained three reporting requirements for drug manufacturers:

(i) Provide certain "registered" purchasers 60 days advance notice of an increase in the WAC of certain drugs when that increase is greater than 16 percent for the previous three years;[2]

(ii) Submit to the California Office of Statewide Health Planning and Development ("OSHPD") the rationale for cost increases for existing drugs that fall under the reporting requirement; and

(iii) Notify OSHPD within three days of introducing a new drug at a WAC that exceeds the Medicare Part D threshold (currently $670) for specialty drugs.

A manufacturer's price increase rationale report is to include the factors that led the company to increase the price, the history of the price increases, the drug's patent expiration date, and any changes to the drug that might justify the price increases. If the drug was acquired from another company, the manufacturer must report the acquisition price. Manufacturers' disclosure obligations began January 1, 2019. Beginning April 2019, after time to collect and review the information, OSHPD will publish manufacturer reported information on its website. For example, OSHPD intends to publish drug cost increase information for existing drugs reported by manufacturers during the first quarter of 2019 on its website by June 2019.

Also beginning January 1, 2019, manufacturers must notify OSHPD within three days of introducing a new drug that has a WAC that exceeds the Medicare Part D threshold (currently $670) for specialty drugs. Within 30 days of this notification, manufacturers must submit additional information such as drug launch marketing and pricing plans, number of patients in the United States

[2] The price increase advance notice requirement has been criticized because it allows competitors to increase prices and allows wholesalers and distributers to purchase drugs, hold them in inventory, and then sell them later after the price increase.

with a condition for which the new drug may be prescribed, whether the drug was granted breakthrough therapy designation or priority review by the FDA, and, if the drug was acquired from another company, the acquisition date and price. OSHPD intends to make this information publicly available on its website on a quarterly basis.

Notwithstanding the requirements of the law passed by the legislature, at the end of November 2018, OSHPD implemented regulations gutting much of the intended effect of SB 17's drug reporting transparency goals. Specifically, OSHPD limited manufacturers' reporting obligations to information "which is otherwise in the public domain or publicly available." Thus, all the information regarding the rationale for cost/price increase for existing drugs is limited to information already publicly available. The same is true with respect to the additional information manufacturers are required to report with respect to new drugs.

Nevada

In June 2017, Nevada Senate Bill 539 required manufacturers to report pricing data for drugs "essential for treating diabetes." The law provides different disclosure requirements depending on whether a drug's WAC increased by an amount equal to or greater than inflation during the prior calendar year or equal to twice or more than inflation during the preceding two years. Manufacturer reports to the Nevada Department of Health and Human Services ("DHHS") were to include, but not limited to, the cost of producing the drug, administrative expenses (including marketing and advertising) relating to the drug, profit earned from the drug, each factor that contributed to the increase, the percentage of total increases attributable to each factor, an explanation of the role of each factor in the increase, and any other information prescribed by DHHS in regulation. Manufacturers' first reports were due April 1, 2018.

However, pharmaceutical manufacturers, and other providers, filed lawsuits challenging Nevada's right to obtain trade secret information and the ability of the state to protect such information. While the litigation was pending, no manufacturers filed the required reports. On May 31, 2018, DHHS adopted regulations regarding how it would support the submission of manufacturers' reports and how confidentiality of such information would be protected. The regulations explained how manufacturers could claim trade secret protection for information they submit and the procedures DHHS would follow based on such requests. Significantly, with respect to the report and information DHHS will make publicly available, the regulations state that only aggregated data that does not disclose the identity of any drug or manufacturer will be publicly reported.

Thereafter, on June 7, 2018, DHHS provided notice that it would not proceed with enforcement action for reports made during the first six months. DHHS stated that it expected all entities "will work in good faith during the six-month period, but wants to ensure manufacturers . . . have ample opportunity to come into compliance with the statutes and regulations by January 15, 2019, before any enforcement action will be taken."

In September 2018, DHHS issued two reports: Essential Diabetes Drugs Price Increase Report and Analysis of Essential Diabetes Drugs that had a Price Increase. The state's reports determined price increases based upon WAC data presumably obtained from one of the national price reporting compendia. For the September 2018 reports, the state did not yet have the benefit of any manufacturer reporting. The state identified 175 national drug codes ("NDCs") that had prices increase by more than the rate of medical inflation. Manufacturers of the 175 NDCs were required to report the specific data identified above for each NDC.

By the January 15, 2019, deadline, more than 30 diabetes drug manufacturers timely submitted reports to DHHS. More than 20 additional manufacturers failed to submit reports. DHHS stated it is reviewing the manufacturer reports and intends to issue a supplemental analysis with aggregated data to protect the identity of any specific manufacturer. In addition, on February 1, 2019, DHHS posted its 2019 Essential Diabetes Drug List. Manufacturers of drugs on that list were required to report the detailed information outlined above by April 1, 2019.

Thus, it appears Nevada is the state furthest along in terms of receiving manufacturer price disclosure reports. Some believe Nevada's success is based upon its more surgical approach of focusing on diabetes drugs, as opposed to all drugs. However, it remains to be seen what aggregated manufacturer information DHHS includes in its upcoming report and whether there will be any litigation with drug manufacturers regarding the claimed release of trade secrets. Finally, the most important unknown is what the state will do with this data. Can this additional pricing information transparency be used to lower prices paid by the state or consumers?

DRUG MANUFACTURERS' PRICING DISCLOSURES IN 2019

To date, except possibly for Nevada, states have made little progress toward their goal of drug pricing transparency for purposes of lowering drug costs for state programs and consumers. One would hope states considering such legislation in the future heed some of the "lessons learned" by other states. For example, a state needs to assess whether there truly are benefits in obtaining prices and related information when the use of such information is limited by the protection of manufacturers' trade secrets. Further, regardless of the

information a state collects, a state needs to determine if that information can be used to lower state healthcare program costs and/or the prices paid by consumers. A good example is requesting that manufacturers report WACs. WACs are list prices and have no relationship to what consumers pay and have fallen out of favor for Medicaid reimbursement purposes.

Arguably, state laws mandating manufacturer price disclosures are in their infancy, but at some point, states need to decide whether the complex and inconsistent reporting requirements are resulting in lower prices or simply adding another layer of burdensome compliance costs for manufacturers. Manufacturers should be asking similar questions and whether they should advocate for a uniform price reporting system.