THE
NATIONAL LAW REVIEW

California Law Aims to Scrutinize Drug Pricing

Tuesday, December 5, 2017

Over the last few weeks, much attention has been paid to California's recently enacted SB 17, legislation that requires pharmaceutical manufacturers to report certain price increases of prescription drugs and, in some cases, provide a justification for such increases. The legislation also requires health insurers and health plans to report additional rate information to state agencies. California's push to impose disclosure of prescription drug pricing information is part of a growing trend of proposed and enacted legislation across the country purportedly aimed at increased price transparency and control.

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Summary of the California Drug Pricing Transparency Statute

The California Legislature's stated purpose of SB 17 is to provide accountability to the State for prescription drug pricing. The statute includes reporting requirements that apply to pharmaceutical manufacturers, as well as separate requirements that apply to health insurers and health care service plans.

Reporting Requirements for Pharmaceutical Manufacturers

California's manufacturer reporting requirements apply when three criteria are met. First, the requirements apply broadly to any "manufacturer" of a prescription drug that is purchased or reimbursed by (1) a licensed health care service plan, (2) a health insurer, (3) a pharmacy benefit manager, or (4) a state purchaser in California (*e.g.*, the Public Employees' Retirement System). Second, the prescription drug must have a wholesale acquisition cost ("WAC") of more than $40 for a "course of therapy." And third, the increase in the WAC of a prescription drug must be more than 16 percent, including the proposed increase *and* the cumulative increases that occurred within the previous two calendar years.

The new notice requirements for prescription drug manufacturers take effect on January 1, 2018, and although the State has provided an implementation plan, it has not provided details regarding how specific provisions phase in during early 2018. Under SB 17, when the three criteria discussed above are met, the manufacturer must provide written notice at least 60 days prior to the WAC increase to each state purchaser and any applicable health care service plan, health insurer, or pharmacy benefit manager that has registered with the state to receive such notice. In the notice, the manufacturer must include the date of the increase, the current WAC of the prescription drug and the dollar amount of the anticipated increase. Further, the notice must include "a statement regarding whether a change or improvement in the drug necessitates the price increase," and if so, a description of the change or improvement.

Additional requirements will become effective beginning in January 2019. At that time, or a later date set by California's Office of Statewide Health Planning and Development ("OSHPD"), prescription drug manufacturers will also have quarterly reporting requirements for each drug with a WAC increase that requires the notice described above. OSHPD's current implementation plan contemplates beginning to collect data in April 2019. Under this reporting requirement, manufacturers will be required to provide OSHPD: (1) a description of the financial and nonfinancial factors used to make the decision to increase the WAC and the amount of the increase; (2) a schedule of WAC increases for the drug for the previous five years if the drug was manufactured by the company; (3) if the drug was acquired by the manufacturer within the previous five years, a list of additional information, including the purchase price for acquiring the drug; (4) the patent expiration date of the drug if it is under patent;

(5) whether the drug is a multiple source drug, an innovator multiple source drug, a noninnovator multiple source drug, or a single source drug; (6) a description of the change or improvement in the drug, if any, that necessitates the price increase; and (7) the volume of sales of the manufacturer's drug in the United States for the previous year.

California will also impose additional reporting requirements when a manufacturer introduces a "new prescription drug" to market at a WAC that exceeds the threshold set for a "specialty drug" under the Medicare Part D program. Notably, SB 17 requires OSHPD to publish the information disclosed by manufacturers "on a per-drug basis," rather than in the aggregate, to "allow identification of the drug." Manufacturers may, however, limit information disclosed to that already in the public domain.

According to OSHPD's implementation plan, OSHPD will begin outreach to stakeholders in early 2018, will draft regulations in mid-2018, and the regulations will take effect in January 2019.

Reporting Requirements for Health Insurers and Health Plans

Preexisting California law has required health insurers and health care service plans to file certain rate information with the Department of Insurance ("DOI") or the Department of Managed Health Care ("DMHC"). For health insurers and health plans that already report rate information to either department, SB 17 requires additional information on an annual basis. Beginning on October 1, 2018, health insurers and health plans must report to DOI or DMHC the 25 most frequently prescribed drugs, the 25 most costly drugs, and the 25 drugs with the highest year-over-year increase in plan spending. This information will be compiled and published in a report for the public and legislators. California also will require the disclosure of more detailed rate information for health plans with "large group" health care service plan contracts, and for health insurers with "large group" health insurance policies. The statute shields from public disclosure the proprietary information submitted by health insurers and health plans (*e.g.*, prescription drug utilization and spending information).

Other Drug Pricing Transparency Statutes

Lawmakers at both the state and federal level have been active in pushing drug pricing transparency legislation. In fact, three other states have recently enacted such legislation.

- In **Vermont**, a first-of-its-kind bill (S. 216) enacted in 2016 requires a state board to identify annually up to 15 prescription drugs for which the WAC has increased by 50 percent or more over the past five years or by 15 percent or more over the past 12 months. This information is posted on the Board's website and the drug's manufacturer must provide a justification for the WAC increase to the state Attorney General.
- In **Nevada**, new legislation (SB 539) requires pharmaceutical manufacturers to file an annual report with the cost of "essential" diabetes drugs and, if applicable, the reasons for a substantial increase in the cost of a drug.
- For any FDA-approved drugs marketed in **Louisiana**, one enacted bill (HB 436) requires pharmaceutical manufacturers and marketers to report WAC information to the state Board of Pharmacy on a quarterly basis. A companion bill (SB 59) requires the Board to make WAC pricing available to prescribers on a website.

Additionally, proposed legislation aimed at increasing drug price transparency are pending in several other states, including Maine, Massachusetts, Oregon, and Washington.

At the federal level, the following four pending bills would include some form of drug pricing transparency:

- the Fair Accountability and Innovative Research Drug Pricing Act of 2017 (in committee in the House) would require "justification" reporting regarding drug price increases;
- the Stopping the Pharmaceutical Industry from Keeping Drugs Expensive Act of 2017 (in committee in the Senate) would require reporting regarding drug price increases;
- the Prescription Drug Price Transparency Act (in committee in the House) would require disclosure of payment methodologies to pharmacies; and
- the Creating Transparency to Have Drug Rebates Unlocked (C-THRU) Act of 2017 (in committee in the Senate) would require disclosure of rebates provided to drug manufacturers.

Implications for Pharmaceutical Industry

Although California's new drug pricing transparency statute does not prohibit price increases, the new law is likely to create compliance challenges for pharmaceutical manufacturers that must now ensure certain disclosures are made. Potentially more important, the statute will require the submission of justification and pricing information that would typically be considered proprietary to the drug manufacturer. Finally, once manufacturers provide notice, it remains unclear how entities, such as state purchasers, will use that information (unless, of course, the state or courts provide clear guidance on the subject), but information disclosed will likely form the basis of continued advocacy around the pricing of pharmaceuticals.

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