

October 16, 2017

## California Enacts Bill on Drug Pricing Transparency

On October 9, 2017, California Governor Jerry Brown (D) signed into law what may be the most comprehensive prescription drug pricing transparency bill in the country. The bill, [SB-17](#), is intended to foster transparency in connection with drug pricing and its impact on insurance costs, with an eye towards improving competitive pricing and reducing health care spending. The law imposes new reporting requirements on drug manufacturers, pharmacy benefit managers, health care service plans and health insurers operating in California, and mandates state agencies to report to the public about drug price increases and their effects on health care premiums.

California is one of several states to have recently enacted drug pricing laws in response to growing debate over prescription drug costs. For example, [Vermont](#) recently passed a law requiring drug manufacturers to justify their price increases. A new law in [New York](#) caps Medicaid prescription drug spending. [Nevada](#) has passed a new pricing transparency law focused on insulin for diabetes patients. The [Maryland](#) attorney general, meanwhile, is now authorized to take action against certain increases in generic drug prices. And drug pricing legislation is currently pending in many other states. For their part, federal lawmakers have also investigated drug pricing and introduced several related bills on the subject, but thus far there has been no major federal legislative action.

### Requirements to notify purchasers of drug price increases

The new California law requires a drug manufacturer to provide 60 days' notice to certain purchasers of any planned increase in a drug's wholesale acquisition cost ("WAC") of 16 percent or more over a two-year period, if the drug has a WAC of over \$40. The purchasers to be notified pursuant to this requirement include state agencies, health care service plans, health insurers and pharmacy benefit managers. The notice must include the date and amount of the increase, and a statement as to whether the price increase is necessitated by a change or improvement in the drug.

A pharmacy benefit manager that receives such a notice from a manufacturer must, in turn, notify large contracting purchasers with coverage of 500 or more persons.

### Requirement to report price increase information to OSHPD

Beginning January 1, 2019, for each drug price increase that meets the criteria set forth above, a drug manufacturer must also provide the following information to the Office of Statewide Health Planning and Development ("OSHPD") on a quarterly basis:

1. a description of the specific financial and non-financial factors used to make the decision to increase the WAC of the drug and the decision as to the amount of the increase;
2. if the drug has been manufactured by the company for at least five years, a schedule of WAC increases for the drug for the previous five years;
3. if the drug was acquired by the manufacturer within the previous five years, the WAC at the time of acquisition, the WAC in the year prior to acquisition, the name of the company from which the drug was acquired, the acquisition date, the acquisition purchase price, the year the drug was introduced to market, and its WAC at that time;

4. the patent expiration date, if applicable;
5. whether the drug is classified as a single source, multiple source, innovator multiple source or non-innovator multiple source drug under [42 U.S.C. § 1396r-8\(k\)\(7\)\(A\)](#);
6. a description of the change or improvement in the drug, if any, that necessitates the price increase; and
7. the volume of U.S. sales of the drug for the previous year.

Further requirements apply to certain specialty drugs. A drug manufacturer must notify OSHPD three days after FDA approval of a new prescription drug to market at a WAC that exceeds the [Medicare Part D specialty drug threshold](#) (currently \$670). Within 30 days of that initial notification, the manufacturer must also provide to OSHPD the following:

1. a description of the marketing and pricing plans used in the launch of the new drug;
2. the estimated volume of patients that may be prescribed the drug;
3. whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval; and
4. the date and price of acquisition, if the drug was not developed by the manufacturer.

A manufacturer may limit the information that it reports to OSHPD regarding price increases and specialty drug prices to that which is publicly available. OSHPD will publish the reported information on its website, identifying the drug to which it applies.

A manufacturer that fails to comply with these reporting requirements could face a civil penalty of \$1000 per day for every day after the reporting period for which the information is not reported. Any such penalty received by OSHPD will be paid into the state's [Managed Care Fund](#).

### Reporting requirements for health care service plans and health insurers

Although the enhanced reporting requirements set forth in the new bill generally apply to drug manufacturers, some of them also apply to certain health care plans and insurers. Under current state law, health care service plans and health insurers that operate in California and are regulated by the California Department of Managed Health Care ("DMHC") and the California Department of Insurance ("CDI") are required to report to those agencies certain rate information related to their health plan contracts and health insurance policies. Under the new law, beginning October 1, 2018, each such plan and insurer will also be required to report to DMHC and CDI, in connection with these rate information reports, the following drug pricing information:

1. the plan or insurer's 25 most frequently prescribed drugs;
2. the plan or insurer's 25 most costly drugs by total annual plan spending; and
3. the 25 drugs with the highest year-over-year increases in the plan or insurer's total annual plan spending.

Beginning January 1, 2019, DMHC and CDI will compile this information into a public report that demonstrates the overall impact of drug costs on health care premiums. The data available in the report will be aggregated and will not reveal information specific to health care plans and insurers, unlike the information contained in the OSHPD report

discussed above. Moreover, beyond publishing the aggregated information in the report, DMHC and CDI will otherwise keep confidential the information that is reported to them.

In addition, beginning October 1, 2018, health care plans with large group health care service plans contracts will have to report annually certain information regarding the impact of drug prices on patient premiums. This information will be used as part of the large group rate review process rather than in connection with DMHC's and CDI's reports.