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California SB 17: New Requirements for Drug Manufacturers

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California Life Sciences

On Monday, October 9, 2017, California Governor Jerry Brown signed into law Senate Bill 17 (SB 17), establishing substantial new reporting and notification requirements in California for prescription drug manufacturers related to drug pricing. California is the latest of several states to enact legislation related to drug pricing.[1] This alert summarizes the key provisions of the new California law that are most relevant to pharmaceutical companies.[2]

Notification of Price Increases: Once fully effective, the new law will require manufacturers of prescription drugs to provide advance notice of certain increases in the drugs' wholesale acquisition cost (WAC). Specifically, SB 17 states that drugs with a WAC of more than $40 for a course of therapy (typically a 30-day supply, unless a shorter course of treatment is approved by FDA) must notify certain purchasers 60 days in advance of increasing the drug's WAC if the cumulative increase is more than 16% over a period of time specified in the law.[3] The notice must include:

- the date of the increase,
- the current WAC of the drug,
- the dollar amount of the increase, and
- a statement regarding whether a change or improvement in the drug necessitates the price increase (and if so, a description of such change or improvement).[4]

For each drug with a WAC increase subject to the notification requirement above, a manufacturer also must submit a report to California's Office of Statewide Health Planning and Development (OSHPD) that includes, among other things, a description of the "specific financial and nonfinancial factors used to make the decision to increase the [WAC] of the drug and the amount of the increase, including, but not limited to, an explanation of how these factors explain the increase in the" drug's WAC.[5] A manufacturer is not obligated to include any non-public

[1] *See, e.g.*, S. 216 (Vt. 2016), 2016 Vermont Laws No. 165; H.B. 631 (Md. 2017), 2017 Maryland Laws Ch. 818; S.B. 539, 79th Sess. (Nev. 2017).
[2] The provisions of the law most relevant to pharmaceutical companies are found primarily in section 4 of SB 17 (which adds chapter 9 to Part 2 of Division 107 of the Health and Safety Code).
[3] S.B. 17, 2017-2018 Reg. Sess. (Cal. 2017), at Section 4 (adding Health and Safety Code sections 127677(a) and 127675(a)).
[4] *Id.* (adding Health and Safety Code section 127677).
[5] *Id.* (adding Health and Safety Code section 127679).

information in its report to OSHPD. Reporting to OSHPD under this provision will be required on a quarterly basis.[6]

Reporting around Market Launch: SB 17 also requires manufacturers to notify OSHPD within three days after releasing a new prescription drug into the commercial market if the WAC exceeds the threshold set for a specialty drug under the Medicare Part D Program.[7] Additional information must be reported to OSHPD within 30 days of the notice, including a description of launch marketing and pricing plans, as well as the estimated volume of patients; whether the drug was granted breakthrough therapy designation or priority review by the FDA; and the date and price of acquisition if the drug was not developed by the manufacturer.[8] As with the price increase notifications to OSPHD, a manufacturer may limit its reporting to information that is in the public domain or publicly available.

A manufacturer's failure to report the required information to OSHPD may result in civil penalties.[9] OSHPD is required to publish the collected information on the Internet on a quarterly basis in a manner that allows for the identification of the relevant drug.[10]

Although there are nuances that merit consideration, certain provisions of the law will be effective on January 1, 2018,[11] while others have a delayed effective date until January 1, 2019. In addition to the obligations on drug manufacturers, the new law also requires, among other items, certain health care entities to provide information annually, which will be compiled by the State "into a report for the public and legislators that demonstrates the overall impact of drug costs on health care premiums."[12]

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food, Drugs, and Devices and Health Care practices:

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[6] *Id.*
[7] *Id.* (adding Health and Safety Code section 127681).
[8] *Id.*
[9] *Id.*
[10] *Id.*
[11] *See* Cal. Const. art. 4, § 8(c)(1).
[12] S.B. 17, Section 1 (adding Health and Safety Code section 1367.243).