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Oregon HB 4005: New Reporting Requirements for Drug Manufacturers, Health Insurers

March 15, 2018

Food, Drugs, and Devices

On Tuesday, March 13, 2018, Oregon Governor Kate Brown signed into law House Bill 4005 (HB 4005), which imposes substantial new state reporting requirements on pharmaceutical manufacturers regarding drug pricing, including details on manufacturer-sponsored patient assistance programs. HB 4005 also imposes new reporting requirements on health insurers and establishes a temporary task force charged with developing "a strategy to create transparency for drug prices across the entire supply chain of pharmaceutical products."[1]

HB 4005 is the latest of several state-level drug pricing transparency laws aimed at containing the cost of prescription drugs,[2] and is similar to recent California legislation described here that is the subject of a legal challenge. Unlike the California legislation, HB 4005 appears to require manufacturers to disclose confidential and competitively sensitive information. Thus, HB 4005 could be viewed as the next step in state drug-pricing legislation, justified by some stakeholders on the ground that forcing disclosure of such information will give states—which are often among the largest purchasers of prescription drugs—additional leverage in their negotiation of drug purchases.

This alert summarizes key aspects of HB 4005. Many of the reporting provisions in the new law are ambiguous, meaning full compliance may be difficult without further guidance from the State.

Annual Reporting Requirements: HB 4005 requires manufacturers to make an annual report to Oregon's Department of Consumer and Business Services (DCBS) for any drug with a wholesale acquisition cost (WAC) of $100 or more for a one-month supply or course of treatment lasting less than one month that had a WAC increase of 10% or more during the previous calendar year.[3] The first report must be submitted no later than July 1, 2019;

[1] HB 4005 2018 Reg. Sess. (Ore. 2018), at Section 11.
[2] *See, e.g.*, S.B. 17 (Cal. 2017), 2017 California Laws Ch. 603; S.B. 539, 79th Sess. (Nev. 2017); H.B. 631 (Md. 2017), 2017 Maryland Laws Ch. 818; S. 216 (Vt. 2016), 2016 Vermont Laws No. 165.
[3] HB 4005 2018 Reg. Sess. (Ore. 2018), at Section 2.

subsequent reports must be submitted no later than March 15 annually thereafter.[4] Among other information that must be submitted as part of the annual report, manufacturers must include:

- the factors that contributed to the price increase;
- the direct costs incurred by the manufacturer to manufacture, distribute, and market the drug, and for ongoing safety and effectiveness research associated with the drug;
- the total sales revenue for the drug during the previous calendar year;
- the 10 highest prices paid for the drug during the previous calendar year in any country other than the United States; and
- documentation necessary to support the information provided in the report.[5]

For each of the prescription drugs identified in the annual report, manufacturers must also submit information about associated patient assistance programs offered by the manufacturer to Oregon consumers.[6] Required information includes:

- the number of consumers who participated in the program;
- the total value of coupons, discounts, and copayment assistance or other reduction in costs provided to program participants in Oregon;
- the number of refills that qualify for the program (for each drug, as applicable);
- the period of time that the program is available to each consumer (if the program expires after a specified period of time); and
- eligibility criteria for the program and how eligibility is verified.

Other Reporting Requirements: Effective March 15, 2019, HB 4005 requires that within 30 days of introducing a new prescription drug for sale in the U.S. with a WAC that exceeds the Medicare Part D threshold for specialty drugs (currently $670 per month), a manufacturer must report to DCBS (among other information):

- a description of the marketing used in the introduction of the drug;
- the methodology used to establish the price of the drug;
- whether FDA granted the drug breakthrough therapy designation or priority review; and
- if the drug was not developed by the manufacturer, the date and price paid for acquisition of the drug.[7]

HB 4005 authorizes DCBS to issue a written request to manufacturers for supporting documentation or additional information concerning the annual report or price increase report.[8] The new law does not limit the information required to be submitted in an annual report or a price increase report to information that is in the public domain or otherwise publicly available. Information submitted to DCBS under HB 4005's reporting requirements will be made available

[4] *Id.*; *id.*, Section 7.
[5] *Id.*, Section 2.
[6] *Id.*
[7] *Id.*
[8] *Id.*

on DCBS's website; trade secret information is exempt from disclosure on DCBS's website.[9] Failure to report the required information to DCBS—that is, (1) failure to submit timely reports or notices, (2) failure to provide the required information, (3) failure to timely respond to a written request for information from DCBS, or (4) provision of inaccurate or incomplete information—could result in civil penalties of up to $10,000 per day of violation.[10] The new law also authorizes DCBS to adopt rules that establish fees to be paid by manufacturers that will cover DCBS's implementation and enforcement costs associated with HB 4005.[11]

Health insurers also are subject to heightened reporting requirements under the new law. HB 4005 requires insurers to disclose the following information about drugs reimbursed by the insurer under state policies or certificates:

- the 25 most frequently prescribed drugs;
- the 25 most costly drugs as a portion of total annual spending;
- the 25 drugs that have caused the greatest increase in total plan spending from one year to the next; and
- the impact of the costs of prescription drugs on premium rates.[12]

HB 4005 requires DCBS to conduct an annual public hearing on prescription drug prices, information reported via the annual drug pricing reports, and information reported via the insurer prescription drug reports.[13]

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HB 4005 also establishes a temporary 18-member task force to "develop a strategy to create transparency for drug prices across the entire supply chain of pharmaceutical products."[14] The President of the Senate is to appoint certain members from the legislature (non-voting members) and the Governor is to appoint members including representatives from DCBS, pharmaceutical manufacturers, insurance companies, consumers, medical providers, and biopharmaceutical companies based in Oregon, among others.[15] The task force is to submit a report to the Oregon legislature by November 1, 2018, which may contain recommendations for legislation and "must contain a cost-effective and enforceable solution that exposes the cost factors that negatively impact prices paid by Oregonians for pharmaceutical products."[16]

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[9] *Id*.
[10] *Id.*, Section 3.
[11] *Id.*, Section 2.
[12] *Id.*, Section 5.
[13] *Id.*
[14] *Id.*, Section 11. HB 4005's provisions creating the task force are repealed on December 31, 2020. *Id.*, Section 12.
[15] *Id.* Section 11.
[16] *Id.*

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

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