



Report to Agency on Public Comment Period

Date: April 15, 2020

To: Department of Consumer and Business Services

From: Jesse Ellis O'Brien, Senior Policy Advisor

Subject: Oregon Division of Financial Regulation Proposed Bulletin on Implementation of 60-day advance notice of specified prescription drug price increases as required by 2019 House Bill 2658

First Comment Period Start: October 18, 2019
First Comment Period End: November 18, 2019

Second Comment Period Start: April 6, 2020
Second Comment Period End: April 10, 2020

Background

Oregon House Bill 2658 (the Act) from the 2019 Legislative Session requires manufacturers of prescription drugs sold in Oregon to provide a report to the Department of Consumer and Business Services (department) on certain planned price increases. The Act requires a report 60 days in advance of a price increase that will result, on the date the increase goes into effect, in a cumulative increase meeting criteria specified in the Act. The Act has been codified at ORS 646A.683.

This bulletin has been developed to provide guidance on the form and manner of reports provided under the Act and to clarify the department's approach to implementing the reporting program under the Act.

The department requested public comment on two occasions to receive additional feedback on revisions made in response to comments received during the first public comment period.

Summary and Discussion of Comments Received During First Comment Period

The Pharmaceutical Research and Manufacturers of America (PhRMA) provided written comments. PhRMA expressed concern about the price increase threshold for reporting under the Act, stating that the threshold as described in the Bulletin would result in reports in instances where a drug experienced a cumulative price decrease. PhRMA expressed opposition to the Bulletin's approach to making reports received under the Act available to the public, and requested that the Bulletin be revised to include a process for reviewing whether information reported under the Act may constitute trade secrets that should be exempt from public disclosure.

The department revised the Bulletin to establish a process for reviewing drug manufacturer trade secret claims prior to making reports available to the public, and to clarify that a report is not required by the Act in the event of a price decrease.

Summary and Discussion of Comments Received During Second Comment Period

PhRMA provided additional written comments expressing concerns about issues related to the constitutionality of the Act and potential conflicts with federal law, reiterating opposition to the public disclosure of reports provided under the Act, and providing feedback regarding the wording used in tables and graphics included in the Bulletin for purposes of illustrating the Act's reporting thresholds.

The Association for Accessible Medicines (AAM) provided written comments recommending that the Bulletin incorporate definitions of "brand name prescription drug" and "generic prescription drug," and requesting clarification regarding the department's interpretation of the Act's exemption from reporting for drugs manufactured by four or more companies.

Individual commenters Ann Watters and Todd Yorke provided written comments expressing concerns that the reporting thresholds under the Act are too high.

The department did not revise the draft to reflect these comments. The department cannot alter the statutory requirements of the Act through the issuance of a Bulletin. Withholding all reports provided under the Act from public disclosure is not consistent with the department's understanding of the legislative intent of the Act. The department has determined that the wording used in the tables and graphics included in the Bulletin is sufficiently clear in the context of the entirety of the document, but the department may provide additional clarification in future guidance if necessary. The department intends to provide the additional clarification requested by AAM in future guidance.

Modification and Adoption

Having fully considered all written submissions, I recommend the bulletin be adopted with the following modifications from the original draft:

1. On pages 2 and 3, clarification that the first 12-month period that will have elapsed after July 1, 2019, will end on June 30, 2020, not July 1, 2020.
2. On page 2, clarification that the reporting threshold is determined via a rolling 12-month lookback.
3. On page 4, clarification that a manufacturer does not have to report if a price decrease occurs, with an example for purposes of illustration.
4. On page 5, establishing that the department will review drug manufacturer trade secret claims prior to making reports submitted under the Act publicly available.
5. Minor wording and phrasing clarifications throughout the document.

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