



Oregon Department of Consumer and Business Services Division of Financial Regulation, Bulletin No. DFR 2020-12

TO: All manufacturers of prescription drugs sold in Oregon

DATE: April 22, 2020

RE: Implementation of 60-day advance notice of specified prescription drug price increases as required by 2019 House Bill 2658

Purpose

This Bulletin provides guidance on the form and manner of reports due from pharmaceutical manufacturers at least 60 days in advance of specified increases in the price of prescription drugs, and clarifies the Department of Consumer and Business Services (department), Division of Financial Regulation's (division) approach to implementing the reporting program under HB 2658.

Authority

- Or Laws 2019, ch 436 (Enrolled House Bill 2658, "Act")

Background

Oregon House Bill 2658 (2019) requires manufacturers of prescription drugs sold in Oregon to provide a report to the department on certain planned price increases. Section 2(2) and (3) of the Act require a report 60 days in advance of an increase that will result, on the date the increase goes into effect, in an increase within a 12-month period beginning on or after July 1, 2019, meeting these criteria specified in the Act:

Brand-name drugs "a cumulative increase of 10 percent or more" **OR**
"an increase of \$10,000 or more in the price of the brand-name prescription drug."

Generic drugs "a cumulative increase of 25 percent or more" **AND**
"an increase of \$300 or more in the price of the generic prescription drug."

A prescription drug is exempt from this requirement, and a manufacturer is not required to report, if the drug is manufactured by four or more companies *and* meets one of these criteria provided by HB 2658, Section 2(4):

1. The drug is marketed and distributed pursuant to an abbreviated new drug application approved under 21 U.S.C. 355(j);
2. The drug is an authorized generic drug as defined by 41 C.F.R. 447.502; or
3. The drug entered the market before the year 1962 and was not originally marketed under a new drug application.

Section 2(2) of HB 2658 specifies the information required in a manufacturer’s report, which includes the effective date of the increase, the current price of the drug, the dollar amount of the planned increase, and the year the drug became available for sale in the United States. The manufacturer must also include a statement regarding any changes or improvements in the drug that may have necessitated the price increase. HB 2658 is effective as of January 1, 2020.

As noted above, the purpose of this Bulletin is to provide guidance on the form and manner of reports provided under HB 2658 and to clarify the division’s approach to implementing the reporting program under HB 2658.

Guidance for manufacturers

Applicability and timing

The Act’s reporting requirements apply to cumulative price increases occurring “within a 12-month period beginning on or after July 1, 2019.” The first 12-month period that will have elapsed after July 1, 2019, will end on June 30, 2020. Therefore, the first reports will be required for cumulative price increases meeting the reporting thresholds that occur on or after June 30, 2020. Cumulative price increases for a one-year period ending before June 30, 2020 do not require a report.

The 12-month period defines the cumulative price increases subject to the reporting requirements, not the due date of the reports. Required reports are due 60 days in advance of the effective date of the price increase. Drug manufacturers planning to implement a price increase that will result in a cumulative price increase meeting the criteria specified in HB 2658 as of or after June 30, 2020, must provide the division with a report at least 60 calendar days before the effective date of the price increase.

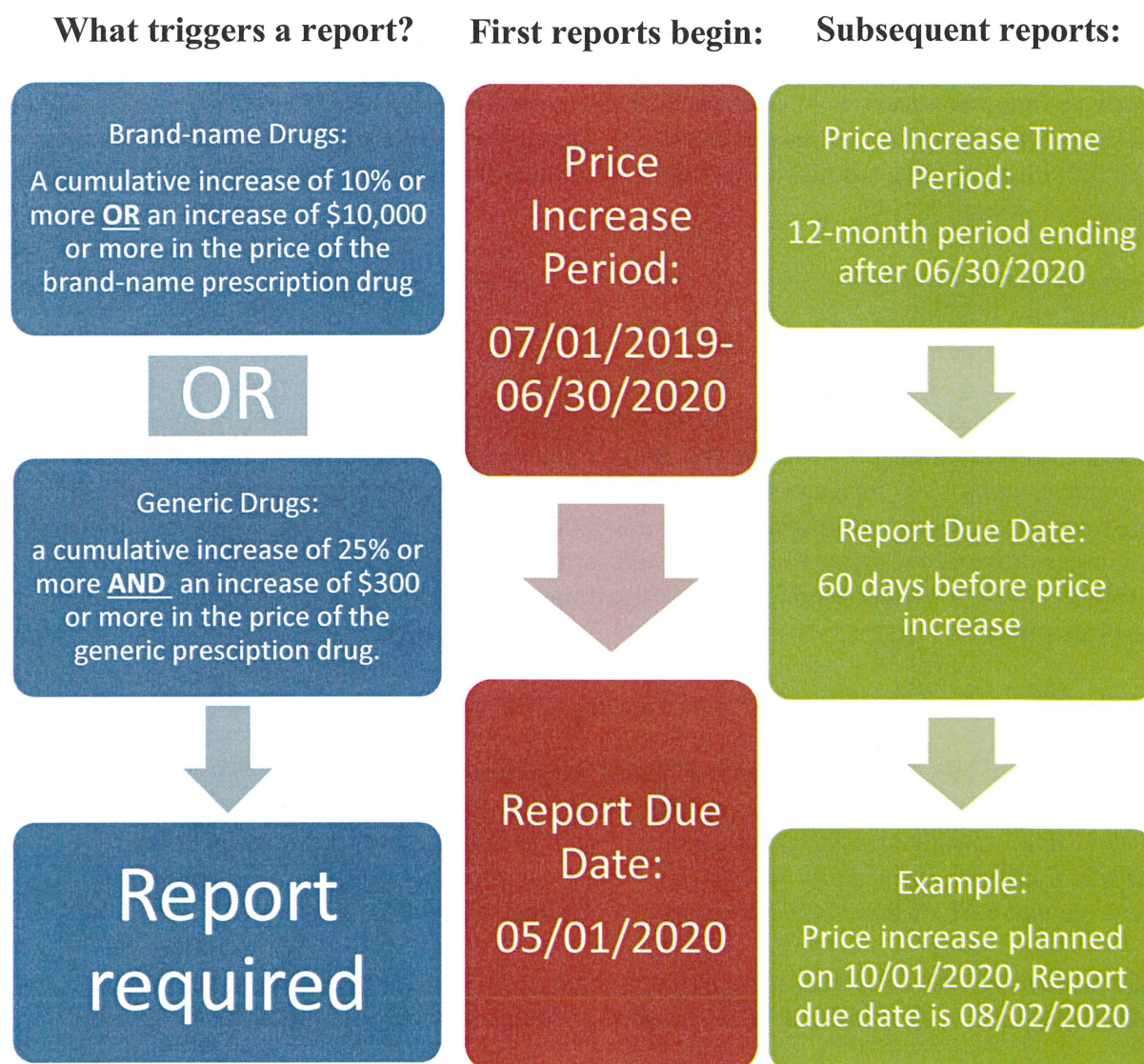
This is a rolling 12-month period and the 12-month look back will occur each day beginning June 30, 2020. For example, a 12-month period subject to reporting could consist of the period from July 5, 2019 to July 4, 2020, but could not consist of the period from June 5, 2019 to June 4, 2020.

The following table illustrates the due dates for 60-day advance reports for price increases within the specified 12-month periods:

| Price increase time period | Report due date |
|-----------------------------------|------------------------|
| 7/1/19 – 6/30/20 | 5/1/20 |
| 7/2/19 – 7/1/20 | 5/2/20 |
| 7/3/19 – 7/2/20 | 5/3/20 |

See Exhibit A below for a graphic illustration of the applicability and timing of reports required by HB 2658.

Exhibit A:



Price increases subject to reporting requirement

The Act's threshold for reporting a planned price increase is defined as a cumulative increase within a 12-month period. A cumulative increase occurs if the planned price increase would meet or exceed the specified threshold relative to the price of the drug at any prior time within the applicable 12-month period.

A manufacturer may determine whether a planned price increase would meet or exceed the threshold by comparing the price the drug will have once the increase goes into effect with the lowest price for the drug at any point over the applicable 12-month period. If, for example, the price after the planned price increase of a brand-name drug will be \$10,000 more than the price of the drug at any prior point in the relevant 12-month period, the manufacturer is subject to the

60-day reporting requirement. This applies regardless of whether the price after the planned increase may be less than \$10,000 in excess of its prior price at any other time during the 12-month period.

A manufacturer does not have to report if a price decrease occurs, even if the decrease results in a price that would exceed the specified threshold relative to the price of the drug at a prior time within the applicable 12-month period. For example, if a manufacturer makes the following price changes, the manufacturer would have to file a report for the increase effective July 1, but would not have to file a report for the decrease effective December 31, because it is a decrease—even though the resulting price would still be higher than the price at a prior point within the applicable 12-month period:

Price as of January 1: \$1,000

Price as of July 1: \$10,000

Price as of December 31: \$9,999

Under HB 2658, the reporting thresholds for brand-name and generic drugs are different. For the reporting requirement to apply to a generic drug, a planned price increase must result in *both* a 25% increase *and* a \$300 increase. For brand-name drugs, the reporting requirement applies if a planned price increase would result in *either* a \$10,000 increase *or* a 10% increase. Any planned price increase for a brand-name drug that would result in a 10% cumulative increase within the applicable 12-month period is subject to the reporting requirement, regardless of the dollar value of the price increase.

Reporting Wholesale Acquisition Cost and National Drug Code

Section 2(1)(e) of HB 2658 defines “price” as the wholesale acquisition cost (WAC) of the drug. A drug’s WAC is associated with the National Drug Code (NDC), a uniform 11-digit numerical drug identification code maintained by the U.S. Food and Drug Administration. A single prescription drug may have multiple NDCs for different strengths, formulations and packaging of the drug, and each of these NDCs may have a different associated WAC.

For the purposes of the form and manner of reporting under HB 2658, a report is required for each 11-digit NDC with a planned WAC increase meeting or exceeding the law’s thresholds.

HB 2658 specifies a WAC increase of \$10,000 or 10% for a brand-name drug, or \$300 and 25% for a generic drug, as key thresholds for reporting, as discussed above. However, HB 2658 does not specify the quantity of a drug to be used to determine these dollar amounts. For the purposes of the form and manner of reporting under the Act, and to help ensure uniformity and fair treatment of manufacturers and enhance alignment with the existing drug price reporting program established by HB 4005 (2018), calculation of price increases should follow OAR 836-200-0505:

A "one-month supply" is the total daily dosage units of a prescription drug recommended by its prescribing label as approved by the federal Food and Drug Administration for 30 days. If there is more than one such recommended daily dosage, the largest recommended daily dosage will be considered for the purposes of determining a one-month supply.

A "course of treatment" is the total dosage of a drug that would be prescribed in a single prescription to a patient taking the drug as recommended by its prescribing label as approved by the federal Food and Drug Administration. If there is more than one such recommended dosage, the largest recommended total dosage will be considered for the purposes of determining a course of treatment.

Public disclosure of 60-day advance notice reports and trade secret review

The legislative history of HB 2658 conclusively demonstrates that the Act was intended to make information about future increases in the price of prescription drugs available to the general public in advance. Once received by the division, the reports required by the Act constitute public records and may be provided to the public, subject to any generally applicable exemptions in Oregon public records law. As such, the division will disclose the reports required by the Act by posting them to the division's website, as is the division's longstanding practice with a variety of reports received from regulated industries.

The division will not post information reported under the Act if the manufacturer demonstrates that information to be a trade secret and exempt from disclosure under ORS 192.345. A manufacturer seeking to exempt a particular piece of information in a report submitted under the Act must specify which information is subject to the trade secret claim and provide evidence that the information meets the statutory definition of a trade secret under ORS 192.345.

The division will review trade secret claims on a case-by-case basis. If the division determines that information claimed as trade secret by the manufacturer does not meet the statutory definition of a trade secret under ORS 192.345, the division will notify the manufacturer at least 15 days before disclosing the information.

The division will provide additional technical details regarding the submission and public posting of reports as they become available.

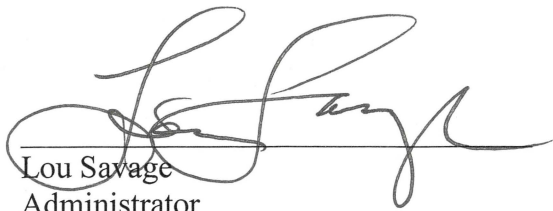
Funding

HB 2658 does not establish a specific funding source for the new reporting program it creates. The division will absorb the costs using existing resources.

The reporting program established by HB 2658 will not be funded by the fees established by HB 4005 (2018), and those fees do not apply to the new reporting program. Those fees, detailed in OAR 836-200-0555, include an additional fee for each report submitted in compliance with HB 4005. Reports submitted in compliance with HB 2658 will not be subject to this additional fee and will not be included in calculating a manufacturer's assessment amount under OAR 836-200-0555.

Nothing in this Bulletin shall be construed to limit the division's statutory authority or its ability to continue enforcing the laws of the State of Oregon.

This Bulletin takes effect immediately. It remains in effect until amended by a further Bulletin of the Division of Financial Regulation.



Lou Savage
Administrator
Division of Financial Regulation

4/22/2020
Date