



Drug Price Transparency Program

60-Day Notice - User Guide

April 2020

## I. Overview

House Bill 2658 enacted during the 2019 legislative session requires pharmaceutical manufacturers to provide a report to the Department of Consumer and Business Services 60 days in advance of a drug price increase meeting certain specified criteria. HB 2658 has been codified at [ORS 646A.683](#).

The purpose of this guide is to help pharmaceutical manufacturers comply with the reporting requirements as specified in ORS 646A.683. The Oregon Division of Financial Regulation [Bulletin No. 2020-12](#) also provides guidance on the implementation of the reporting requirements.

## II. 60-Day Notice Reporting

A report is required 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:

Brand-name drugs	“a cumulative increase of 10 percent or more” <b>OR</b> “an increase of \$10,000 or more in the price of the brand-name prescription drug.”
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Generic drugs	“a cumulative increase of 25 percent or more” <b>AND</b> “an increase of \$300 or more in the price of the generic prescription drug.”
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A manufacturer would be responsible for filing a report if: (1) engages in the act of manufacturing the drug either directly or by contracting out the manufacture of the drug and (2) is responsible for setting or changing the wholesale acquisition cost of the drug.

### *Determining Price Increases*

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

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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.

### *Reportable Data Elements*

Reports for advance notice of price increases are required to report the following data elements:

1. Full trade name of the drug
2. Full chemical or biologic product name of the drug
3. 11-digit National Drug Code (NDC) for the drug product
4. Year the drug became available for sale in the United States
5. Current price of the prescription drug
6. New price of the prescription drug
7. The date that the increase becomes effective
8. Statement of whether the price increase is necessitated by a change to or improvement in the prescription drug and, if so, a description of the change or improvement

All data elements have specific data fields for the manufacturer to provide their information. The department offers the following guidance to help manufacturers in their reporting:

1. Full trade name of the drug

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- Refers to the exclusive name of a drug product owned by a company under trademark law. If the trade name is the same as the chemical name, please submit the chemical name in this field.
2. Full chemical or biologic name of the drug
    - Refers to the nonproprietary name of the drug product, usually the active ingredients of the product.
  3. 11-digit NDCs for the drug
    - Identifies the labeler, product, and trade package size by unique code created by the Food and Drug Administration (FDA) and the manufacturer. Manufacturers are required to report all NDCs for the drug meeting the reporting thresholds. NDCs will be reported to the program in the 11-digit configuration.
  4. Year the drug became available for sale in the United States
    - Refers to the year of market entry in the United States for purchase.
  5. Current price of the prescription drug
    - The current wholesale acquisition cost of the drug on the date of submitting the report.
  6. New price of the prescription drug
    - The new wholesale acquisition cost of the drug effective 60 days from submitting the report.
  7. The date that the increase becomes effective
    - The date, at least 60 days from submitting the report, when the new price increase becomes effective.
  8. Statement of whether the price increase is necessitated by a change to or improvement in the prescription drug and, if so, a description of the change or improvement
    - Refers to a change or improvement in the value or quality to any of the following in a drug: the identity, strength, quality, purity, potency of the product, or other category which require submission of a supplement application and approval by FDA prior to distribution
      - i. Examples include but are not limited to: components and composition, manufacturing sites, manufacturing process, specifications, container closure system, labeling, or other similar types of improvements that would be reported to the FDA on a supplemental drug application.

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### *Exemptions from Reporting*

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 in ORS 646A.683:

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.

The statutory exemption to reporting will be evaluated using the following guidance to help clarify the exemption requirements:

- A drug subject to the exemption is a pharmaceutical product where the active ingredient is the same and produced by four or more companies. The active ingredient is any component that provides pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body.<sup>1</sup>
- For there to be four or more companies manufacturing a drug, there must be four or more entities which have obtained an approved abbreviated new drug application (ANDA) or a 351(k) biologics license application (BLA) from the U.S. Food and Drug Administration (FDA) for the manufacture of that generic or biosimilar drug for sale in the U.S..
- Determination of whether four companies are currently manufacturing a drug will be based on the number of companies holding an ANDA or a BLA at the time the report is submitted.

### **III. New Manufacturer Account**

One account is created for the specific prescription drug manufacturer entity for the purposes of reporting for the company. The program requires all subsidiaries of a parent company falling within the definition of a reporting manufacturer to create their own separate account with the department.

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<sup>1</sup> U.S. Food and Drug Administration. *Drugs@FDA Glossary of Terms – Active Ingredient*. Accessed April 2020. <https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms>

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To create an account, manufacturers can fill out the [form located on the Drug Price Transparency program website](#). This form asks the primary contact for the company to fill out information including manufacturer name, manufacturer address, primary contact name, phone, and email address. Once the department receives this information, an account will be generated on iReg and a confirmation email will be sent to the individual identified as the primary contact for the manufacturer.

A walkthrough of how to create new users and use iReg is found in the Manufacturer User Guide on the Drug Price Transparency Website.