

## 836-200-0500

### Purpose and Statutory Authority

The purpose of OAR 836-200-0500 to 836-200-0560 is to administer the Oregon Prescription Drug Price Transparency Program established in the Department of Consumer and Business Services for the purposes of providing notice and disclosure of information relating to the cost and pricing of prescription drugs in order to provide accountability for prescription drug pricing.

**Statutory/Other Authority:** [2018 Or Laws ch 7 ORS 646A.689](#)

**Statutes/Other Implemented:** [2018 Or Laws ch 7 ORS 646A.689](#)

### History:

[ID 2-2019, adopt filed 02/26/2019, effective 03/01/2019](#)

## 836-200-0505

### Definitions

For purposes of 836-200-0500 to 836-200-0560, the following definitions apply, unless the context requires otherwise:

(1) "Course of treatment" means 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 United States](#) 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.

(2) "Developed by the manufacturer" means, for a prescription drug, that its research and development costs were funded by the manufacturer in whole or in part through Phase I, II, or III trials as defined in 21 CFR 312.21.

~~(3) "Dosage" is the highest amount, strength, and frequency that a patient would take the drug as recommended by its prescribing label as approved by the United States Food and Drug Administration (such as one 10mg pill per day or one 5mL injection per week). (3) "Inaccurate information" means false or misleading representations or statements.~~

~~(4) "Inaccurate or incomplete information" means representations or statements that are false or misleading or that fail to provide all available information required in a report or in response to a request for additional information under OAR 836-200-0515 to 836-200-0535.~~

(5) "Net yearly increase" means an increase in the wholesale acquisition cost of a drug over the course of a calendar year dividing the average wholesale acquisition cost of the drug over the course of a calendar year by the average wholesale acquisition cost over the course of the previous calendar year.

(6) "New prescription drug" means a prescription drug that has received initial approval under an original new drug application under 21 U.S.C. 355(b), under an abbreviated new drug application under 21 U.S.C. 355(j), or under a biologics license application under 42 U.S.C. 262. In cases where multiple products are included on an application [or approved later based on the prior approval or a supplemental approval](#), each product will be considered a new prescription drug. A new prescription drug's introduction date is the date of [the product's initial](#) market entry. [A new prescription drug does not include:](#)

[\(a\) A product that is only for use under an emergency use authorization \(EUA\).](#)

(b) A product with a change in the national drug code or labeler name that has been continuously marketed by the same or a different manufacturer.

(c) A vaccine that has been reformulated and replaces a vaccine using the same name, application number, manufacturer, and labeler.

(7) "One-month supply" means the total daily-dosage units of a prescription drug recommended by its prescribing label as approved by the federal-United States Food and Drug Administration for 30 days or for a course of treatment lasting less than one month. ~~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.~~

(8) "Price" means the wholesale acquisition cost of a prescription drug.

(9) "Price increase" means any increase in the wholesale acquisition cost of a prescription drug.

(10) "Public funds" means any funds granted, loaned or otherwise provided by a national, state, local or foreign government entity.

(11) "Reporting manufacturer" means an entity meeting all the following characteristics:

(a) Required to be registered with the Oregon Board of Pharmacy as a drug manufacturer;

(b) ~~That e~~Engages in the manufacture of prescription drugs available for sale in this state, as defined by ~~2018 Or Laws ch 7~~ ORS 646A.689(1)(d), that are approved by the United States Food and Drug Administration under; ~~and~~

(A) A new drug application;

(B) An abbreviated new drug application; or

(C) A biologics license application.

(c) ~~That s~~Sets or changes the wholesale acquisition cost of the drugs it directly manufacturers or indirectly manufacturers through, including but not limited to, contracts with other entities.

(d) Does not only manufacture prescription drugs as a registered 503B facility (section 503B of the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. 353b).

~~(12) "The threshold established by the Centers for Medicare and Medicaid Services for specialty drugs in the Medicare Part D program" means \$670, which is the dollar amount specified for minimum Part D specialty tier eligibility in the 2018 Final Call Letter from the Centers for Medicare and Medicaid Services.~~

~~(123)~~ "Timely" and "timely manner" mean in compliance with the required deadlines for reporting and providing responses to requests for additional information detailed in OAR 826-200-0515 to 826-200-0535.

~~(134)~~ "Wholesale acquisition cost" or "WAC" has the meaning given to the term in 42 U.S.C. 1395w-3a(c)(6)(B).

Statutory/Other Authority: [646A.689 2018 Or Laws ch 7](#)  
Statutes/Other Implemented: [2018 Or Laws ch 7 646A.689](#)

History:

[ID 2-2019, adopt filed 02/26/2019, effective 03/01/2019](#)

**[836-200-0510](#)**

**Account Generation Requirement**

~~(1) No later than March 15, 2019, all reporting manufacturers required to file a report by July 1, 2019, under OAR 836-200-0515 (1) must create an online account with the department.~~

~~(2) Beginning in 2020 and for any subsequent year, reporting manufacturers without an online account with the department that are required to file a report by March 15 of that year under OAR 836-200-0515 (2) must create an online account with the department no later than 30 days after becoming a reporting manufacturer or 10 days prior to a required reporting deadline, whichever is earlier. February 15 of that same year.~~

~~(3) Reporting manufacturers without an online account with the department that are required to file a new specialty drug report under OAR 836-200-0520 must create an online account with the department no later than 10 days prior to submitting the report. (2) Reporting manufacturers are responsible for ensuring that they designate at least one contact person, with a valid email address, mailing address, and phone number, in the department's reporting system for purposes of communications and notices by the department. At least one contact person must be a reporting manufacturer employee who manages access to the account and receipt of trade secret determinations.~~

Statutory/Other Authority: [646A.689 2018 Or Laws ch 7](#)  
Statutes/Other Implemented: [646A.689](#)

[2018 Or Laws ch 7](#)

History:

[ID 2-2019, adopt filed 02/26/2019, effective 03/01/2019](#)

**[836-200-0515](#)**

**Threshold for Reporting Drug Price Increase**

(1) No later than July 1, 2019, a reporting manufacturer must report the information described in OAR 836-200-0530 (2) to the department regarding each prescription drug for which:

(a) The price at any point in 2018 was \$100 or more for a one-month supply ~~or for a course of treatment lasting less than one month~~; and

(b) There was a net yearly increase of 10 percent or more in the price of the prescription drug described in paragraph (a) of this ~~sub~~section during 2018.

(2) Beginning ~~March 15, 2020~~ [February 16, 2024](#), no later than March 15 annually, a reporting manufacturer ~~must~~ [may voluntarily](#) report to the department the information described in OAR 836-200-0530 (2) regarding each prescription drug for which:

(a) The price at any point during the previous year was \$100 or more for a one-month supply ~~or for a course of treatment lasting less than one month~~; and

(b) There was a net yearly increase of 10 percent or more in the price of the prescription drug described in paragraph (a) of this ~~sub~~section over the course of the previous calendar year.

**Statutory/Other Authority:** [646A.6892018-Or-Laws-ch-7](#)

**Statutes/Other Implemented:** [646A.6892018-Or-Laws-ch-7](#)

**History:**

[ID 2-2019, adopt filed 02/26/2019, effective 03/01/2019](#)

### **836-200-0520**

#### **Threshold for Reporting New Specialty-Prescription Drug**

~~(1) Beginning For new prescription drugs introduced on or after March 15, 2019, with a 30 days or less after a manufacturer introduces a new prescription drug for sale in the United States at a price for a 30 day one-month supply or for a course of treatment lasting less than one month that exceeds the threshold established by the Centers for Medicare and Medicaid Services for specialty drugs in the Medicare Part D program, the manufacturer must report to the department the information described in OAR 836-200-05310(4).~~

(2) For new prescription drugs introduced on or after January 1, 2025, the threshold is \$950, which is the dollar amount specified for minimum Medicare Part D specialty tier eligibility in the 2024 Final Call Letter from the Centers for Medicare and Medicaid Services.

(3) For new prescription drugs introduced prior to January 1, 2025, the threshold is \$670, which is the dollar amount specified for minimum Medicare Part D specialty tier eligibility in the 2018 Final Call Letter from the Centers for Medicare and Medicaid Services.

(4) The date of introduction is the FDA start marketing date or the date the product is first listed for sale in the United States, whichever is later.

**Statutory/Other Authority:** [646A.6892018-Or-Laws-ch-7](#)

**Statutes/Other Implemented:** [646A.6892018-Or-Laws-ch-7](#)

**History:**

[ID 2-2019, adopt filed 02/26/2019, effective 03/01/2019](#)

### **836-200-0525**

#### **Expectations of Reporting Manufacturers**

(1) Reporting manufacturers must ~~make a good-faith effort to~~ include all of the information required in a report or a response to a request for additional information under OAR 836-200-0530 ~~and to~~ 836-200-0535, and conduct a reasonable investigation to ensure the accuracy and completeness of their reports.

(2) If any of the information required in a report or a response to a request for additional information under OAR 836-200-0530 ~~and to~~ 836-200-0535 is not available to the reporting manufacturer at the time of the filing due to circumstances outside the manufacturer's control, the manufacturer must provide any available portion of the required information and a thorough explanation. The explanation must include a description of the missing information and the circumstances contributing to the manufacturer's inability to meet the requirement.

(3) If the information required in a report or a response to a request for additional information under OAR 836-200-0530 ~~and to~~ 836-200-0535 is not currently available to the manufacturer but is expected to be available in the future, the manufacturer must provide an explanation and a timeline for providing the required information to the department.

(4) ~~When providing information required by ORS 646A.689 (2) to (7), R~~reporting manufacturers ~~must make a good faith effort to~~ must limit information provided to the department to information that is necessary for the director's review and analysis of drug prices ~~under 2018 Or Laws ch 7.~~

(5) A reporting manufacturer's failure to comply with ~~sections the expectations specified in~~ (1) to (4) of this ~~section rule~~ may subject the manufacturer to a civil penalty under OAR 836-200-0560.

**Statutory/Other Authority:** ~~ORS 646A.689 2018 Or Laws ch 7~~

**Statutes/Other Implemented:** ~~ORS 646A.689 2018 Or Laws ch 7~~

**History:**

ID 2-2019, adopt filed 02/26/2019, effective 03/01/2019

### 836-200-0530

#### **Form and Manner Requirements for Drug Pricing Reporting**

(1) General requirements. All reports submitted by drug manufacturers under ~~ORS 646A.689~~ this section must:

- (a) Be provided in an electronic format specified by the department;
- (b) Be provided via an electronic system specified by the department;
- (c) Be machine readable;
- (d) Be capable of being reduced to written form;
- (e) Clearly indicate the information the manufacturer asserts to be conditionally exempt from disclosure under ORS 192.345 as a trade secret in adherence with OAR 836-200-0540;
- (f) Include a certification of compliance document certifying that the filing complies with all applicable Oregon statutes, rules, standards and filing requirements; and
- (g) Adhere to the standards set forth on the department's website.

(2) Prescription Drug Reporting - Price Increase. For drugs meeting the conditions specified in OAR 836-200-0515, ~~the a~~ report may be voluntarily furnished to the department ~~and must~~ include the following information, along with any documentation ~~necessary~~ to support the information reported under this ~~sub~~section:

- (a) The full trade name of the drug, full chemical name or biologic product name of the drug, and recognized industry standard drug identification information for the drug as specified on the department's website;
- (b) The price of the drug at the beginning of the calendar year preceding the report;

- (c) The price of the drug at the end of the calendar year preceding the report;
- (d) The highest and lowest prices of the drug at any point during the calendar year preceding the report;
- (e) The increase in the price of the drug over the preceding calendar year, expressed as a percentage;
- (f) The price and dosage of the drug the reporting manufacturer used to determine that the drug cost \$100 or more for a 30-day supply or a course of treatment lasting less than one month;
- (g) The length of time the prescription drug has been on the market;
- (h) The factors that contributed to the price increase, including a narrative description and explanation of all major financial and nonfinancial factors that influenced the decision to increase the wholesale acquisition cost of the drug product and to decide on the amount of the increase;
- (i) The name of any generic version or biosimilar of the prescription drug available for sale in the United States at the time of the report;
- (j) The research and development costs associated with the prescription drug that were paid using public funds, including all available information about the sources and uses of these public funds;
- (k) The direct costs incurred and specific total dollars expended by the manufacturer in the previous calendar year:
  - (A) To manufacture the prescription drug;
  - (B) To market the prescription drug, including spending on direct-to-consumer marketing such as paid advertising, as well as spending to promote the drug to physicians;
  - (C) To distribute the prescription drug; and
  - (D) For ongoing safety and effectiveness research associated with the prescription drug.
- (l) The total sales revenue for the prescription drug during the previous calendar year;
- (m) The manufacturer's net profit attributable to the prescription drug during the previous calendar year;
- (n) The introductory price of the prescription drug when it was approved for marketing by the United States Food and Drug Administration;
- (o) The net yearly increase, if any, by calendar year, in the price of the prescription drug during the previous five calendar years;
- (p) The 10 highest prices paid for the prescription drug during the previous calendar year in any country other than the United States, expressed in dollars according to the prevailing exchange rate at the time of the report; and
- (q) Any other information that the manufacturer deems relevant to the price increase and that the manufacturer deems will assist the director to complete a review of a drug price under [ORS 646A.689](#) ~~2018 Or Laws ch 7~~.