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~~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~~its~~ 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 manufacture~~r~~s 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.~~

(12~~3~~) "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.

(13~~4~~) "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.~~

(1~~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.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

836-200-0520
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 836-200-053~~10 (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 available for purchase ~~listed for sale~~ in the United States, whichever is later.

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

836-200-0525
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 one-month supply ~~30-day supply or a course of treatment lasting less than on 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~~.

~~(3) Prescription Drug Reporting – Patient Assistance Programs:~~

~~(a) If a reporting manufacturer offers one or more patient assistance programs to consumers residing in Oregon to reduce consumer out-of-pocket costs for a drug meeting the conditions specified in OAR 836-200-0515, the report furnished to the department under subsection (2) of this section must have an appendix that includes at least the following information for each patient assistance program relevant to the drug that is the subject of the report:~~

~~(A) The number of consumers residing in Oregon who participated in the patient assistance program over the previous calendar year;~~

~~(B) The total dollar value of the coupons, discounts, copayment assistance or other reduction in costs provided to consumers in this state who participated in the program over the previous calendar year;~~

~~(C) For each drug, the number of refills that qualify for the program, if applicable;~~

~~(D) If the program expires after a specified period of time, the period of time that the program is available to each consumer; and~~

~~(E) The eligibility criteria for the program and how eligibility is verified for accuracy.~~

~~(b) If a reporting manufacturer provides funding for an independent patient assistance program that reduces consumer out-of-pocket costs for a drug meeting the conditions specified in OAR 836-200-0515, the report furnished to the department under subsection (2) of this section must have an appendix that provides the name of the independent program and includes all of the information specified in this subsection that is available to the manufacturer at the time of the report. If the independent program provides services in addition to reducing consumer out-of-pocket costs for the drug that is the subject of the report, the manufacturer may limit the information provided to the information applicable to the drug that is the subject of the report. Reporting manufacturers that provide funding for independent patient assistance programs must make a good faith effort to secure this information.~~

~~(c) Reporting manufacturers that provide funding for a bona fide Independent Charity Patient Assistance Program operating in full compliance with the guidance provided in the Department of Health and Human Services Office of the Inspector General's Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs (Federal Register / Vol. 79, No. 104 / Friday, May 30, 2014 / Notices) are not required to include information about the bona fide Independent Charity Patient Assistance Program in any appendix required by this section.~~

836-200-0531

Prescription Drug Reporting – New Prescription Drug

(14) ~~Prescription Drug Reporting – New Specialty Drug.~~ For new prescription drugs meeting the conditions specified in OAR 836-200-0520, the report furnished to the department must include the following information:

(a) The full trade name of the drug (proprietary), full chemical name or biologic product name of the drug (nonproprietary), ~~and~~ recognized industry standard drug identification information for the drug as specified on the department's website, drug strength, drug package size, the date the drug was initially approved by the United States Food and Drug Administration, and the date the drug was introduced in the United States market.~~;~~

(b) The price and dosage of the drug the reporting manufacturer used to determine that the price of the drug for a ~~30-day~~ one-month supply ~~or for a course of treatment lasting less than one month~~ exceeds the threshold defined in OAR 836-200-0520 ~~established by the Centers for Medicare and Medicaid Services for specialty drugs in the Medicare Part D program.~~;

(c) The types of marketing, target audience, and associated actual costs for the four quarters prior to launch and planned costs for the four quarters following launch used in the introduction of the new prescription drug, with any associated explanation:

(A) Types of marketing includes digital (e.g., consumer or industry websites, social media), TV or audio, and other types of promotion;

(B) Target audience includes consumers, health care professionals, pharmacy benefit managers, insurance carriers, and other entities in the pharmaceutical supply chain.~~A description of the marketing used in the introduction of the new prescription drug including spending on direct-to-consumer marketing such as paid advertising, as well as spending to promote the drug to physicians, if applicable~~;

(d) The methodology used to establish the price of the new prescription drug, including ~~a narrative description and explanation of~~ all ~~major financial and nonfinancial~~ factors, with any associated impact or explanation, that influenced the decision to set the price of the drug at the level it was first set by the reporting manufacturer following its approval for marketing by the United States Food and Drug Administration. Factors include, but are not limited to:~~;~~

(A) Other prescription drugs, regardless of generic or brand status, including the availability, price, drug name, and labeler name;

(B) Estimated manufacturing costs for the prescription drug;

(C) Estimated marketing costs for the prescription drug;

(D) Estimated distribution costs for the prescription drug:

(E) Estimated costs of ongoing safety and effectiveness research associated with the prescription drug;

(F) Other costs for the prescription drug; and,

(G) Other costs not specifically associated with the prescription drug.

(e) Whether the United States Food and Drug Administration granted the new prescription drug a breakthrough therapy designation or a priority review, ~~along with any supporting documentation~~;

(f) If the new prescription drug was not developed by the manufacturer, the date of and the price paid for acquisition of the new prescription drug by the manufacturer;

(g) The manufacturer's estimate of the average number of patients in the United States who will be prescribed the new prescription drug each month; and

(h) The research and development costs associated with the new prescription drug that were paid using public funds, including all available information about the sources and uses of these public funds such as the institution name, program name and location, dates when the research was conducted, and the date when the research and development efforts was purchased.

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

836-200-0532

~~(3)~~ Prescription Drug Reporting – Patient Assistance Programs~~:~~

(1~~a~~) If a reporting manufacturer offers one or more patient assistance programs to consumers residing in Oregon to reduce consumer out-of-pocket costs for a drug meeting the conditions specified in OAR 836-200-0515, the report furnished to the department under ~~subsection (2) of this section~~OAR 836-200-0530(2) must have an appendix that includes at least the following information for each patient assistance program relevant to the drug that is the subject of the report:

(a~~A~~) The number of consumers residing in Oregon who participated in the patient assistance program over the previous calendar year;

(b~~B~~) The total dollar value of the coupons, discounts, copayment assistance or other reduction in costs provided to consumers in this state who participated in the program over the previous calendar year;

(c~~C~~) For each drug, the number of refills that qualify for the program, if applicable;

(d~~D~~) If the program expires after a specified period of time, the period of time that the program is available to each consumer; and

(e~~E~~) The eligibility criteria for the program and how eligibility is verified for accuracy.

(~~b~~2) If a reporting manufacturer provides funding for an independent patient assistance program that reduces consumer out-of-pocket costs for a drug meeting the conditions specified in OAR 836-200-0515, the report furnished to the department under OAR 836-200-0530 (2)~~subsection (2) of this section~~ must have an appendix that provides the name of the independent program and includes all of the information specified in ~~this sub~~section (1) that is available to the manufacturer at the time of the report. If the independent program provides services in addition to reducing consumer out-of-pocket costs for the drug that is the subject of the report, the manufacturer may limit the information provided to the information applicable to the drug that is the subject of the report. Reporting manufacturers that provide funding for independent patient assistance programs must make a good faith effort to secure this information.

(3~~c~~) Reporting manufacturers that provide funding for a bona fide Independent Charity Patient Assistance Program operating in full compliance with the guidance provided in the Department of Health and Human Services Office of the Inspector General's Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs (Federal Register / Vol. 79, No. 104 / Friday, May 30, 2014 / Notices) are not required to include information about the bona fide Independent Charity Patient Assistance Program in any appendix required by this section.

Statutory/Other Authority: ORS 646A.689
Statutes/Other Implemented: ORS 646A.689
History:

836-200-0535

Additional Information Requests

(1) Within 60 calendar days of receiving a report from a prescription drug manufacturer in accordance with OAR 836-200-0515 to 836-200-05320, the director or director's designee may submit one or more ~~a~~ written requests for supporting documentation or additional information to the manufacturer.

(2) The department's request shall be limited to information necessary to clarify or substantiate the material previously reported, or to enable the department to conduct an analysis of factors affecting drug prices for the purposes of providing recommendations to the Legislature as provided by ~~2018 Or Laws ch 7~~ORS 646A.689.

(3) Within 60 calendar days of receiving the department's request for supporting documentation or additional information following a report provided in accordance with OAR 836-200-0515 to 836-200-05320, a prescription drug manufacturer must provide a full and complete written response, including any requested documentation. Supporting documentation or additional information submitted will be part of the report published to the department's website.~~If any of the requested information or documentation is unavailable to a prescription drug manufacturer, the response must include an explanation as specified by 836-200-0525.~~ If the manufacturer asserts that any of the requested information is conditionally exempt from disclosure as a trade secret, the manufacturer must clearly ~~indicate~~ identify the~~at~~ information claimed as trade secret and provide an explanation, as specified under 836-200-0540, for each piece of information that is claimed to be exempt from disclosure.

(4) If additional time is needed, w~~W~~ithin 15 calendar days of receiving the department's request for supporting documentation or additional information following a report provided in accordance with ~~2018 Or Laws ch 7~~ORS 646A.689 and OAR 836-200-0515 to 836-200-05320, a prescription drug manufacturer ~~may~~ must submit a notice to the department for ~~request~~ up to 30 additional days to prepare and submit a response. A drug manufacturer's request for additional time must be in writing, and must explain the grounds for the request and the need for additional time to prepare a response.

~~(5) Within 15 days of receiving a manufacturer's request for additional time under subsection (4), the director or director's designee shall respond to the manufacturer in writing to specify that the director or director's designee grants the request, denies the request, or grants an amount of additional time less than requested, and explain the basis for the decision.~~

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