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NOTICE OF PROPOSED RULEMAKING

INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 836
DEPARTMENT OF CONSUMER AND BUSINESS SERVICES
INSURANCE REGULATION

FILED: 07/29/2026 11:22 AM
ARCHIVES DIVISION SECRETARY OF STATE

FILING CAPTION: Prescription Drug Price Transparency program updates

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 09/02/2026 5:00 PM
The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

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Filed By:
Karen Winkel
Rules Coordinator

HEARING(S)
Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 08/26/2026
TIME: 9:30 AM
OFFICER: Lily Sobolik

IN-PERSON HEARING DETAILS
ADDRESS: Labor and Industries Building, 350 Winter St NE, Basement, Conf Rm E, Salem, OR 97301

REMOTE HEARING DETAILS
MEETING URL: Click here to join the meeting
PHONE NUMBER: 503-446-4951
CONFERENCE ID: 285096309
SPECIAL INSTRUCTIONS:
This is a hybrid meeting conducted in-person and virtually via Microsoft Teams:

Meeting ID: 250 362 517 793 61
Passcode: ue3nQ2uy

NOTE: Public comments are public records and may be made available to the public.

NEED FOR THE RULE(S):

The Oregon Prescription Drug Price Transparency (DPT) program, housed in the Department of Consumer and Business Services (DCBS), was established under the Prescription Drug Price Transparency Act (2018 Oregon House Bill 4005). The DPT program collects and reports information from prescription drug manufacturers, health insurance carriers and consumers to increase the transparency of prescription drug pricing in Oregon. The law directs DCBS to engage in rulemaking to define key terms and timelines, and empowers DCBS to establish fees, adopt a schedule of civil penalties for violations and adopt any other rules necessary for carrying out the provisions of Section 2 of the law.

In December 2019, the Pharmaceutical Research and Manufacturing Association (PhRMA) sued the state of Oregon in federal district court challenging the provisions of HB 4005. This case was captioned as PhRMA vs. Stolfi, naming the former director of the department, Andrew Stolfi, as defendant in his official capacity. In February 2024, the District Court issued a Declaratory Judgment in favor of PhRMA, declaring the annual price increase reporting requirement unconstitutional on First and Fifth Amendment grounds. Oregon appealed this ruling to the Federal Ninth Circuit Court of Appeals.

On February 21, 2024, the department issued Bulletin No. DFR 2024-3 suspending required reports from manufacturers under ORS 646A.689(3), while clarifying that the court's order was limited to that subsection and did not apply to other reporting requirements. In March 2025, the department adopted amendments to the administrative rules implementing HB 4005, including making annual price increase reports by manufacturers voluntary instead of mandatory. These amendments took effect on April 1, 2025.

In August 2025, the Ninth Circuit issued an opinion in PhRMA v. Stolfi reversing the decision of the District Court that took effect on October 31, 2025. Accordingly, the department must resume collection of mandatory price increase reports from manufacturers in 2026.

While updating the rules to reflect this recent court decision, the department also took the opportunity to clarify requirements, update a reporting threshold, and add minor data collection points to allow program staff to verify accurate reporting. A Rulemaking Advisory Committee (RAC) included nine stakeholders representing a range of industries and perspectives. The RAC members represented consumer advocates and coalitions, large and small pharmaceutical manufacturers, trade associations, and third-party compliance partners. One member represented small business with less than 50 employees. The RAC met twice in June 2026. Each meeting included discussion of draft changes to the rules, member comments, questions and discussion, and public comments. The proposed changes to the rules include:

- Adding a clarifying definition for "drug;"
- Correction of internal references;
- Reverting annual price increase reporting from voluntary to mandatory per a recent court judgment;
- Clarifying language about the timing of data reporting;
- Adding examples of factors that may contribute to price increases;
- Updating the threshold for reporting new prescription drugs; and
- Adding minor data collection points to allow for DPT program staff verification.

The proposed rule changes are necessary to ensure that the program is administered in a fair and equal manner for all

participating drug manufacturers, to minimize the administrative burden and cost of the program for the state and the industry, and to achieve the program's purpose 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.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

Draft rules are available from Karen Winkel, Rules Coordinator, Division of Financial Regulation located at 350 Winter St. NE, Salem, OR 97301 and are available on the division's website: https://dfr.oregon.gov/laws-rules/Pages/proposed-rules.aspx.

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE:

The proposed rules will impact pharmaceutical drug manufacturers subject to the Prescription Drug Price Transparency Act as well as consumers and purchasers of prescription drugs. To the extent that the rule changes improve the effectiveness of the program in creating transparency in pharmaceutical pricing, greater transparency may impact the price of prescription drugs and thus have a downstream economic impact on consumers and the public. However, the extent of this impact and any differential impacts for different groups of affected people is impossible to predict from the information available to the department.

FISCAL AND ECONOMIC IMPACT:

The proposed rules will not have a new significant economic impact, however, the Prescription Drug Price Transparency Act and the underlying rules continue to have a significant economic impact on prescription drug manufacturers. There are likely a limited number of drug manufacturers that are also small businesses; those would have compliance costs. The proposed rules continue to not be likely to have a fiscal or economic impact on state agencies, local governments, or the public.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) The proposed rules continue to not be likely to have a fiscal or economic impact on state agencies, local governments, or the public. While the underlying statutory provisions have a significant impact on DCBS, the proposed rules do not. The proposed rules provide finer details regarding the administration of the program and are expected to have a negligible impact on costs to the department and indeed will perhaps increase program efficiency.

The proposed rules do not add any new requirements on public entities but instead clarify DCBS's supervisory expectations with regard to the administration of the Oregon Prescription Drug Price Transparency program. Other state agencies and local governments are not expected to incur any fiscal impact, because the requirements established by the Prescription Drug Price Transparency Act are not applicable to these entities.

The proposed rules will not have economic impact on the general public beyond the underlying, existing statutory requirements.

(2)(a) The proposed rules are not expected to require significant additional costs beyond the costs of the existing compliance requirements of the underlying rules. DCBS does not have data on the specific number of pharmaceutical

manufacturers that are small businesses doing business in Oregon.

DCBS convened a rulemaking advisory committee, which included representatives from drug manufacturers, trade associations, and consumer advocates. One committee member was a representative from a drug manufacturer that is a small business. The changes in the proposed rules would not significantly alter the existing requirements of reporting manufacturers subject to the rules, including any that are small businesses.

(2)(b) The administrative costs for complying with the Prescription Drug Price Transparency Act are substantial. However, the proposed rules largely provide clarification of the existing rules, and the new requirements are minimal. The overarching intent is to improve language consistency, align the annual price increase section with previous rulemaking revisions, which clarifies statutory intent, and resume mandatory data collection following a Ninth Circuit opinion.

The proposed rules increase the price threshold for reporting new prescription drugs, which would result in fewer reports for manufacturers and, thus, a decreased administrative burden.

The proposed rules clarify the reporting requirements for the description of marketing to include types of marketing, target audience, and timeframes for the marketing spending. The proposed rules also enumerate potential factors that a reporting manufacturer may use in its methodology to increase prices. The potential factors include other prescription drugs, and estimated costs for manufacturing, marketing, distribution, and ongoing safety and effectiveness research for the new prescription drug. These changes in the proposed rules, which have already been adopted for new prescription drug reports, are intended as clarifications of existing requirements and are unlikely to represent a significant increase in administrative costs.

Additionally, the proposed rules add two reporting requirements for the annual price increase reports. First, it adds reporting the wholesale acquisition cost of the annual price increase drug at the beginning and end of the calendar year before the year preceding the report. It also adds reporting any wholesale acquisition cost changes, and the associated dates, during the calendar year preceding the report. This newly proposed information should be easily accessible by the manufacturer, is publicly available, and it is necessary for program staff to verify that a report is statutorily required.

(2)(c) The administrative costs for complying with the Prescription Drug Price Transparency Act and the underlying rules are substantial, and may include additional equipment, supplies and labor costs, but the proposed rules largely provide clarification of the existing rules and do not impose additional requirements. The additional requirements and clarifications in the proposed rule outlined in subsection (2)(b) above may impose limited additional equipment, supplies and labor costs on prescription drug manufacturers.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

Representatives of small businesses were invited to provide comment on the rule.

The RAC members represented consumer advocates and coalitions, large and small pharmaceutical manufacturers, trade associations, and third-party compliance partners. One member of the RAC represented a small business.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:
836-200-0505, 836-200-0515, 836-200-0520, 836-200-0530, 836-200-0531, 836-200-0532, 836-200-0533, 836-200-0535, 836-200-0545, 836-200-0555

AMEND: 836-200-0505

RULE SUMMARY: Adds the definition of “drug.”

CHANGES TO RULE:

836-200-0505
Definitions
For purposes of OAR 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 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) "Drug" means "prescription drug" as defined in ORS 646A.689(1)(h).¶
(4) "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).~~-~~¶
(~~4~~5) "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~~6) "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~~7) "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, each product with a unique national drug code will be considered a new prescription drug. A new prescription drug's introduction date is the FDA start marketing date or the date the product is first available for purchase in the United States, whichever is later. 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 previously 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~~8) "One-month supply" means the total dosage of a prescription drug recommended by its prescribing label as approved by the United States Food and Drug Administration for 30 days or for a course of treatment lasting less than one month.~~-~~¶
(~~8~~9) "Price" means the wholesale acquisition cost of a prescription drug.¶
(~~9~~10) "Price increase" means any increase in the wholesale acquisition cost of a prescription drug.¶
(1~~0~~1) "Public funds" means any funds granted, loaned or otherwise provided by a national, state, local or foreign government entity.¶
(1~~1~~2) "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) Engages in the manufacture, directly or indirectly including through contracts with other entities, of prescription drugs available for sale in this state, as defined by ORS 646A.689(1)(d), that are approved by the United States Food and Drug Administration under:¶
(A) A new drug application;¶
(B) An abbreviated new drug application; or¶
(C) A biologics license application.~~-~~¶
(c) Sets or changes the wholesale acquisition cost of the drugs it manufactures.¶
(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).¶
(1~~2~~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.¶
(1~~3~~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: ORS 646A.689, 646A.692

Statutes/Other Implemented: ORS 646A.689, 646A.692

AMEND: 836-200-0515

RULE SUMMARY: Reverts the annual price increase reporting from voluntary to mandatory per the most recent court judgement; updates internal references.

CHANGES TO RULE:

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 836-200-053~~0(2)~~3 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; and¶
(b) There was a net yearly increase of 10 percent or more in the price of the prescription drug described in subsection (a) of this section during 2018.¶
(2) Beginning ~~February~~March 1~~6~~5, 202~~4~~0, no later than March 15 annually, a reporting manufacturer m~~ay voluntarily~~ust report to the department the information described in OAR 836-200-053~~0(2)~~3 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; and¶
(b) There was a net yearly increase of 10 percent or more in the price of the prescription drug described in subsection (a) of this section over the course of the previous calendar year.
Statutory/Other Authority: ORS 646A.689, 646A.692
Statutes/Other Implemented: ORS 646A.689, 646A.692

AMEND: 836-200-0520

RULE SUMMARY: Updates the threshold for reporting new prescription drugs to reflect current specifications in Medicare Part D.

CHANGES TO RULE:

836-200-0520
Threshold for Reporting New Prescription Drug
(1) For new prescription drugs introduced on or after March 15, 2019, with a price for a one-month supply 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 836-200-0531. ¶
~~(~~2The report is due no later than 30 days after the date of introduction for the new prescription drug.¶
(2) For new prescription drugs introduced on or after January 1, 2027, the threshold is $1,080, which is the dollar amount specified for minimum Medicare Part D specialty tier eligibility in the Contract Year (CY) 2027 Final Part D Bidding Instructions memorandum from the Centers for Medicare and Medicaid Services.¶
(3) 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~~4) 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~~5) The date of introduction is the FDA start marketing date or the date the product is first available for purchase in the United States, whichever is later.
Statutory/Other Authority: ORS 646A.689, 646A.692
Statutes/Other Implemented: ORS 646A.689, 646A.692

AMEND: 836-200-0530

RULE SUMMARY: Removes Section 2 of this rule. This section of the rule is not being deleted from the Drug Price Transparency rules as it will now be a separate rule.

CHANGES TO RULE:

836-200-0530
Form and Manner Requirements for Drug Pricing Reporting
~~(1)~~ General requirements. All reports submitted by drug manufacturers under ORS 646A.689 must:¶
(~~a~~1) Be provided in an electronic format specified by the department;¶
(~~b~~2) Be provided via an electronic system specified by the department;¶
(~~c~~3) Be machine readable;¶
(~~d~~4) Be capable of being reduced to written form;¶
(~~e~~5) 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~~6) Include a certification of compliance document certifying that the filing complies with all applicable Oregon statutes, rules, standards and filing requirements; and¶
(~~g~~7) 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, a report may be voluntarily furnished to the department and include the following information, along with any documentation to support the information reported under this 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;¶~~
~~(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.~~
Statutory/Other Authority: ORS 646A.689, 646A.692
Statutes/Other Implemented: ORS 646A.689, 646A.692

AMEND: 836-200-0531

RULE SUMMARY: Deletes the term “price” and replace it with “wholesale acquisition cost.” This is not a substantive change because “price” is already defined as “wholesale acquisition cost” but is intended to be clarifying.

CHANGES TO RULE:

836-200-0531
Prescription Drug Reporting - New Prescription 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:¶
(1) The full trade name of the drug (proprietary), full chemical name or biologic product name of the drug (nonproprietary), 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~~.~~:¶
(2) The price and dosage of the drug the reporting manufacturer used to determine that the price of the drug for a one-month supply exceeds the threshold defined in OAR 836-200-0520~~.~~:¶
(3) A description of the marketing used in the introduction of the drug, including the types of marketing, target audience, and associated spending for the four quarters prior to launch and planned costs for the four quarters following launch, 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; and¶
(b) Target audience includes consumers, health care professionals, pharmacy benefit managers, insurance carriers, and other entities in the pharmaceutical supply chain.¶
(4) The methodology used to establish the price of the new prescription drug, including all 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 may include, but are not limited to:¶
(a) Other prescription drugs including the drug name, labeler name, and ~~price~~wholesale acquisition cost;¶
(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.¶
(5) Whether the United States Food and Drug Administration granted the new prescription drug a breakthrough therapy designation or a priority review;¶
(6) 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;¶
(7) 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¶
(8) 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.
Statutory/Other Authority: ORS 646A.689, 646A.692
Statutes/Other Implemented: ORS 646A.689, 646A.692

AMEND: 836-200-0532

RULE SUMMARY: Updates internal references.

CHANGES TO RULE:

836-200-0532
Prescription Drug Reporting - Patient Assistance Programs
(1) 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 OAR 836-200-053~~0(2)~~3 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 residing in Oregon who participated in the patient assistance 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.¶
(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 836-200-053~~0(2)~~3 must have an appendix that provides the name of the independent program and includes all of the information specified in 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 act in good faith to secure this information.¶
(3) 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 rule.
Statutory/Other Authority: ORS 646A.689, 646A.692
Statutes/Other Implemented: ORS 646A.689, 646A.692

ADOPT: 836-200-0533

RULE SUMMARY: Makes 836-200-0530(2) its own rule; reverts the annual price increase reporting from voluntary to mandatory to align with a recent court judgement; clarifies language about the timing of data reporting; adds examples of factors that may contribute to price increases aligning with changes finalized in 2025 for new prescription drug reporting (836-200-0531(4)); adds data collection points, which reporting manufacturers currently need for accurate reporting, allowing for DPT program staff verification.

CHANGES TO RULE:

836-200-0533
Prescription Drug Reporting - Annual Price Increase
For drugs meeting the conditions specified in OAR 836-200-0515, the report furnished to the department must include the following information, along with any documentation to support the information reported under this section:¶
(1) 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;¶
(2) The price of the drug at the beginning and the end of the calendar year preceding the report;¶
(3) The price of the drug at the beginning and the end of the calendar year prior to the year described in section (2) of this rule;¶
(4) The price, and associated date, of the drug for each price change during the calendar year preceding the report, if applicable;¶
(5) The price, and associated date, of the drug for each price change during the calendar year preceding the year described in section (4) of this rule, if applicable;¶
(6) The net yearly increase in the price of the drug over the calendar year preceding the report, expressed as a percentage;¶
(7) The dosage of the drug the reporting manufacturer used to determine that the drug cost $100 or more for a one-month supply;¶
(8) The date and price when the prescription drug first entered the market with approval from the U.S. Food and Drug Administration;¶
(9) All factors that contributed to the price increase, with any associated impact or explanation, that influenced the decision to increase the wholesale acquisition cost of the drug product and to decide on the amount of the increase. Factors may include, but are not limited to:¶
(a) Other prescription drugs, including the drug name, labeler name, and wholesale acquisition cost;¶
(b) Changes to manufacturing costs for the prescription drug;¶
(c) Changes to marketing costs for the prescription drug;¶
(d) Changes to distribution costs for the prescription drug;¶
(e) Changes to costs of ongoing safety and effectiveness research associated with the prescription drug;¶
(f) Other cost changes for the prescription drug; and¶
(g) Other cost changes not specifically associated with the prescription drug.¶
(10) 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;¶
(11) 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;¶
(12) The direct costs incurred and specific total dollars expended by the manufacturer in the calendar year preceding the report:¶
(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 health care professionals;¶
(c) To distribute the prescription drug; and¶
(d) For ongoing safety and effectiveness research associated with the prescription drug.¶
(13) The total sales revenue for the prescription drug during the calendar year preceding the report;¶
(14) The manufacturer's net profit attributable to the prescription drug during the calendar year preceding the report;¶
(15) The net yearly increase, if any, by calendar year, in the price of the prescription drug during the five calendar years preceding the report;¶
(16) The 10 highest prices paid for the prescription drug during the calendar year preceding the report in any country other than the United States, expressed in dollars according to the prevailing exchange rate at the time of

the report; and¶
(17) 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.
Statutory/Other Authority: ORS 646A.689, 646A.692
Statutes/Other Implemented: ORS 646A.689, 646A.692

AMEND: 836-200-0535

RULE SUMMARY: Updates internal references.

CHANGES TO RULE:

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 836-200-0532~~2~~3, the director or director's designee may submit one or more 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 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 836-200-0532~~2~~3, 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 the manufacturer asserts that any of the requested information is conditionally exempt from disclosure as a trade secret, the manufacturer must clearly identify the information claimed as trade secret and provide an explanation, as specified under OAR 836-200-0540, for each piece of information that is claimed to be exempt from disclosure.¶
(4) If additional time is needed, within 15 calendar days of receiving the department's request for supporting documentation or additional information following a report provided in accordance with ORS 646A.689 and OAR 836-200-0515 to 836-200-0532~~2~~3, a prescription drug manufacturer must submit a notice to the department for 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. The department will automatically grant requests submitted in accordance with this section.
Statutory/Other Authority: ORS 646A.689, 646A.692
Statutes/Other Implemented: ORS 646A.689, 646A.692

AMEND: 836-200-0545

RULE SUMMARY: Updates internal references.

CHANGES TO RULE:

836-200-0545
Public Disclosure of Prescription Drug Manufacturer Filings
(1) As soon as practicable after receiving a filing from a prescription drug manufacturer under OAR 836-200-0530 to 836-200-053~~2~~3, the department shall post to its website the name of the manufacturer and the prescription drug that is the subject of the filing.¶
(2) Notwithstanding section (1), if a manufacturer has made a trade secret claim, the information that is the subject of the trade secret claim will not be posted to the department's website until a determination has been made by the department or, in the case of a manufacturer's appeal, the director, as specified by OAR 836-200-0540.¶
(3) No information determined by the department or the director to be exempt from disclosure under OAR 836-200-0540 shall be included in the information posted to the department's website.
Statutory/Other Authority: ORS 646A.689, 646A.692
Statutes/Other Implemented: ORS 646A.689, 646A.692

AMEND: 836-200-0555

RULE SUMMARY: Updates internal references.

CHANGES TO RULE:

836-200-0555
Assessments Against Prescription Drug Manufacturers for 2023 and prior
(1) Once annually, no later than October 1, all reporting manufacturers will pay an assessment of $400. The director may by order reduce the fees assessed for any specific year.¶
(2) Once annually, no later than October 1, reporting manufacturers that have filed one or more reports under OAR 836-200-0515 to 836-200-0532~~2~~23 between August 1 of the previous year and July 31 of the current year must pay an additional assessment for each report filed.¶
(3) For the purposes of section (2), the director shall determine the amount of the assessment by subtracting the revenue collected under section (1) from the amount of revenue needed to cover the department's estimated expenses in administering ORS 646A.689 and OAR 836-200-0500 to 836-200-0550, and dividing the resulting amount by the total number of filings subject to assessment between August 1 of the previous year and July 31 of the current year. The director shall determine the amount of revenue needed by considering the legislatively approved expenditures for administration of ORS 646A.689 and OAR 836-200-0500 to 836-200-0555, as well as the timing of cash revenues and expenditures.¶
(4) The revenue collected under sections (1) and (2) of this rule must be used solely for expenses incurred in the administration of ORS 646A.689 and OAR 836-200-0500 to 836-200-0555.¶
(5) A manufacturer must pay each assessment imposed under this rule no later than 30 days after the date of the assessment by the department. A manufacturer must pay interest at nine percent per annum on any assessment that is not paid when due.¶
(6) Reporting manufacturers shall be subject to the assessment requirements set forth in sections (1) to (5) of this rule for billing periods through July 31, 2023. For billing periods on or after August 1, 2023, reporting manufacturers shall be subject to the annual fee set forth in OAR 836-200-0553.
Statutory/Other Authority: ORS 646A.689, 646A.692
Statutes/Other Implemented: ORS 646A.689, 646A.692