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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
01/27/2025 3:20 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Prescription Drug Price Transparency program updates

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 03/03/2025 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: 02/24/2025
TIME: 11:00 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: 459770030
SPECIAL INSTRUCTIONS:
This is a hybrid meeting conducted in-person and virtually via Microsoft Teams:

Meeting ID: 228 076 147 636
Passcode: 2EM7kp7P

NOTE: PUBLIC COMMENTS ARE PUBLIC RECORDS AND MAY BE MADE PUBLICALLY AVAILABLE.

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 five years ago under the Prescription Drug Price Transparency Act (2018 Oregon House Bill 4005, Oregon Revised Statutes 646A.680 et seq.). 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.

A five-year review of the rules pursuant to ORS 183.405 revealed areas to clarify requirements, increase efficiency, and more accurately reflect the existing DPT program processes and procedures. 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, third party compliance partners, and insurance carriers. When the RAC was seated, one member was a small business with less than 50 employees. The RAC met four times between August and November. Each meeting included draft changes to the rules, member comments, questions and discussion, and public comments. The proposed changes to the rules include:

- Clarifying existing definitions of key terms including “new prescription drug,” “one-month supply,” and “reporting manufacturer;"
- Correction of internal references;
- Changing annual price increase reporting from mandatory to voluntary per a recent court judgment;
- Specifying requirements of a designated contact person for a reporting manufacturer;
- Updating the threshold for reporting new prescription drugs;
- Adding clarification about the reported data elements for new prescription drugs;
- Adding automatic approval of appropriately submitted requests for additional time; and,
- Removing rules no longer necessary for program implementation.

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.

Oregon Revised Statute 646A.680 et seq. may be found on the Oregon Legislative Assembly website: https://www.oregonlegislature.gov/bills_laws/ors/ors646A.html.

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 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 that are 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.

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, insurers, and consumer advocates. One committee member was a representative from a drug manufacturer that is a small business. DCBS asked RAC members about impacts to small businesses and received no feedback. 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 do not impose additional requirements. The overarching intent is to reduce administrative burdens on both the reporting manufacturers and the program staff while still accomplishing the mandate of the Act.

For example, the proposed rules add a requirement that, for purposes of communicating with the program, a reporting manufacturer must list at least one contact person that is an employee who manages access to the account and receipt of trade secret designations. Some reporting manufacturers may currently rely on third party vendors to communicate with the program; for those this proposed rule may represent a shift in costs. However, this shift in costs would likely be minimal at most.

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 set the price of a new prescription drug. 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 are intended as clarifications of existing requirements and are unlikely to represent a significant increase in administrative costs.

(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 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):

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

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:
836-200-0500, 836-200-0505, 836-200-0510, 836-200-0515, 836-200-0520, 836-200-0525, 836-200-0530, 836-200-0531, 836-200-0532, 836-200-0535, 836-200-0540, 836-200-0545, 836-200-0550, 836-200-0555, 836-200-0560

AMEND: 836-200-0500

RULE SUMMARY: Updates statutory references.

CHANGES TO RULE:

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, 646A.692

AMEND: 836-200-0505

RULE SUMMARY: Adds a definition for “dosage;” combines the definitions for “inaccurate information” and “incomplete information;” adds clarification about what is not included in the definition of “new prescription drug;” removes dosage guidance from the definition of “one-month supply;” adds clarification to the definition of “reporting manufacturer;” and updates statutory references.

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 ~~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) "~~Inaccurate information" me~~Dosage" is the highest amount, strength, an~~s~~d ~~false or misleading representations or~~ requency that a patient would take the drug as recommended by its prescribing label as approved by the United States Food and Drug Administrat~~ements.¶~~
~~(4) "I~~ion (such as one 10mg pill per day or one 5mL injection per week). ¶
(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~~, calculated by~~ 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~~, each product~~ 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 date of ~~its market entry~~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 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) "One-month supply" means the total d~~aily dosage units~~osage of a prescription drug recommended by its prescribing label as approved by the ~~federal~~United States Food and Drug Administration for 30 days~~. If there is more than one such recommended daily dosage, the largest recommended daily dosage will be considered for the purposes of determining a~~ or for a course of treatment lasting less than 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 as defined by 2018 Or Laws ch 7; and¶~~
~~(c) That s~~, 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 manufacture~~rs~~.¶
~~(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~~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~~3~~2) "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.¶
(14~~3~~) "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: ~~2018 Or Laws ch 7~~ORS 646A.689
Statutes/Other Implemented: ~~2018 Or Laws ch 7~~ORS 646A.689

AMEND: 836-200-0510

RULE SUMMARY: Removes outdated timelines; sets timeline for reporting manufacturers to create an online account with the department; requires reporting manufacturers to provide the department with at least one contact person, with valid contact information, that is an employee who manages access to the account and receipt of trade secret determinations.

CHANGES TO RULE:

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)~~Beginning in 2020 and for any subsequent year, reporting manufacturers must create an online account with the department.~~¶~~
~~(2) Beginning in 2020 and for any subsequent year,~~ no later than 30 days after becoming a reporting manufacturer~~s without an online account with the d~~ or 10 days prior to a required reporting deadline, whichever is earlier. ¶
(2) Repa~~o~~rt~~ment 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 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~~ing 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: ~~2018 Or Laws ch 7~~ORS 646A.689
Statutes/Other Implemented: ~~2018 Or Laws ch 7~~ORS 646A.689

AMEND: 836-200-0515

RULE SUMMARY: Corrects internal references; changes the requirements from mandatory to voluntary per current judicial judgement; removes language no longer needed because of definition changes.

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 836-200-0530 (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~~subsection (a) of this ~~sub~~section during 2018.¶
(2) Beginning ~~March~~February 1~~5~~6, 202~~0~~4, no later than March 15 annually, a reporting manufacturer m~~ust~~ay 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~~subsection (a) of this ~~sub~~section over the course of the previous calendar year.
Statutory/Other Authority: ~~2018 Or Laws ch 7~~ORS 646A.689
Statutes/Other Implemented: ~~2018 Or Laws ch 7~~ORS 646A.689

AMEND: 836-200-0520

RULE SUMMARY: Updates the threshold for reporting new prescription drugs to reflect current specifications in Medicare Part D; provides a definition for the “date of introduction.”

CHANGES TO RULE:

836-200-0520
Threshold for Reporting New ~~Specialty~~Prescription Drug
~~Beginning March 15, 2019, 30 days or less after a manufacturer introduces a~~(1) For new prescription drug ~~for sale in the United States at a price for a 30 day supply or for a course of treatment lasting less than~~s 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 836-200-053~~0 (4)~~1. ¶
(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 in the United States, whichever is later.
Statutory/Other Authority: ~~2018 Or Laws ch 7~~ORS 646A.689
Statutes/Other Implemented: ~~2018 Or Laws ch 7~~ORS 646A.689

AMEND: 836-200-0525

RULE SUMMARY: Updates statutory and internal references; clarifies “good faith” language.

CHANGES TO RULE:

836-200-0525
Expectations of Reporting Manufacturers
(1) Reporting manufacturers must ~~make a~~act in 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) ~~R~~When providing information required by ORS 646A.689 (2) to (7), reporting manufacturers must ~~make a~~act in good~~-~~ faith ~~effort~~ to 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 ~~the exp~~sectat~~ions specified in (1)~~ (1) to (4) of this ~~section~~rule may subject the manufacturer to a civil penalty under OAR 836-200-0560.
Statutory/Other Authority: ~~2018 Or Laws ch 7~~ORS 646A.689
Statutes/Other Implemented: ~~2018 Or Laws ch 7~~ORS 646A.689, 646A.692

AMEND: 836-200-0530

RULE SUMMARY: Updates statutory references; changes the requirements of annual price increase reporting from mandatory to voluntary per current judicial judgement; updates language based on definition changes; removes the sections on patient assistance programs and new prescription drugs.

CHANGES TO RULE:

836-200-0530
Form and Manner Requirements for Drug Pricing Reporting
(1) General requirements. All reports submitted by drug manufacturers under ~~this section~~ORS 646A.689 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 ~~must~~and 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 on month~~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 ~~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.¶~~
~~(4) Prescription Drug Reporting - New Specialty Drug. For 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, 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 and dosage of the drug the reporting manufacturer used to determine that the price of the drug for a 30 day supply or for a course of treatment lasting less than one month exceeds the threshold established by the Centers for Medicare and Medicaid Services for specialty drugs in the Medicare Part D program;¶~~
~~(c) 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 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;¶~~
~~(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 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~~ORS 646A.689.
Statutory/Other Authority: ~~2018 Or Laws ch 7~~ORS 646A.689
Statutes/Other Implemented: ~~2018 Or Laws ch 7~~ORS 646A.689

ADOPT: 836-200-0531

RULE SUMMARY: Creates a new rule for the new prescription drug section of 836-200-0530; clarifies requirements of manufacturer reporting including: drug strength, package size, and the date the drug was first approved; the description of the marketing used in the drug's introduction; and potential factors used to establish the price of the new drug.

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;¶
(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;¶
(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
Statutes/Other Implemented: ORS 646A.689

ADOPT: 836-200-0532

RULE SUMMARY: Creates a new rule for the patience assistance programs section of 836-200-0530; updates internal references; clarifies “good faith” language.

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 836-200-0530 (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) 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 836-200-0530 (2) 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
Statutes/Other Implemented: ORS 646A.689

AMEND: 836-200-0535

RULE SUMMARY: Updates statutory and internal references; clarifies that the department may submit one or more requests for additional information to the reporting manufacturer; specifies that supporting documentation will be part of the report published to the department's website; automatically grants appropriately submitted requests for additional time, removing the need for the department to evaluate and respond to such requests.

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 836-200-053~~0~~2, the director or director's designee may submit ~~a~~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 ~~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 836-200-053~~0~~2, a prescription drug manufacturer must provide a full and complete written response, including any requested documentation. ~~If any of the requested information or documentation is unavailable to a prescription drug manufacturer,~~Supporting documentation or additional information submitted will be part of the respo~~nse must include an explanation as specified by 836-200-0525~~rt 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 ~~indicate~~dentify th~~at~~e 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) ~~W~~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 ~~2018 Or Laws ch 7~~ORS 646A.689 and OAR 836-200-0515 to 836-200-053~~0~~2, a prescription drug manufacturer m~~ay request~~ust 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.¶
~~(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~~ The department will automatically grant~~s the~~ request~~, denies the request, or grants an amount of additional time less than requested, and explain the basis for the decis~~s submitted in accordance with this section.
Statutory/Other Authority: ~~2018 Or Laws ch 7~~ORS 646A.689
Statutes/Other Implemented: ~~2018 Or Laws ch 7~~ORS 646A.689

AMEND: 836-200-0540

RULE SUMMARY: Updates statutory and internal references; clarifies what constitutes a trade secret and the supporting information required; removes the department's requirement to post an explanation of the right to petition for Attorney General review.

CHANGES TO RULE:

836-200-0540
Information Claimed to be Trade Secret
(1) To request exemption from the disclosures required under OAR 836-200-0545, reporting manufacturers must clearly i~~ndicate~~dentify any information provided to the department that they assert to be conditionally exempt from disclosure under ORS 192.345 as a trade secret, in the following fashion:¶
(a) Each line and informational element in every filed document that is claimed to be a trade secret must be clearly marked by the manufacturer;¶
(b) Each filing that contains information claimed as trade secret by the manufacturer must include, in accordance with standards set forth on the department's website ~~and,~~ for each individual piece of information claimed as trade secret~~, a succinct written explanation of why:~~¶
(A) The name of the data element;¶
(B) A detailed written explanation, including factual information, demonstrating the information is exempt from disclosure ~~that demonstrates all of the following:~~in accordance with the following requirements: ¶
(~~A~~i) The information is not patented;¶
(~~B~~ii) The information is known only to certain individuals within the manufacturer's organization and used in any business the organization conducts;¶
(~~C~~iii) The information has actual or potential commercial value;¶
(~~D~~iv) The information gives the manufacturer an opportunity to obtain a business advantage over competitors who do not know or use it; and¶
(~~E~~v) To the extent required by law, the public interest does not require disclosure of the information.¶
(c) If the manufacturer asserts that disclosure of any information provided in a report is affirmatively prohibited by state or federal law, the manufacturer must clearly indicate the relevant information and explain the basis of this assertion, including citations of the applicable state and federal laws and the facts that support the assertion.¶
(2) The burden of proof to establish that information in a filing is conditionally exempt from disclosure as a trade secret is on the manufacturer submitting the filing. The department shall review the manufacturer's explanations and supporting information, as well as other information available to the department, and determine exemptions from the disclosures required under OAR 836-200-0545 on a case-by-case basis.¶
(3) If the department determines that any information claimed as trade secret by a reporting manufacturer must be disclosed, the department shall notify the manufacturer and provide a written explanation of the department's determination. Within 15 days after receiving this notification, a manufacturer may submit a letter to the director to appeal the department's determination and request reconsideration. The letter must explain the grounds for the request.¶
(4) The director or the director's designee will review appeals provided under ~~sub~~section (3) of this ~~section~~rule and issue a determination within 15 days, or within a time period necessary to obtain legal review, of receiving an appeal letter. If the director's determination would result in the release of information claimed as trade secret by the manufacturer, the department shall notify the manufacturer of the director's decision at least 21 days in advance of disclosing the information as provided under OAR 836-200-0545.¶
(5) If the department exempts information provided by a manufacturer under OAR 836-200-0515 to 836-200-0535 from disclosure under OAR 836-200-0545, the department shall post an explanation of the basis of the exemption to its website along with a general description of the nature of the information exempted.¶
(6) A person may petition the Attorney General, as provided in ORS 192.411, to review a decision by the department to exempt information from disclosure under this ~~section. The department shall include an explanation of the right to petition for Attorney General review in the explanation posted under subsection (5)~~rule.
Statutory/Other Authority: ~~2018 Or Laws ch 7~~ORS 646A.689
Statutes/Other Implemented: ~~2018 Or Laws ch 7~~ORS 646A.689

AMEND: 836-200-0545

RULE SUMMARY: Updates statutory and internal references; removes outdates filing timelines.

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~~, the department shall post to it's website the name of the manufacturer and the prescription drug that is the subject of the filing.¶~~
~~(2) No later than the applicable date as specified in subsection (3) following the receipt of a filing from a manufacturer under OAR 836-200-0530 or a response to a request for additional information from a manufacturer under OAR 836-200-0535~~ to 836-200-0532, the department shall post to it~~'~~s website the ~~information provided by the prescription drug manufacturer in the filing or response.¶~~
~~(3) Each year, the department shall post the information specified in subsection (2) no later than:¶~~
~~(a) March 31, for filings or responses to requests for additional information received between October 1 and December 31 of the previous calendar year;¶~~
~~(b) June 30, for filings or responses to requests for additional information received between January 1 and March 31;¶~~
~~(c) September 30, for filings or responses to requests for additional information received between April 1 and June 30; and¶~~
~~(d) December 31, for filings or responses to requests for additional information received between July 1 and September 30.¶~~
~~(4) As soon as practicable after submission of a request for additional information by the department under OAR 836-200-0535, receipt of a manufacturer's request for additional time to complete a response under 836-200-0535, or submission or receipt of any other correspondence pertaining to the filing from the department or the manufacturer, the department shall post these documents to its website~~name of the manufacturer and the prescription drug that is the subject of the filing.¶
(~~5~~2) Notwithstanding ~~sub~~sections (1)~~ to (4)~~, 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.¶
(~~6~~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: O~~r Laws 2018, ch 7~~RS 646A.689
Statutes/Other Implemented: O~~r Laws 2018, ch 7~~RS 646A.689

AMEND: 836-200-0550

RULE SUMMARY: Updates statutory and internal references.

CHANGES TO RULE:

836-200-0550
Consumer Notices to the Department
(1) The department shall make available a telephone line and an online mechanism to receive notices from members of the public about increases in the cost of prescription drugs. The department shall prominently display the telephone and online contact information on its website.¶
(2) The department shall include a summary of the notices received in its annual report to the Legislature for that calendar year under ~~2018 Or Laws ch 7~~ORS 646A.689.
Statutory/Other Authority: ~~2018 Or Laws ch 7~~ORS 646A.689
Statutes/Other Implemented: ~~2018 Or Laws ch 7~~ORS 646A.689

AMEND: 836-200-0555

RULE SUMMARY: Updates statutory and 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 836-200-053~~0~~2 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 O~~regon Laws 2018, chapter 7, section 2~~RS 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 O~~regon Laws 2018, chapter 7, section 2~~RS 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 O~~regon Laws 2018, chapter 7, section 2~~RS 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: O~~r Laws 2018, ch 7~~RS 646A.689
Statutes/Other Implemented: O~~r Laws 2018, ch 7~~RS 646A.689

AMEND: 836-200-0560

RULE SUMMARY: Updates statutory and internal references; clarifies that required reports be submitted in a timely manner.

CHANGES TO RULE:

836-200-0560
Civil Penalties
(1) The director may impose civil penalties on reporting manufacturers for violations of ~~2018 Or Laws ch 7 and~~ORS 646A.689 or OAR 836-200-0500 to 836-200-0560 including the following:¶
(a) Failing to provide required information, or providing inaccurate or incomplete information;¶
(b) Failing to respond in a timely manner to a written request by the department for additional information; or¶
(c) Failing to submit timely required reports.¶
(2) For a reporting manufacturer's first violation of ~~2018 Or Laws ch 7 and~~ORS 646A.689 or OAR 836-200-0500 to 836-200-0560, the civil penalties imposed under this section will adhere to the following schedule:¶
(a) For failing to provide required information or providing inaccurate or incomplete information, and for each missing, inaccurate or incomplete data element. No greater than $500 per day of violation for the first 30 days, and no greater than $1,000 per day of violation thereafter.¶
(b) For failing to respond in a timely manner to a written request by the department for additional information. No greater than $1,500 per day of violation for the first 30 days, and no greater than $3,000 per day of violation thereafter.¶
(c) For failing to submit timely required reports. No greater than $2,500 per day of violation for the first 30 days, and no greater than $5,000 per day of violation thereafter.¶
(3) For reporting manufacturers that have previously violated ~~2018 Or Laws ch 7~~ORS 646A.689 or OAR 836-200-0500 to 836-200-0560, the civil penalties imposed under this section will adhere to the following schedule:¶
(a) For failing to provide required information or providing inaccurate or incomplete information, and for each missing, inaccurate or incomplete data element. No greater than $1,000 per day of violation.¶
(b) For failing to respond in a timely manner to a written request by the department for additional information. No greater than $3,000 per day of violation.¶
(c) For failing to submit timely required reports. No greater than $5,000 per day of violation.¶
(4) For any other violation, including any violation constituting a breach of the good faith expectations specified in OAR 836-200-05~~0~~425, any violation committed with intent to obstruct the department's administration of ~~2018 Or Laws ch 7 and~~ORS 646A.689 or OAR 836-200-0500 to 836-200-0560, or any violation committed with intent to engage in conduct injurious to the public, the civil penalty imposed under this section will be no greater than $10,000 per day of violation.
Statutory/Other Authority: ~~2018 Or Laws ch 7~~ORS 646A.689, 646A.692
Statutes/Other Implemented: ~~2018 Or Laws ch 7~~ORS 646A.689, 646A.692