

Second Draft HB 4005 Rules

836-200-0500 Definitions

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

(1) "Course of treatment" means the total dosage of a drug that would be prescribed in a single prescription to a patient taking the drug as recommended by its prescribing label as approved by the federal 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" means knowingly false or misleading representations or statements.

(4) "Incomplete information" means representations or statements that fail to provide all available information required in a report or in response to a request for additional information under 836-200-0502 to 836-200-0510.

(5) "Net yearly wholesale acquisition cost increase" means the increase in the wholesale acquisition cost of a drug over the course of a calendar year. For a drug on the market for the entire year, the net yearly increase is calculated by subtracting the wholesale acquisition cost on January 1 of the year from the wholesale acquisition cost on December 31 of the same year. For a new prescription drug introduced after January 1 of any year, the net yearly increase is calculated by subtracting the wholesale acquisition cost on the drug's introduction date from the wholesale acquisition cost on December 31 of the same year.

(6) "New Prescription Drug" means a prescription drug that has received initial approval under an original Type 1 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 will be considered a new prescription drug. A new prescription drug's introduction date is the date of its initial market entry approval.

(7) "One-month supply" means the total daily dosage units of a prescription drug recommended by its prescribing label as approved by the federal Food and Drug Administration for 30 calendar 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 one-month supply.

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

(9) "Public Funds" has the meaning given that term in ORS 295.001(16). (refers to "public official" defined in 244.020(15) means any funds granted, loaned or otherwise provided by a national, state, local or foreign government entity.

(10) "Reporting manufacturer" means an entity

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

Commented [A1]: How does this apply to weight or other patient specific dosing, as in hemophilia or diabetes, respectively ?

Commented [A2]: this qualification is necessary to assure the distinction between list and net increase is maintained

Commented [A3]: How does this apply to weight or other patient specific dosing, as in hemophilia or diabetes, respectively ?

Commented [A4]: Again, important to distinguish the WAC from net increase and that this may not reflect an increase in cost to the patient.

- (b) That engages in the manufacture of drugs as defined by 2018 Or Laws ch 7; and
- (c) That sets or changes the wholesale acquisition cost of the drugs it manufactures.
- (11) "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-current plan year Final Call Letter from the Centers for Medicare and Medicaid Services.
- (12) "Timely" and "timely manner" mean in compliance with the required deadlines for reporting and providing responses to requests for additional information detailed in 826-200-0501 to 826-200-0510.
- (13) "Wholesale acquisition cost" has the meaning given the term in 42 U.S.C. 1395w-3a(c)(6)(B).

Commented [A5]: This threshold reflect that the federal amount changes from year to year and also conform to §836-200-0503

836-200-0501 Account Generation Requirement

- (1) No later than March 15, 2019, all reporting manufacturers required to file a report by July 1, 2019 under 836-200-0502 (1) must create an online account with the department.
- (2) Beginning in 2020 and for any subsequent year, reporting manufacturers without an online account with the department that are required to file a report by March 15 of that year under 836-200-0502 (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-prescription drug report under 836-200-0503 must create an online account with the department no later than 30 calendar days prior to submitting the report.

Commented [A6]: What will be the verification process? Will it be a secure creation?

836-200-0502 Threshold for Reporting Drug Price Increase

- (1) No later than July 1, 2019, a reporting manufacturer must report the information described in 836-200-0505(2) to the department regarding each prescription drug for which:
 - (a) The ~~price~~ wholesale acquisition cost 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 wholesale acquisition cost ~~price~~ of the prescription drug described in paragraph (a) of this subsection during 2018.
- (2) Beginning March 15, 2020, no later than March 15 annually, a reporting manufacturer must report to the department the information described in 836-200-0505(2) regarding each prescription drug for which:
 - (a) The wholesale acquisition cost ~~price~~ 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 wholesale acquisition cost ~~price~~ of the prescription drug described in paragraph (a) of this subsection over the course of the previous calendar year.

Commented [A7]: "Price" itself is not a defined term. We recommend changing the term in this section to "wholesale acquisition cost" or stating a definition of "price" as the "Wholesale acquisition cost."

Commented [A8]: "Price" itself is not a defined term. We recommend changing the term in this section to "wholesale acquisition cost" or stating a definition of "price" as the "Wholesale acquisition cost."

Commented [A9]: "Price" itself is not a defined term. We recommend changing the term in this section to "wholesale acquisition cost" or stating a definition of "price" as the "Wholesale acquisition cost."

Commented [A10]: "Price" itself is not a defined term. We recommend changing the term in this section to "wholesale acquisition cost" or stating a definition of "price" as the "Wholesale acquisition cost."

836-200-0503 Threshold for Reporting New Specialty Drug

Beginning March 15, 2019, 30 days or less after a manufacturer introduces a new prescription drug for sale in the United States at a price for a 30 [calendar](#) day supply or for a course of treatment

lasting less than one month that exceeds the threshold established by the Centers for Medicare and Medicaid Services for specialty drugs in the Medicare Part D program for the calendar year including the drug's introduction date, the manufacturer must report to the department the information described in 836-200-0505 (4).

836-200-0504 Expectations of Reporting Manufacturers

(1) Reporting manufacturers [must shall](#) make a good-faith effort to include all of the information required in a report or a response to a request for additional information under 836-200-0505 and 836-200-0510, 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 836-200-0505 and 836-200-0510 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 a thorough explanation. The explanation must include a description of the information and the circumstances contributing to the manufacturer's inability to meet the requirement.

~~(3) If only a portion of the information required in a report or a response to a request for additional information under 836-200-0505 and 836-200-0510 is available to the manufacturer due to circumstances outside the manufacturer's control, the manufacturer must supply the available portion and include a description of the missing information and the circumstances contributing to the manufacturer's inability to fully meet the requirement.~~

(4) If the information required in a report or a response to a request for additional information under 836-200-0505 and 836-200-0510 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.

(5) Reporting manufacturers must [make a 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, ~~and not excessive or extraneous.~~

(6) A reporting manufacturer's failure to comply with the expectations specified in (1)-(5) of this section may result in an inaccurate or incomplete report and may subject the manufacturer to a civil penalty under 836-200-0560.

836-200-0505 Form and Manner Requirements for Drug Pricing Reporting

(1) General requirements. All reports submitted by drug manufacturers under this section must:

- (a) Be provided in an electronic format specified by the department;
- (b) Be provided via an electronic system specified by the department;
- (c) Be machine readable;
- (d) Be capable of being reduced to written form;

Commented [A11]: Manufacturers data collection systems may not collect much of the desired information, and US affiliates of global parent companies, may have other larger challenges in accessing information and, even where available, appropriately apportioning the costs across US market activities. This inability must be taken into account in the language of the rule, so as to recognize these limitations as part of a good faith effort.

Commented [A12]: This is redundant to the second point, and could cause some confusion.

Commented [A13]: Believe this also could be eliminated because of redundancy of the first, but if not, suggested edits should be allowed.

- (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 836-200-0520;
- (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 836-200-0502, the report furnished to the department must include ~~at least~~ the following information, along with any documentation necessary to support the information reported under this subsection:

- (a) The full trade name, full chemical name or biologic product name, and generic product identifier of the drug;
- (b) The ~~WAC~~ price of the drug at the beginning of the calendar year preceding the report;
- (c) The ~~price-WAC~~ 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;
- (g) The length of time the prescription drug has been on the market;
- (h) The factors that contributed to the price increase, ~~including but not limited to 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 of the prescription drug available for sale in the United States ~~during the reported time period 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:~~
 - A. To manufacture the prescription drug;
 - B. To market the prescription drug, ~~including but not limited to 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 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, by calendar year, in the price of the prescription drug during the previous five calendar years, or any portion of the past five years if the drug has been

Commented [A14]: Carryover the stipulation that "price" is the "wholesale acquisition cost" to this section.

Commented [A15]: We believe this exceeds the scope of the statute. It should be limited to net increases in price, NOT cumulative increases.

Commented [A16]: We believe this also exceeds the scope of the statute. The statute only requires the "factors contributing" to the price increase.

Commented [A17]: We believe this exceeds the scope of the statute. HB 4005 only requires reporting of costs, not the multiple sources.

Commented [A18]: Once again, this exceeds the scope of the statute, which only states "marketing costs."

available for less than five years. For drugs that have been available for less than five years, the manufacturer shall calculate the net increase in the drug's introductory year by subtracting the introductory price specified in (n) from the price of the drug on December 31 of the same year;

(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

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 836-200-0502, the report furnished to the department under subsection (2) of this section must have an appendix that includes at least the following information:

(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. ~~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 836-200-0502, 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.~~

(4) Prescription Drug Reporting – New Specialty-Prescription Drug

For drugs meeting the conditions specified in 836-200-0503, the report furnished to the department must include the following information:

(a) The full trade name, full chemical name or biologic product name, and generic product identifier of the drug;

(b) The price-WAC and dosage of the drug the reporting manufacturer used to determine that the price of the drug for a 30 calendar day supply or for a course of treatment lasting less than one month exceeds the threshold established by the Centers for Medicare and Medicaid

Commented [A19]: Somewhere there should be language that acknowledges that Wholesale Acquisition Cost does not reflect the net cost of the product as it works its way through the supply chain. At the very least, (q) should permit the manufacturer to counter the assumptions associated with reference to WAC, and to have this information actually mitigate the state's/director's conclusions about the price increases and report to the legislature,

Commented [A20]: Statute only requires "number of consumers."

Commented [A21]: This exceeds the scope of the PAP reporting requirements of the statute. Moreover, this information is not knowable unless the manufacturer has access to the books of the independent patient assistance program, which they would not have. If this information was wanted by the Legislature, they would have required the independent authorities to report.

Services for specialty drugs in the Medicare Part D program for the calendar year including the drug's introduction date;

(c) A description of the marketing used in the introduction of the new prescription drug ~~including but not limited to spending on direct to consumer marketing such as paid advertising, as well as spending to promote the drug to physicians, if applicable;~~

Commented [A22]: Exceeds scope of the statute.

(d) The methodology used to establish the price of the new prescription drug ~~including but not limited to 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;~~

Commented [A23]: Exceeds scope of the statute.

(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;~~

Commented [A24]: Exceeds scope of the statute.

836-200-0510 Additional Information Requests

(1) Within 60 calendar days of receiving a report from a prescription drug manufacturer in accordance with 836-200-0502 to 836-200-0505, the director may submit a written request for supporting documentation or additional information to the manufacturer.

(2) The director's request shall be limited to information necessary to clarify or substantiate the material previously reported, or to enable the director 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.

(3) Within 60 calendar days of receiving the director's request for supporting documentation or additional information following a report provided in accordance with 836-200-0502 to 836-200-0505, 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, the response must include an explanation as specified by 836-200-0504. If the manufacturer asserts that any of the requested information is conditionally exempt from disclosure as a trade secret, the manufacturer must clearly indicate that information and provide an explanation, as specified under 836-200-520, for each piece of information that is claimed to be exempt from disclosure.

(4) Within 15 calendar days of receiving the director's request for supporting documentation or additional information following a report provided in accordance with 2018 Or Laws ch 7 and 836-200-0502 to 836-200-0505, a prescription drug manufacturer may request up to 30 additional calendar 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 calendar days of receiving a manufacturer's request for additional time, the director shall respond to the manufacturer in writing to specify that the director grants the request, denies the request, or grants an amount of additional time less than requested, and explain the basis for the decision.

836-200-0520 Information Claimed to be Trade Secret

~~(1) For reports and responses to requests for additional information provided to the department by reporting manufacturers, the department shall consider the following informational elements to be eligible for conditional exemption from disclosure as a trade secret:~~

~~(a) Of the informational elements required by 836-200-0505 (2): (h), (k), (l), (m), (p), (q);~~

~~(b) Of the informational elements required by 836-200-0505 (3): (b);~~

~~(c) Of the informational elements required by 836-200-0505 (4): (c), (d), (f).~~

~~Reporting manufacturers may request that these elements be exempted from the disclosures required under 836-200-0530. Other required informational elements included in reports and responses to requests for additional information provided to the department by reporting manufacturers will be disclosed as required under 836-200-0530. If a manufacturer believes a specific element requested in the report is a trade secret consistent with ORS 192.345 and the federal Defense of Trade Secrets Act (DTSA), 18 U.S.C. § 1836, et seq., then the manufacturer shall submit a request for trade secret exemption to the director.~~

(2) To request exemption from the disclosures required under 836-200-0530, reporting manufacturers must clearly indicate any information provided to the department that is eligible for exemption from disclosure under (1) that they assert to be conditionally exempt from disclosure under ORS 192.345 and the DTSA 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 piece of information claimed as trade secret, a succinct written explanation of why the information is exempt from disclosure that demonstrates all of the following:

1. The information is not patented;
2. The information is known only to certain individuals within the manufacturer's organization and used in a business the organization conducts;
3. The information has actual or potential commercial value;
4. The information gives the manufacturers an opportunity to obtain a business advantage over competitors who do not know or use it; and
5. 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.

~~(3) 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

Commented [A25]: We believe this section unduly weakens the trade secret protections provided for in HB 4005. The statute guaranteed broad protections of any information believed to be a conditionally exempt as a trade secret, while this regulation discriminates based on specific sections of the law and regulations. This is an overreach by the Department. We continue to believe that trade secret protections must be consistent with the federal Defense of Trade Secrets Act (DTSA), 18 U.S.C. § 1836, et seq. In the DTSA, information is a trade secret if it has commercial value, and the company or person has taken reasonable steps to ensure its security. The DTSA gives the holder of trade secrets, the power to implement strict policies maintaining confidentiality of trade secrets to prevent litigation.

However, these regulations imply that the state believes information is not a protected trade secret unless proven otherwise. This is fundamentally at odds with federal law. As we recommended in previous comments to the Department, the trade secret provisions of Nevada SB 539, provide for an appropriate balance between the state law and the DTSA.

review the manufacturer's explanations and determine exemptions from the disclosures required under 836-200-0530 on a case-by-case basis.

(4) If the department determines that any information claimed as trade secret by a reporting manufacturer must be disclosed, the department shall notify the manufacturer at least ~~15-60-~~ days in advance of disclosing the information as provided under 836-200-0530 and provide a written explanation of the department's determination.

(5) If the department exempts information provided by a manufacturer under 836-200-0502 to 836-200-0510 from disclosure under 836-200-0530, 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 or manufacturer 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 (7).

Commented [A26]: The Department should provide for a minimum of 60-days notice in advance of disclosing information. The DTSA provides for a legal remedy for violations of the Act. Fifteen days would not provide enough time for manufacturers to obtain counsel, review the Department's determination, and file the appropriate legal documents in accordance with federal and state law.

836-200-0530 Public Disclosure of Prescription Drug Manufacturer Filings

(1) As soon as practicable after receiving a filing from a prescription drug manufacturer under 836-200-0505, the department shall post to its website the name of the manufacturer and the prescription drug that is the subject of the filing.

(2) No later than 90 days after receiving a filing from a manufacturer under 836-200-0505, the department shall post to its website the information provided by the prescription drug manufacturer in the filing.

(3) No later than 60 days after receiving a response to a request for additional information from a manufacturer under 836-200-0510, the department shall post the response to its website.

(4) As soon as practicable after submission of a request for additional information by the department under 836-200-0510, receipt of a manufacturer's request for additional time to complete a response under 836-200-0510, 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.

(5) No information ~~determined by the department to be~~ exempt from disclosure under 836-200-0520 or any other provision of state or federal law shall be included in the information posted to the department's website.

836-200-0540 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) ~~If the department receives notices under this section in a calendar year,~~ 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.

836-200-0550 Assessments Against Prescription Drug Manufacturers

(1) Once annually, no later than October 1, ~~all reporting~~ manufacturers required to submit a report under 836-200-0502 or 836-200-0503 will pay an assessment of \$400.

(2) No later than October 1 annually, reporting manufacturers that have filed one or more reports under 836-200-0502 ~~or 836-200-0503~~ since October 1 of the prior year must pay an additional assessment for each report filed. The director shall determine the amount of the assessment by dividing the amount of revenue needed to cover expenses to be incurred by the department in administering 2018 Or Laws ch 7 Section 2 and 836-200-0500 to 836-200-0550 by the total number of filings, minus the revenue collected under subsection (1). The director shall determine the amount of revenue needed by considering the legislatively approved expenditures for administration of 2018 Or Laws ch 7 Section 2 and 836-200-0500 to 836-200-0550, as well as the timing of cash revenues and expenditures.

(3) The revenue collected under subsections (1) and (2) of this section must be used solely for expenses incurred in the administration of 2018 Or Laws ch 7 Section 2 and 836-200-0500 to 836-200-0550.

(4) 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.

836-200-0560 Civil Penalties

(1) The director may impose civil penalties on reporting manufacturers for violations of 2018 Or Laws ch 7 and 836-200-0500 to 836-200-0560 including the following:

- (a) Failing to submit required reports or notices;
- (b) Failing to provide information required;
- (c) Failing to respond in a timely manner to a written request by the department for additional information; or
- (d) Providing inaccurate or incomplete information.

(2) The director shall adhere to the following schedule in imposing civil penalties under this section:

- (a) No greater than \$250 per day of violation for an inadvertent or unintentional violation;
- (b) No greater than \$10,000 per day of violation for a knowing violation, except the first such violation shall be limited to a fine of \$1000.

(3) The civil penalties imposed under this section may be remitted, mitigated, or suspended ~~at~~by the director's ~~discretion in the event it is found the manufacturer made a good faith effort to~~ comply with the regulations of this section.

836-053-0473 Required Materials for Rate Filing for Individual or Small Employer Health Benefit Plans [PROPOSED CHANGES IN RED]

(1) Every insurer that offers a health benefit plan for small employers or an individual health benefit plan must file the information specified in section (2) of this rule when the insurer files with the director a schedule or table of premium rates for approval.

(2) A schedule or table of base premium rates filed under section (1) of this rule must include sufficient information and data to allow the director to consider the factors set forth in ORS 743.018(4) and (5). The filing must include all of the following separately set forth and labeled as indicated:

(a) A filing description labeled "Filing Description." The filing description must:

(A) Be submitted in the form of a cover letter;

(B) Provide a summary of the reasons an insurer is requesting a rate change and the minimum and maximum rate impact to all groups or members affected by the rate change, including the anticipated change in number of enrollees if the proposed premium rate is approved;

(C) Explain the rate change in a manner understandable to the average consumer; and

(D) Include a description of any significant changes the insurer is making to the following:

(i) Rating factor changes; and

(ii) Benefit or administration changes.

(b) Rate tables and factors labeled "Rate Tables and Factors." The rate tables and factors must:

(A) Include base and geographic average rate tables;

(B) Identify factors used by the insurer in developing the rates;

(C) Explain how the information is used in the development of rates;

(D) Include a table of rating factors reflecting ages of employees and dependents and geographic area.

(E) Include rate tier tables if base rates are not provided by rating tier;

(F) Indicate whether the rate increases are the same for all policies;

(G) Explain how the rate increases apply to different policies;

(H) Provide the entire distribution of rate changes and the average of the highest and lowest rates resulting from the application of other rating factors;

(I) Within the geographic average rate table, include family type, geographic area and the average of the highest and lowest rates resulting from the application of other rating factors;

(J) Within the base rate table, include the base rates for each available plan and sufficient information for determination of rates for each health benefit plan, including but not limited to:

(i) Each age bracket;

(ii) Each geographic area;

(iii) Each rate tier;

(iv) Any other variable used to determine rates; and

(v) If the rates vary more frequently than annually, separate rates for each effective date of change or sufficient information to permit the determination of the rates and the justification for the variation in the rates;

(K) For a grandfathered small group health benefit plan, include the following factors if applied by the insurer:

(i) Contribution;

- (ii) Level of participation;
 - (iii) Family composition;
 - (iv) The level at which enrollees or dependents engage in health promotion, disease prevention or wellness programs;
 - (v) Duration of coverage in force;
 - (vi) Any adjustment to reflect expected claims experience; and
 - (vii) Age.
- (L) For a grandfathered individual health benefit plan, include the following factors to the extent applied by the insurer:
- (i) Family composition; and
 - (ii) Age; and
- (M) For a non-grandfathered health benefit plan, include the following factors if applied by the insurer:
- (i) Tobacco usage; and
 - (ii) The level at which enrollees or dependents engage in health promotion, disease prevention, or wellness programs.
- (c) An actuarial memorandum consistent with the requirements of both state and federal law labeled "Actuarial Memorandum." The actuarial memorandum must include all of the following:
- (A) A description of the benefit plan and a quantification of any changes to the benefit plan as set forth in subsection (e) of this section;
 - (B) A discussion of assumptions, factors, calculations, rate tables and any other information pertinent to the proposed rate, including an explanation of the impact of risk corridors, risk adjustment and state and federal reinsurance on the proposed rate;
 - (C) A description of any changes in rating methodology supported by sufficient detail to permit the department to evaluate the effect on rates and the rationale for the change;
 - (D) The range of rate impact to groups or members including the distribution of the impact on members;
 - (E) A cross-reference of all supporting documentation in the filing in the form of an index and citations;
 - (F) The dated signature of the qualified actuary or actuaries who reviewed and authorized the rate filing; and
 - (G) The contact information of the filer.
- (d) A description of the development of the proposed rate change or base rate that is included as an exhibit to the filing and labeled "Exhibit 1: Development of Rate Change." The development of rate change is the core of the rate filing and must:
- (A) Explain how the proposed rate or rate change was calculated using generally accepted actuarial rating principles for rating blocks of business;
 - (B) Include actual or expected membership information;
 - (C) Identify a proposed loss ratio for the rating period;
 - (D) Include a rate renewal calculation that:
 - (i) Begins with an assumed experience period of at least one year and ends within the immediately preceding year; or
 - (ii) If more recent data is available, uses the one-year period that ends with

the most recent period for which data is available;

(E) Show adjustments to total premium earned during the experience period to yield premium adjusted to current rates;

(F) Include a projection of premiums and claims for the period during which the proposed rates are to be effective; and

(G) Provide a renewal projection using claims underlying the projection that reflect an assumed medical trend rate and other expected changes in claims cost, including but not limited to, the impact of benefit changes or provider reimbursement.

(e) A description of changes to covered benefits or health benefit plan design that is included as an exhibit to the rate filing and labeled "Exhibit 2: Covered Benefit or Plan Design Changes." The covered benefit or plan design changes must:

(A) Explain all applicable benefit and administrative changes with a rating impact, including but not limited to:

(i) Covered benefit level changes;

(ii) Member cost-sharing changes;

(iii) Elimination of plans;

(iv) Implementation of new plan designs;

(v) Provider network changes;

(vi) New utilization or prior authorization programs;

(vii) Changes to eligibility requirements; and

(viii) Changes to exclusions; and

(B) Show any change in the plan offerings that impacts costs or coverage provided not otherwise provided pursuant to subsection (e)(A) of this section.

(f) The average annual rate change included as an exhibit to the filing and labeled "Exhibit 3: Average Annual Rate Change." The average annual rate change must:

(A) Provide the average, maximum and minimum annual rate changes for each effective date in the filing;

(B) Include a meaningful distribution of rate changes; and

(C) Provide an estimate of contributing factors to the annual rate change.

(g) Trend information and projection included as an exhibit to the filing and labeled "Exhibit 4: Trend Information and Projection." The trend information and projection must:

(A) Describe how the assumed future growth of medical claims (the medical trends rate) was developed based on generally accepted actuarial principles; and

(B) At a minimum, include historical monthly average claim costs for the two years immediately preceding the period for which the proposed rate is to apply. If the carrier's structure does not include claims cost, the carrier must submit this information based on allocated costs.

(h) A statement of administrative expenses and premium retention included as an exhibit to the filing and labeled "Exhibit 5: Statement of Administrative Expenses and Premium Retention." The statement of administrative expenses and premium retention must:

(A) Include a completed chart displaying the five-year trend of administrative costs and enumerating the insurer's administrative expenses detailed as follows:

(i) Salaries;

(ii) Rent;

- (iii) Advertising;
 - (iv) General office expenses;
 - (v) Third party administration expenses;
 - (vi) Legal and other professional fees; and
 - (vii) Travel and other administrative costs not accounted for under a category in subsections (h)(B)(i)–(vi) of this section;
- (B) Explain how the insurer allocates administrative expenses for the filed line of business;
- (C) Include a description of the amount retained by the insurer to cover all of the insurer’s non-claim costs including expected profit or contribution to surplus for a nonprofit entity reported on a percentage of premium and per member per month basis; and
- (D) Demonstrate the total premium retention for the filing, including total administrative expenses reported under subsection (h)(B) of this section, commissions, taxes, assessments and margin.
- (i) Plan relativities included as an exhibit to the filing and labeled “Exhibit 6: Plan Relativities.” Plan relativities must:
- (A) Explain the presentation of rates for each benefit plan;
 - (B) Explain the methodology of how the benefit plan relativities were developed; and
 - (C) Demonstrate the comparison and reasonableness of benefits and costs between plans.
- (j) Information about the insurer’s financial position included as an appendix to the filing and labeled “Appendix I: Insurer’s Financial Position.” The insurer’s financial position may reference documents filed with the department and available to the public, including the insurer’s annual statement. The insurer’s financial position must include:
- (A) Information about the insurer’s financial position including but not limited to the insurer’s:
 - (i) Profitability;
 - (ii) Surplus;
 - (iii) Reserves; and
 - (iv) Investment earnings; and
 - (B) An analysis, explanation and determination of whether the proposed change in the premium rate is necessary to maintain the insurer’s solvency or to maintain rate stability and prevent excessive rate increases in the future.
 - (k) Changes in the insurer’s health care cost containment and quality improvement efforts included as an appendix to the filing and labeled “Appendix II: Cost Containment and Quality Improvement Efforts. The cost containment and quality improvement efforts must:
 - (A) Explain any changes the insurer has made in its health care cost containment efforts and quality improvement efforts since the insurer’s last rate filing for the same category of health benefit plan.
 - (B) Describe significant new health care cost containment initiatives and quality improvement efforts;
 - (C) Include an estimate of the potential savings from the initiatives and efforts described in subsection (2)(g)(B) of this section together with an estimate of the

cost or savings for the projection period; and

(D) Include information about whether the cost containment initiatives reduce costs by eliminating waste, improving efficiency, by improving health outcomes through incentives, by elimination or reduction of covered services or reduction in the fees paid to providers for services.

(I) Information regarding prescription drug costs included as an appendix to the filing and labeled "Appendix III: Prescription Drug Costs." This document must include, for drugs reimbursed by the insurer under both pharmacy and hospital benefits for policies or certificates issued in this state and for the experience period covered in the filing, all of the following:

(A) The 25 most frequently prescribed drugs;

(B) The 25 most costly drugs. In determining this list, the insurer must consider total annual spending, including the net impact of any rebates or other price concessions if applicable;

(C) The 25 drugs that have caused the greatest increase in total plan spending from one year to the next. In determining this list, the insurer must consider the net impact on total plan spending of any rebates or other price concessions if applicable;

(D) The impact of the costs of prescription drugs on premium rates, on a per member, per month basis, including the net impact of any rebates or other price concessions if applicable.

(m) Certification of compliance labeled "Certification of Compliance." The certification of compliance must:

(A) Comply with OAR 836-010-0011; and

(B) Certify that the filing complies with all applicable Oregon statutes, rules, product standards and filing requirements.

(n) Third party filer's letter of authorization labeled "Third Party Authorization." If the filing is submitted by a person other than the insurer to which the filing applies, the filing must include a letter from the insurer that authorizes the third party to:

(A) Submit the filing to the department;

(B) Correspond with the department on matters pertaining to the rate filing; and

(C) Act on the insurer's behalf regarding all matters related to the filing.

(3) (a) Within 10 [calendar](#) days after receiving a proposed table or schedule of premium rate filing, the director must:

(A) Determine whether the proposed table or schedule of premium rate filing is complete. If the director determines that a filing is complete, the director must review the proposed schedule or table of premium rates in accordance with ORS 742.003, 742.005, 742.007 and 743.018. If the director determines that the filing is not complete, the director must notify the insurer in writing that the filing is deficient and give the insurer an opportunity to provide the missing information.

(B) If the filing is complete, open the 30-day public comment period. For purposes of determining the beginning of the public comment period, the date the carrier files a proposed schedule or table of premium rates shall be the date the director determines that the filing is complete.

(b) Within 10 [calendar](#) days after the close of the public comment period, the director must issue a decision approving, disapproving or modifying the proposed table or schedule of premium rate filing.

(4) At the beginning of the public comment period, the director must post on the Insurance Division website all materials submitted under section (2) of this rule.