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TEMPORARY ADMINISTRATIVE ORDER

INCLUDING STATEMENT OF NEED & JUSTIFICATION

ID 1-2026

CHAPTER 836

DEPARTMENT OF CONSUMER AND BUSINESS SERVICES
INSURANCE REGULATION

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ARCHIVES DIVISION
SECRETARY OF STATE
& LEGISLATIVE COUNSEL

FILING CAPTION: Temporary Rules to Implement ORS 646A.689

EFFECTIVE DATE: 02/13/2026 THROUGH 08/11/2026

AGENCY APPROVED DATE: 02/12/2026

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NEED FOR THE RULE(S):

In 2018, the Oregon Legislature adopted the Prescription Drug Price Transparency Act (Oregon Laws 2018, chapter 7), colloquially known as HB 4005. The bill requires prescription drug manufacturers (manufacturers) and insurance companies to report specified information to the Oregon Department of Consumer and Business Services (the department). One major component of reporting under HB 4005 requires manufacturers to report information related to prescription drugs where the price increased 10% or more over the preceding calendar year.

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

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

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

JUSTIFICATION OF TEMPORARY FILING:

(1) If these amendments are not adopted, the current rule language would be inconsistent with current statutory requirements for manufacturers to report price increase information to the department.

(2) Manufacturers who rely on the current rule language would be at risk of failing to comply with Oregon law by not reporting required information to the department. This could expose manufacturers to civil penalties. Additionally, failure to collect this information would harm the department's ability to implement the Oregon Drug Price Transparency Program.

(3) Annual reporting to the department is due in March, which would make it difficult if not impossible for the department to complete the process of permanent rulemaking before manufacturers would be obligated to report information. The department is adopting this temporary rule to facilitate implementation of annual price increase reporting under HB 4005 in 2026, with a plan to conduct permanent rulemaking for reports due in 2027.

(4) The amended rule text will accurately reflect the requirements of HB 4005 following the judgment of the Ninth Circuit and will provide accurate guidance to reporting entities on their obligations under Oregon law in 2026.

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:

dfr.oregon.gov/laws-rules/Pages/proposed-rules.aspx.

RULES:
836-200-0515, 836-200-0530

AMEND: 836-200-0515

RULE SUMMARY: Delineates drugs subject to annual price increase reporting. Amended in 2025 to make reports voluntary following District Court injunction of mandatory reporting. This rulemaking reverts the voluntary language back to mandatory reporting language and timeframe consistent with ORS 646A.689 (2) and (3).

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; and¶
(b) There was a net yearly increase of 10 percent or more in the price of the prescription drug described in subsection (a) of this section during 2018.¶
(2) Beginning ~~February~~March 1~~6~~5, 2024~~0~~, no later than March 15 annually, a reporting manufacturer m~~ay voluntarily~~ust report to the department the information described in OAR 836-200-0530(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; and¶
(b) There was a net yearly increase of 10 percent or more in the price of the prescription drug described in subsection (a) of this section over the course of the previous calendar year.
Statutory/Other Authority: ORS 646A.689
Statutes/Other Implemented: ORS 646A.689

AMEND: 836-200-0530

RULE SUMMARY: Defines the form and required content of reports by prescription drug manufacturers to the department. Amended in 2025 to make annual price increase reports voluntary following District Court injunction of mandatory reporting. This rulemaking reverts the voluntary language back to the original mandatory reporting language consistent with ORS 646A.689 (2) and (3).

CHANGES TO RULE:

836-200-0530
Form and Manner Requirements for Drug Pricing Reporting
(1) General requirements. All reports submitted by drug manufacturers under ORS 646A.689 must:¶
(a) 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, athe report ~~may be voluntarily~~ furnished to the department ~~and~~must include the following information, along with any documentation to support the information reported under this section:¶
(a) The full trade name of the drug, full chemical name or biologic product name of the drug, and recognized industry standard drug identification information for the drug as specified on the department's website;¶
(b) The price of the drug at the beginning of the calendar year preceding the report;¶
(c) The price of the drug at the end of the calendar year preceding the report;¶
(d) The highest and lowest prices of the drug at any point during the calendar year preceding the report;¶
(e) The increase in the price of the drug over the preceding calendar year, expressed as a percentage;¶
(f) The price and dosage of the drug the reporting manufacturer used to determine that the drug cost $100 or more for a one-month supply;¶
(g) The length of time the prescription drug has been on the market;¶
(h) The factors that contributed to the price increase, including a narrative description and explanation of all major financial and nonfinancial factors that influenced the decision to increase the wholesale acquisition cost of the drug product and to decide on the amount of the increase;¶
(i) The name of any generic version or biosimilar of the prescription drug available for sale in the United States at the time of the report;¶
(j) The research and development costs associated with the prescription drug that were paid using public funds, including all available information about the sources and uses of these public funds;¶
(k) The direct costs incurred and specific total dollars expended by the manufacturer in the previous calendar year:¶
(A) To manufacture the prescription drug;¶
(B) To market the prescription drug, including spending on direct-to-consumer marketing such as paid advertising, as well as spending to promote the drug to physicians;¶
(C) To distribute the prescription drug; and¶
(D) For ongoing safety and effectiveness research associated with the prescription drug.¶
(l) The total sales revenue for the prescription drug during the previous calendar year;¶
(m) The manufacturer's net profit attributable to the prescription drug during the previous calendar year;¶
(n) The introductory price of the prescription drug when it was approved for marketing by the United States Food and Drug Administration;¶
(o) The net yearly increase, if any, by calendar year, in the price of the prescription drug during the previous five calendar years;¶
(p) The 10 highest prices paid for the prescription drug during the previous calendar year in any country other than the United States, expressed in dollars according to the prevailing exchange rate at the time of the report; and¶
(q) Any other information that the manufacturer deems relevant to the price increase and that the manufacturer deems will assist the director to complete a review of a drug price under ORS 646A.689.
Statutory/Other Authority: ORS 646A.689

Statutes/Other Implemented: ORS 646A.689