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**STATEMENT OF NEED AND FISCAL IMPACT WORKSHEET**

A Notice of Proposed Rulemaking Hearing or a Notice of Proposed Rulemaking accompanies this form.  
*For internal agency use only. Not a valid filing form.*

Dept. of Consumer & Business Services, Division of Financial Regulation

836

Agency and Division

Administrative Rules Chapter Number

**RULE CAPTION**

Establishment of Oregon Prescription Drug Price Transparency Program, reporting requirements, fees, civil penalties

*Not more than 15 words.*

**In the Matter of:**

Establishment of Oregon Prescription Drug Price Transparency Program, reporting requirements, fees, civil penalties

**Statutory Authority:** 2018 Oregon Laws, Chapter 7; ORS 743.018

**Other Authority:**

**Stats. Implemented:** 2018 Oregon Laws, Chapter 7; ORS 743.018

**Need for the Rule(s):**

The Prescription Drug Price Transparency Act (2018 Oregon House Bill 4005, enrolled at 2018 Oregon Laws, Chapter 7) directs the Department of Consumer and Business Services (DCBS) to establish a reporting program for prescription drug manufacturers and health insurance carriers to increase the transparency of prescription drug pricing in Oregon. This program will be known as the Oregon Prescription Drug Price Transparency program. 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.

The law requires drug manufacturers to file annual reports for each drug with a net yearly price increase of 10% or more, if the drug costs at least \$100 for a month's supply or for a course of treatment lasting less than one month. These reports are required to include a range of information, such as the factors that contributed to the price increase and the manufacturer's expenses to produce and market the drug. Drug manufacturers offering patient assistance programs to help consumers afford the out-of-pocket expense of the drugs subject to the annual report requirement are required to include specific information on the assistance provided to Oregonians. The law specifies that drug manufacturers' annual price increase reports are due to DCBS by July 1<sup>st</sup> for the first year of the program in 2019, and by March 15<sup>th</sup> in subsequent years.

The law also requires drug manufacturers to file reports for new drugs with a price in excess of the threshold the federal government specifies for specialty drugs in Medicare Part B. The law specifies that these reports are due no later than 30 days after the introduction of a drug subject to this requirement.

The law requires DCBS to make drug manufacturer filings available to the public on its website, but prohibits DCBS from disclosing specific trade secret information. Information conditionally exempt from disclosure under ORS 192.345 as a trade secret may not be disclosed, provided that the public interest does not require disclosure of the information. A member of the public may petition the Attorney General to review DCBS's decision to withhold information from public disclosure as provided in ORS 192.411. The law also requires DCBS to make available to consumers, online and by telephone, a process for consumers to notify DCBS about an increase in the price of a prescription drug.

The law gives DCBS the authority to set fees for drug manufacturers, which may be used solely for the purposes of carrying out the provisions of Section 2. It also directs DCBS to adopt a schedule of civil penalties for drug

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manufacturers that commit violations of the law, not to exceed \$10,000 per day of violation, based on the severity of each violation. Civil penalties under the law are to be deposited in the state General Fund.

The law requires health insurance carriers offering plans in Oregon that are subject to rate review and approval to include specific information about prescription drug costs in rate filings, including information about the most frequently prescribed and most costly drugs, and the impact of prescription drug costs on premium rates. To implement this requirement, the proposed rules exercise DCBS's rulemaking authority under ORS 743.018 to specify all information a carrier must submit as part of a rate filing.

The proposed rule establishes:

- Definitions for key terms including “new prescription drug,” “net annual increase,” “one month supply” and “course of treatment” that clarify the circumstances when a report is required;
- Form, manner and content requirements for reports from drug manufacturers;
- DCBS's supervisory expectations of participating drug manufacturers, including good faith standards;
- Timelines for DCBS to request additional information relating to drug manufacturer reports, and for manufacturers' responses;
- DCBS's process for adjudicating trade secret claims from drug manufacturers;
- Timelines for DCBS to make drug manufacturer reports publicly available, subject to applicable trade secret exemptions;
- DCBS's process for receiving notices from consumers about prescription drug price increases;
- Establishing an annual \$400 fee for drug manufacturers, as well as an additional surcharge fee for manufacturers that file reports with DCBS;
- Adopting a schedule of civil penalties for drug manufacturer violations; and
- Requirements for information on drug pricing to be provided by health insurance carriers in rate filings.

The proposed rules are necessary to ensure that the program is administered in a fair and equal manner for all participating drug manufacturers and health insurance carriers, 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.

DCBS requests public comment on the proposed rule.

**Documents Relied Upon, and where they are available:** Draft rules are available from Karen Winkel located at 350 Winter St. NE, Salem, OR 97301 and are available on DCBS's Web site at: <http://dfr.oregon.gov/laws-rules/Pages/proposed-rules.aspx>.

2018 Or Laws Ch 7 (Enrolled House Bill 4005) may be found on the Oregon Legislative Assembly website at <https://olis.leg.state.or.us/liz/2018R1/Downloads/MeasureDocument/HB4005> or for public inspection at DCBS's Division of Financial Regulation, 350 Winter Street NE, Salem, OR 97301, during regular business hours, 8:00 a.m. to 5:00 p.m., Monday through Friday.

ORS 743.018 may be found on the Oregon Legislative Assembly website at [https://www.oregonlegislature.gov/bills\\_laws/ors/ors743.html](https://www.oregonlegislature.gov/bills_laws/ors/ors743.html) or for public inspection at DCBS's Division of Financial Regulation, 350 Winter Street NE, Salem, OR 97301, during regular business hours, 8:00 a.m. to 5:00 p.m., Monday through Friday.

### **Fiscal and Economic Impact:**

The Prescription Drug Price Transparency Act will have a significant impact on prescription drug manufacturers and health insurers. Based on the information available to DCBS, none of the impacted prescription drug manufacturers or health insurers are small businesses.

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The proposed rules establish an annual \$400 assessment against pharmaceutical manufacturers. Based on DCBS's preliminary analysis of data provided by the Oregon Pharmacy Board about licensed pharmaceutical manufacturers, this assessment is estimated to raise between \$200,000 and \$280,000 in annual revenue to fund the Oregon Prescription Drug Price Transparency Program's operations.

The proposed rules establish an additional surcharge assessment against pharmaceutical manufacturers that file reports. The surcharge amount will be established by dividing the Oregon Prescription Drug Price Transparency Program's operational costs in excess of the amount raised by the annual \$400 assessment by the total number of reports received each year. Based on the information available to DCBS, it is not possible to determine the number of reports that will be received annually or the excess operational cost per report. The total revenue raised by both the annual \$400 assessment and the surcharges is limited by the legislatively approved expenditure limitation for the program, which is \$425,022 for the biennium ending June 30, 2019.

The proposed rules adopt a schedule of civil penalties for prescription drug manufacturers that violate the provisions of 2018 Or Laws Ch 7 based on the severity of each violation, up to a maximum penalty of \$10,000 per day of violation. It is not possible to determine in advance the number or magnitude of civil penalties that will be required to ensure compliance with the law.

As outlined below, the proposed rules incorporate additional requirements that may impose compliance costs on prescription drug manufacturers and health insurance carriers in addition to the cost of compliance with the underlying statute, including additional required data elements and broad interpretations of key terms. Although these statutory requirements could be implemented more narrowly to minimize the impact on the affected industries, administrative rules with a narrower scope would do less to advance the transparency goals of the statute. The proposed rules are intended to advance transparency in pharmaceutical pricing without imposing additional undue burdens on reporting entities.

Based on the information available to DCBS, the proposed rules would not have any additional fiscal or economic impact on state agencies, local governments, the public, nor small businesses beyond the underlying statutory requirements.

### **Statement of Cost of Compliance:**

#### **1. Impact on state agencies, units of local government and the public (ORS 183.335(2)(b)(E)):**

Based on information currently available to DCBS, the proposed rule would not have a fiscal or economic impact on state agencies, local government units, nor the public.

While the underlying statutory provisions will have a significant impact on DCBS, the proposed rule will not. The proposed rule provides finer details regarding the administration of the program and is 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.

DCBS does not have information available to estimate the impact the proposed rules will have on the general public.

#### **2. Cost of compliance effect on small business (ORS 183.336):**

##### **a. Estimate the number of small businesses and types of business and industries with small businesses subject to the rule:**

The proposed rules set expectations for drug manufacturer and health insurance carrier participation in the program, including reporting requirements, fees and civil penalties. Compliance with the reporting requirements will require significant costs for pharmaceutical manufacturers and insurers. DCBS does not have information as to the number of

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employees employed by pharmaceutical manufacturers or insurers authorized to transact insurance in Oregon. Based on the feedback of the Rulemaking Advisory committee, it is unlikely that any insurer or prescription drug manufacturer subject to these rules is a small business (i.e., 50 or fewer employees).

### **b. Projected reporting, recordkeeping and other administrative activities required for compliance, including costs of professional services:**

The administrative costs for complying with 2018 Oregon Laws Chapter 7 are substantial. The proposed rules largely provide clarification of the statutory requirements and do not impose additional requirements.

The proposed rules require drug manufacturers that are required to file reports to establish online accounts with DCBS and to submit the reports in an electronic format specified by DCBS. These requirements are intended to establish a uniform reporting process to minimize the administrative burden of the required reporting and minimize costs to DCBS that would result in higher fees for drug manufacturers.

In some areas, additional required data elements have been added to the statutory requirements for the prescription drug manufacturer reports to advance the transparency goals of the statute and enable DCBS to better monitor industry trends in order to meet its statutory obligation to provide recommendations to the Legislature to address rising prescription drug costs. These additional requirements include disclosing the highest and lowest wholesale acquisition cost (WAC) of a drug subject to the annual reporting requirement over the course of the year, the WAC at the beginning and end of the year, and the price and dosage of the drug the manufacturer used to determine that the drug was subject to the reporting requirement. Since the WAC of a drug is set and maintained by the prescription drug manufacturer, this information should be readily available and these requirements should impose only a modest burden on reporting manufacturers.

In some areas where the statutory requirements required clarification in rule, the proposed rules impose a broad interpretation of key terms. For example, the proposed rules require health insurers to consider drugs reimbursed under both pharmacy and medical benefits, and to include the net impact of rebates and other price concessions when calculating total plan spending on drugs. The proposed rules also require prescription drug manufacturers that offer a patient assistance program through an independent intermediary organization to provide the information required by the statute for those programs as well as programs offered directly by the manufacturer itself, unless the independent program is a bona fide Independent Charity Patient Assistance Program operating in full compliance with guidance promulgated by the Department of Health and Human Services Office of the Inspector General.

Based on the feedback of the Rulemaking Advisory committee, it is unlikely that any insurer or prescription drug manufacturer subject to these rules is a small business (i.e., 50 or fewer employees).

### **c. Equipment, supplies, labor and increased administration required for compliance:**

The administrative costs for complying with 2018 Oregon Laws Chapter 7 are substantial, and may include additional equipment, supplies and labor costs, but the proposed rules largely provide clarification of the statutory requirements and do not impose additional requirements. The additional requirements and clarifications outlined in subsection b. above may impose limited additional equipment, supplies and labor costs on prescription drug manufacturers and health insurers.

Based on the feedback of the Rulemaking Advisory committee, it is unlikely that any insurer or prescription drug manufacturer subject to these rules is a small business (i.e., 50 or fewer employees).

### **How were small businesses involved in the development of this rule?:**

DFR convened a rulemaking advisory committee, which included representatives of drug manufacturers, health care providers, pharmacies, pharmacy benefit managers, insurers, and consumer advocates. Some pharmacies and health care providers are small businesses.

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**Administrative Rule Advisory Committee consulted?:**

**If not, why?:**

DCBS convened a rulemaking advisory committee, which included representatives of drug manufacturers, health care providers, pharmacies, pharmacy benefit managers, insurers, and consumer advocates. The rulemaking advisory committee met on July 31, August 28, September 25, October 22, November 13 and December 4, 2018.

Andrew Stolfi, Administrator

Signature

Printed name

Date

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