

DRAFT FOR DISCUSSION PURPOSES ONLY
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

Other Authority:

Stats. Implemented: 2018 Oregon Laws, Chapter 7

Need for the Rule(s):

Oregon House Bill 4005 (2018), the Prescription Drug Price Transparency Act, is enrolled at 2018 Oregon Laws, Chapter 7. The law 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 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 price in excess of \$100 for a month's supply or for a course of treatment lasting less than one month that increases in price by 10% or more. 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 that offer 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 for the first year of the program in 2019, and by March 15 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 the new specialty drug reports are due no later than 30 days after the introduction of a drug subject to this requirement.

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.

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.

DRAFT FOR DISCUSSION PURPOSES ONLY

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 manufacturers that commit violations of the law, not to exceed \$10,000 per day of violation, based on the severity of each violation.

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 the division'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 the 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 requirements these rules implement were established by HB 4005 and any fiscal or economic impact is a result of the legislation it implements.

Key features of the proposed rule include:

- 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
- Content requirements for information on drug pricing to be provided by health insurance carriers in rate filings.

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.

DRAFT FOR DISCUSSION PURPOSES ONLY

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, but 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 the 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 since the reporting requirements established by HB 4005 are not applicable to these entities.

Based on the information available to DCBS, it is impossible to gauge the impact these rules would 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 rule sets expectations for drug manufacturer and health insurance carrier participation in the program, including reporting requirements, fees and civil penalties. DCBS does not have information as to the number of employees employed by pharmaceutical manufacturers or insurers authorized to transact insurance in Oregon. It is unlikely that any insurer subject to these rules is a small business (i.e., 50 or fewer employees).

DCBS solicits feedback from stakeholders regarding the number and types of small businesses that may be subject to the rule.

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, but the rules are not expected to increase those costs.

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 rules are not expected to increase those costs.

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.

Administrative Rule Advisory Committee consulted?:

If not, why?:

Yes, as noted above, 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