



Oregon

Kate Brown, Governor

Department of Consumer and Business Services

Division of Financial Regulation

350 Winter St. NE, Room 410

P.O. Box 14480

Salem, OR 97309-0405

HEARING OFFICER'S REPORT TO AGENCY ON RULEMAKING

DATE: January 14, 2020
TO: Department of Consumer and Business Services
FROM: Jesse Ellis O'Brien, Hearing Officer

Subject: Amends timelines for public disclosure of drug manufacturer pricing reports and fee assessments

Hearing Date: January 8, 2020
Hearing Location: Labor & Industries Building, 350 Winter St. NE,
Conference Room E
Comment Period End: January 8, 2020

Background:

2018 Oregon Laws, Chapter 7 (the Act), directed the Department of Consumer and Business Services (department) to establish the Oregon Prescription Drug Price Transparency Program. In March of 2019, the department adopted OARs 836-200-0500 to 836-200-0560 to implement the new law's reporting requirements for drug manufacturers.

The Act and the administrative rules implementing it require prescription drug manufacturers to file annual reports for each drug with price increases above a specified threshold, and to file reports following the introduction of new drugs with a price in excess of a specified threshold.

The Act requires the department to make drug manufacturer filings available to the public on its website, but prohibits the department from disclosing trade secret information, provided the public interest does not require disclosure of the information. The timeline for public disclosure of drug manufacturer filings and related materials is specified by OAR 836-200-0545.

The Act gives the department the authority to set fees for drug manufacturers to pay for the department's expenses associated with the drug manufacturer reporting program. These fees are established by OAR 836-200-0555, including a \$400 annual fee and an additional surcharge fee for manufacturers that file reports that is calculated based on the number of reports filed and the revenue required to administer the drug price transparency program.

The proposed rules make minor adjustments to OARs 836-200-0545 and 836-200-0555 to allow for more efficient and effective administration of the Oregon Prescription Drug Price Transparency Program:

- The proposed amendments to OAR 836-200-0545 establish a regular quarterly schedule for public disclosure of drug manufacturer filings. This change will eliminate unnecessary administrative work associated with tracking hundreds of separate deadlines for public disclosure of new drug filings, which may be filed with the department at any time of year. It will also establish clearer timeframes to enable interested stakeholders and members of the public to plan for public disclosures related to the program.
- The proposed amendments to OAR 836-200-0555 provide clarification regarding which filings will be subject to the surcharge assessment each year. The current rule does not provide specific allowance for the department to take the time necessary to reconcile accounts and bill manufacturers, so this clarification is necessary to establish clear expectations and equitable treatment of drug manufacturers that file reports. The proposed amendments also clarify the process that will be used to calculate the amount of the surcharge assessment.

The proposed rules provide clarification of statutory requirements and do not impose additional fiscal impacts on affected industries, state agencies or the public. The proposed rules may result in a small savings due to reduced administrative work for the Drug Price Transparency Program, but overall the proposed changes are expected to have a negligible impact on costs to the department.

The department convened a rulemaking advisory committee, which included representatives of pharmaceutical manufacturers, insurers, health care providers and consumer advocates to provide input on the rule and its estimated fiscal and economic impacts. The rulemaking advisory committee met by conference call on October 21, 2019. The call was open to the public and opportunity was provided for the public to submit comments in person and in writing regarding the proposed rules.

The department filed a notice of proposed rulemaking and statement of need and fiscal impact on November 25, 2019. The documents were published in the Secretary of State's December 2019 Bulletin.

A public hearing was held at 9:00 AM on January 8, 2020. The deadline to provide public comment on the proposed rules was January 8, 2020 at 5:00 P.M. (PST).

Hearing and Public Comments:

A public hearing was held at 9:00 AM on January 8, 2020, at the Labor and Industries Building located at 350 Winter St NE, Salem, OR 97301. No one appeared to testify. No further inquiries or written comments were received during the public comment period.

Recommendation:

The hearing officer recommends that the rules be adopted as proposed.

Jesse Ellis O'Brien
Hearing Officer

This Summary and Recommendation are reviewed and adopted.

Signed January 28, 2020.

Department of Consumer and Business Services



Andrew Stolfi
Administrator
Division of Financial Regulation