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NOTICE OF PROPOSED RULEMAKING

INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 836
DEPARTMENT OF CONSUMER AND BUSINESS SERVICES
INSURANCE REGULATION

FILED
11/25/2019 2:14 PM
ARCHIVES DIVISION
SECRETARY OF STATE

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

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 01/08/2020 5:00 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

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350 Winter St. NE
Salem,OR 97301

Filed By:
Karen Winkel
Rules Coordinator

HEARING(S)

Auxilary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 01/08/2020
TIME: 9:00 AM
OFFICER: Jesse O'Brien
ADDRESS: Labor & Industries Building
350 Winter St. NE
Conference Room E
Salem, OR 97301
SPECIAL INSTRUCTIONS:
Conference phone information:
Call 888-808-6929
Access code 4969117

NEED FOR THE RULE(S):

The Prescription Drug Price Transparency Act (2018 Oregon House Bill 4005, enrolled at 2018 Oregon Laws, Chapter 7) directed the Department of Consumer and Business Services (DCBS) to establish the Oregon Prescription Drug Price Transparency Program. In March, 2019, DCBS 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 no later than 30 days after the introduction of new drugs with a price in excess of $670. These reports are required to cover a range of data elements and comply with a variety of form and manner requirements specified in OAR 836-200-0530. The law specifies that drug manufacturers' annual price increase reports are due to DCBS by July 1st for the first year of the program in 2019, and by March 15th in subsequent years.

The law requires DCBS to make drug manufacturer filings available to the public on its website, but prohibits DCBS 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 law gives DCBS 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 DCBS 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 DCBS 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.

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 website at:
https://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.

OAR 836-200-0545 may be found on the Oregon Secretary of State's website at:
https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=255926.
OAR 836-200-0555 may be found on the Oregon Secretary of State's website at:
https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=255928.

Both documents are available 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:

Oregon Laws 2018, chapter 7 has a significant economic impact on prescription drug manufacturers. The rule amendments proposed relate to administrative processes and timelines for DCBS and, based on the information available to DCBS, are unlikely to have an impact on manufacturers beyond the underlying statutory requirements and the fees previously established by OAR 836-200-0555.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

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

The underlying statutory provisions and the fees previously established by OAR 836-200-0555 have a significant fiscal impact on DCBS. However, the proposed rule will not. 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.

(2)(a) Based on the information available to DCBS, it is unlikely that the proposed rules will impose compliance costs on small businesses. Pharmaceutical manufacturers are the only businesses subject to the proposed rules. DCBS does not have data on the specific number of employees employed by pharmaceutical manufacturers. Regardless, the rule amendments proposed relate to administrative processes and timelines for DCBS and do not have an impact on manufacturers beyond the underlying statutory requirements and the fees previously established by OAR 836-200-0555.

DCBS convened a rulemaking advisory committee, which included representatives of prescription drug manufacturers, health care providers, insurers, and consumer and patient advocates. Committee feedback suggested that it is unlikely that any of the manufacturers to which this rule applies are small businesses.

(2)(b) Based on the information available to DCBS, including feedback from the RAC, the proposed rules do not impose additional compliance costs.

(2)(c) Based on the information available to DCBS, including feedback from the RAC, the proposed rules do not impose additional compliance costs.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

DCBS convened a rulemaking advisory committee, which included representatives of prescription drug manufacturers, health care providers, insurers, and consumer and patient advocates. The rulemaking advisory committee met on October 21, 2019.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:
836-200-0545, 836-200-0555

AMEND: 836-200-0545

RULE SUMMARY: Amends timeline for public disclosure of prescription drug manufacturer filings provided in compliance with Oregon Laws 2018, chapter 7.

CHANGES TO RULE:

836-200-0545
Public Disclosure of Prescription Drug Manufacturer Filings
(1) As soon as practicable after receiving a filing from a prescription drug manufacturer under OAR 836-200-0530, 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~~the applicable date as specified in subsection (3) following the receipt of a filing from a manufacturer under OAR 836-200-0530 or a response to a request for additional information from a manufacturer under OAR 836-200-053~~0~~5, 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~~ or response.¶
(3) Each year, the department shall post the information specified in subsection (2) no later than:¶
(a) March 31, for filings or responses to ~~a~~ requests for additional information ~~from a manufacturer under OAR 836-200-0535, the department shall post the~~received between October 1 and December 31 of the previous calendar year;¶
(b) June 30, for filings or responses to requests for additional information received between January 1 and March 31;¶
(c) September 30, for filings or responses to requests for additional information received between April 1 and June 30; and¶
(d) December 31, for filings or responses to ~~its website~~requests for additional information received between July 1 and September 30.¶
(4) As soon as practicable after submission of a request for additional information by the department under OAR 836-200-0535, receipt of a manufacturer's request for additional time to complete a response under OAR 836-200-0535, 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) Notwithstanding subsections (1)~~-~~ to (4), if a manufacturer has made a trade secret claim, the information that is the subject of the trade secret claim will not be posted to the department's website until a determination has been made by the department or, in the case of a manufacturer's appeal, the director, as specified by OAR 836-200-0540.¶
(6) No information determined by the department to be exempt from disclosure under OAR 836-200-0540 shall be included in the information posted to the department's website.
Statutory/Other Authority: ~~2018~~ Or Laws 2018, ch 7
Statutes/Other Implemented: ~~2018~~ Or Laws 2018, ch 7

AMEND: 836-200-0555

RULE SUMMARY: Establishes that assessments will be determined by considering reports filed between August 1 of the previous year and July 31 of the current year; clarifies procedure used in calculating assessment amount.

CHANGES TO RULE:

836-200-0555
Assessments Against Prescription Drug Manufacturers
(1) Once annually, no later than October 1, all reporting manufacturers will pay an assessment of $400. The ~~D~~d irector may by order reduce the fees assessed for any specific year.¶
(2) ~~N~~Once annually, no later than October 1~~ annually~~, reporting manufacturers that have filed one or more reports under OAR 836-200-0515 to 836-200-0530 ~~since October 1 of the prior~~between August 1 of the previous year and July 31 of the current year must pay an additional assessment for each report filed.~~T~~¶
(3) For the purposes of subsection (2), the director shall determine the amount of the assessment by ~~dividing~~ subtracting the revenue collected under subsection (1) from the amount of revenue needed to cover the department's estimated expenses in administering ~~2018 Or Laws ch 7 S~~Oregon Laws 2018, chapter 7, section 2 and OAR 836-200-0500 to 836-200-0550~~ by the total number of filings, minus~~, and dividing the resulting amount by the total number of filings subject to assessment between August 1 of the prev~~enue collected under subsection (1)~~ious year and July 31 of the current year. The director shall determine the amount of revenue needed by considering the legislatively approved expenditures for administration of ~~2018 Or Laws ch 7 S~~Oregon Laws 2018, chapter 7, section 2 and OAR 836-200-0500 to 836-200-0555, as well as the timing of cash revenues and expenditures.¶
(~~3~~4) The revenue collected under subsections (1) ~~to~~and (~~3~~2) of this section must be used solely for expenses incurred in the administration of ~~2018 Or Laws ch 7 S~~Oregon Laws 2018, chapter 7, section 2 and OAR 836-200-0500 to 836-200-0555.¶
(~~4~~5) 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.
Statutory/Other Authority: ~~2018~~ Or Laws 2018, ch 7
Statutes/Other Implemented: ~~2018~~ Or Laws 2018, ch 7