DCBS | Consumer and Business Services

Oregon Prescription Drug Price Transparency Program

Agenda

1. Overview of Oregon's Prescription Drug Price program
2. New drug reporting
3. Annual price increase reporting
4. Information claimed to be trade secret
5. Report timelines
6. Assessments and civil penalties

Oregon's Drug Price Transparency Program

The Prescription Drug Transparency Act (HB 4005), enacted during the 2018 Legislative Session, established Oregon's Drug Price Transparency program

- Increase transparency on prescription drug costs and prices from pharmaceutical manufacturers
- Collect prescription drug information from health insurance companies
- Provide consumers a way to report personal prescription drug price increases

Overview:
Manufacturer reporting

Prescription drug manufacturers are required to report:

- New prescription drugs – cost more than $670 a month or course of treatment
  - Reporting began on March 15, 2019

- Annual price increase – drugs priced more than $100/month with a 10% net yearly price increase
  - Reports due July 1, 2019

Overview:
Account creation

A reporting manufacturer is defined in the administrative rule (OAR 836-200-0505) as an entity:

- Required to be registered with the Oregon Board of Pharmacy as a drug manufacturer;
- That engages in the manufacture of prescription drugs as defined in 2018 OR Laws ch.7; and
- That sets or changes the wholesale acquisition cost (WAC) of the drug(s) it manufactures.

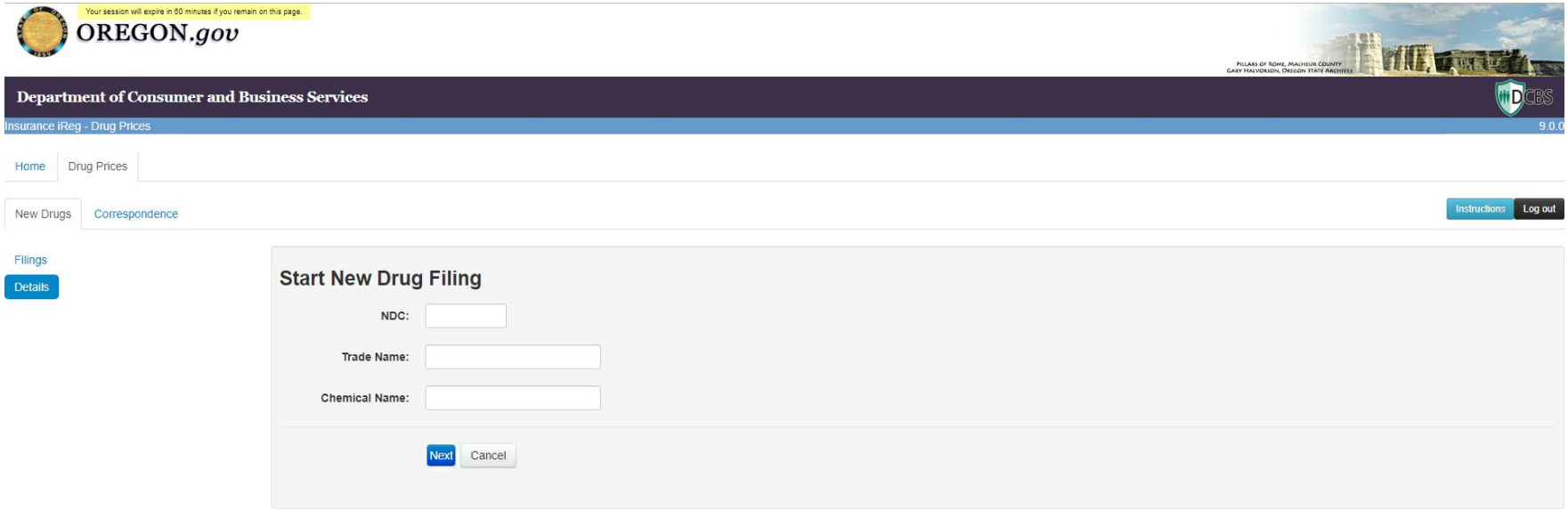
New drug reporting

Required: New drug comes to market at a price exceeding $670 for a thirty-day supply or a course of treatment lasting less than one month

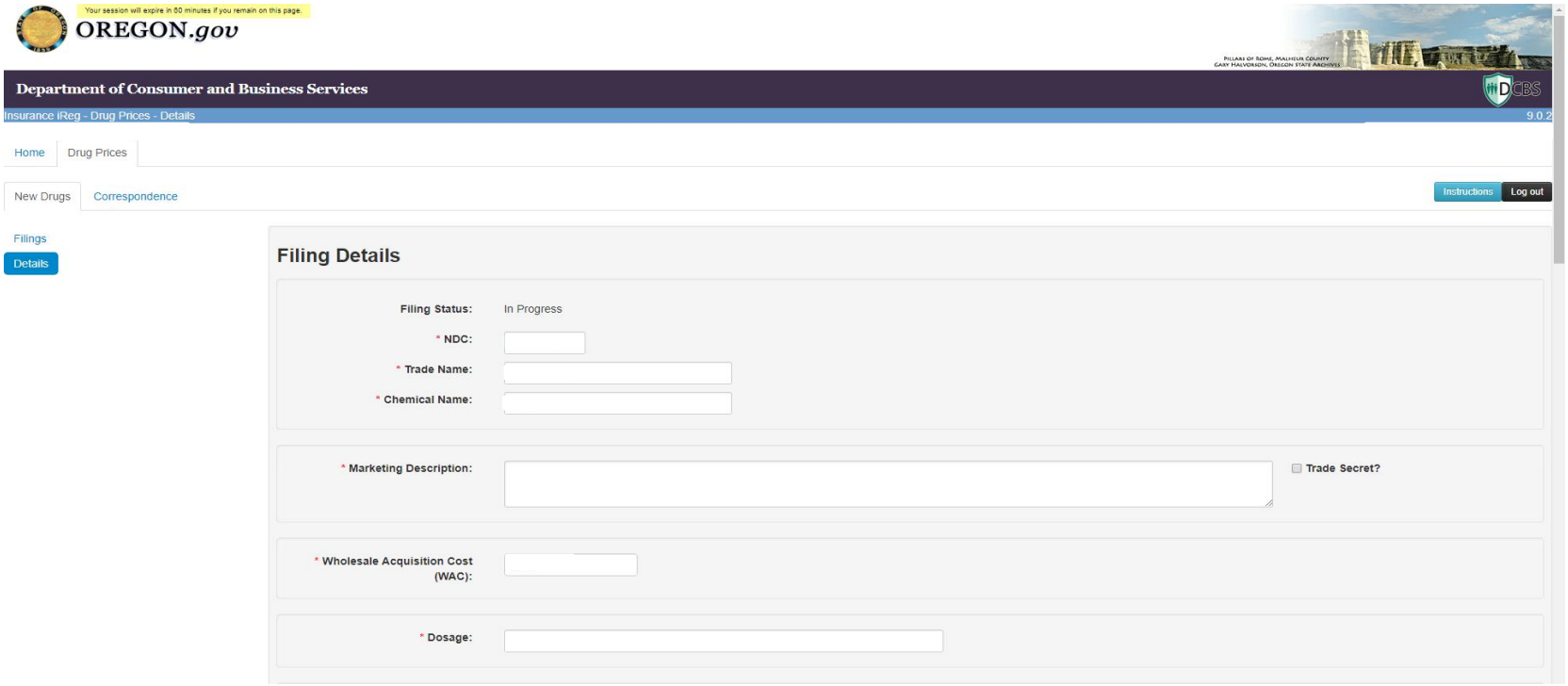
Deadline to Report: Within 30 days of the drug's market entry date

Where to Report: dfr.Oregon.gov/drugtransparency, iReg

New drug reporting



New drug reporting: Data elements



New drug reporting: Data elements

- Full trade name of the drug
- Full chemical or biologic product name of the drug
- 11-digit NDC for the drug product
- Price and dosage of the drug the manufacturer used to determine the price exceeded the threshold

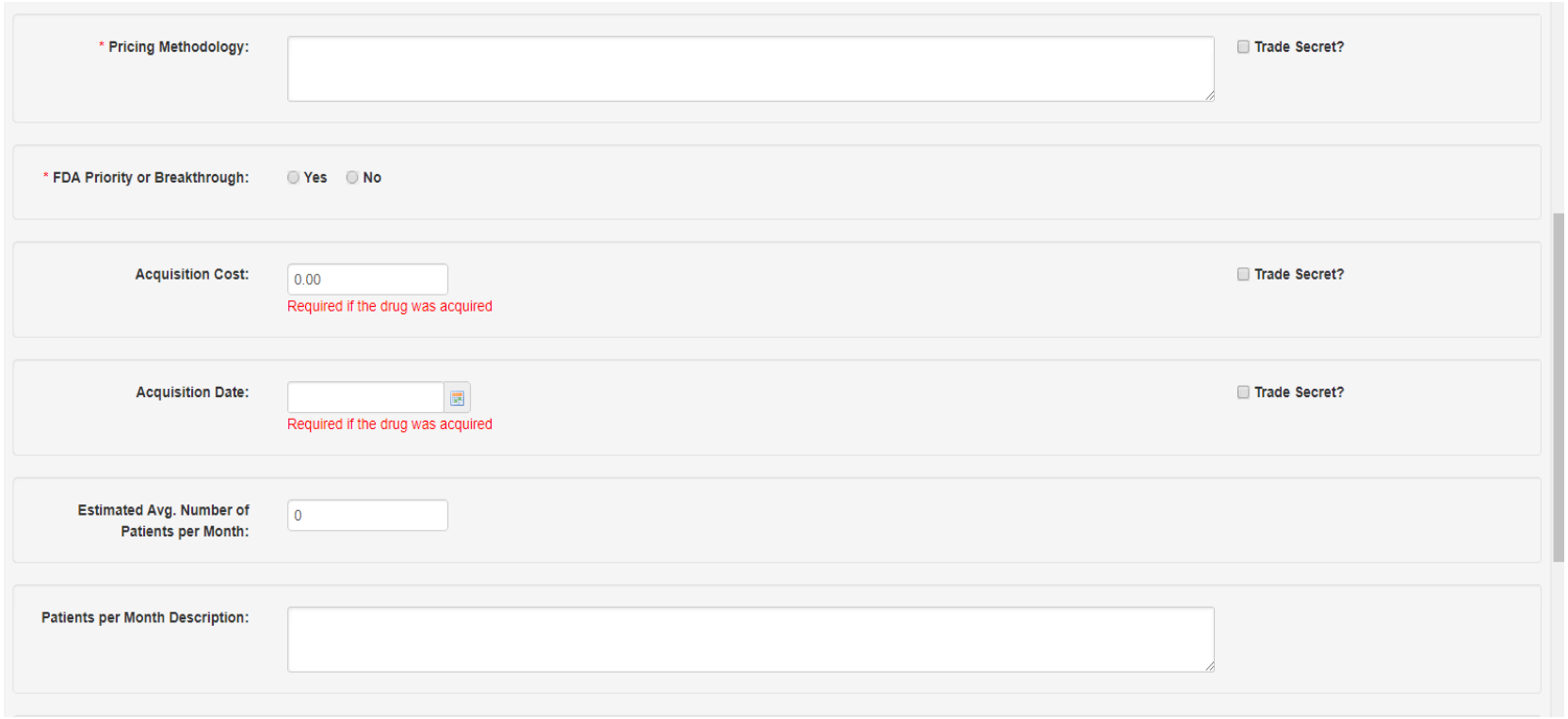
New drug reporting: Data elements

- Description of the marketing used introducing new prescription drug, including:
  - Spending on direct-to-consumer marketing and paid advertising
  - Spending on promotion of drug to physicians or other health professionals
- Methodology used to establish the price of the new prescription drug, including:
  - narrative description and explanation of all major financial and nonfinancial factors that influenced the set the price of the drug

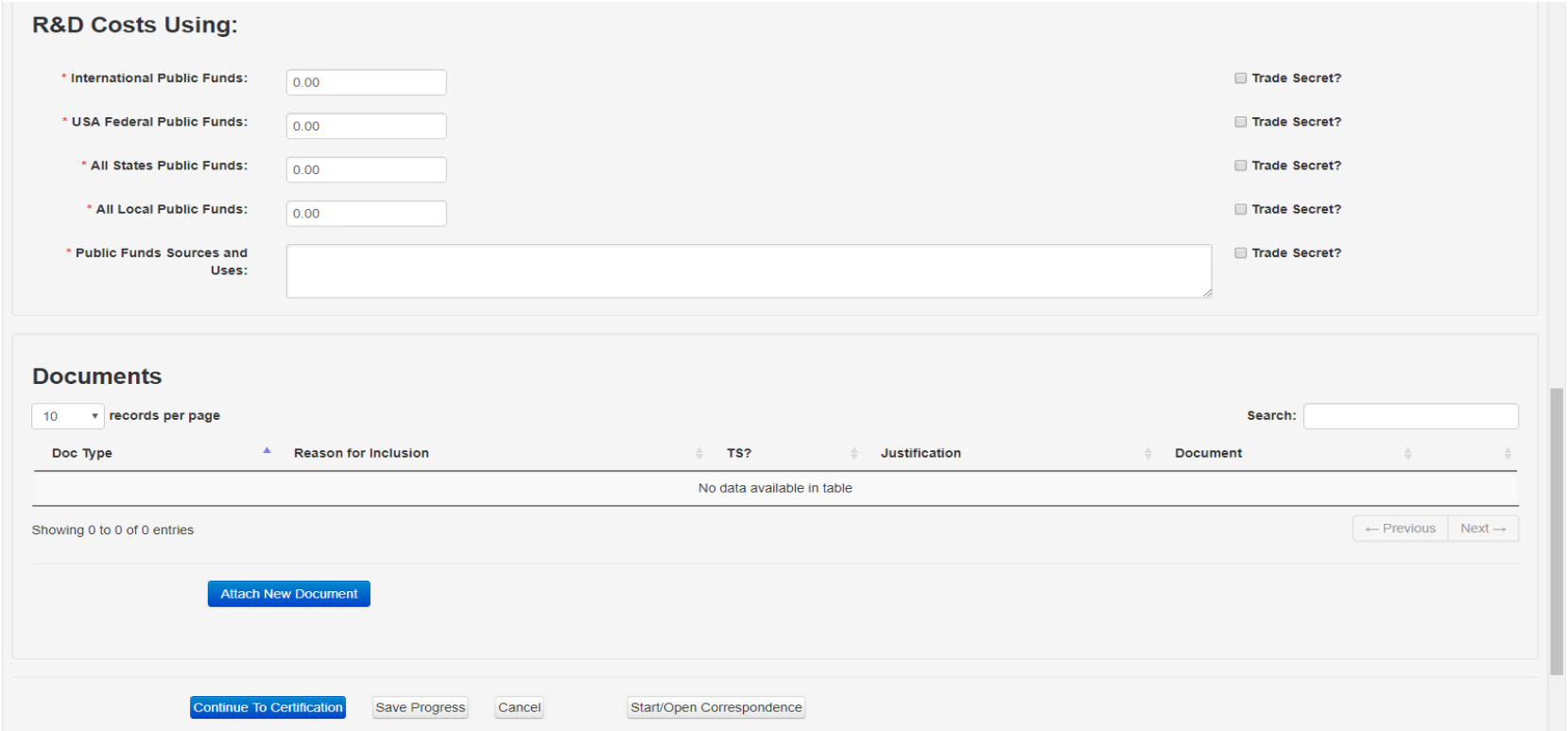
New drug reporting: Data elements

- Whether there was a breakthrough designation or priority review granted and any support documentation
- Date and price paid for acquisition of the new prescription drug
- Estimate of the average number of patients who will be prescribed the new prescription drug each month
- Research and development costs associated with the new prescription drug that were paid using public funds

New drug reporting: Data elements



New drug reporting: Data elements



Annual price increase reporting

Required: WAC was $100 or more **and** there was a net yearly increase of 10 percent or more in the WAC of the prescription drug

Deadline to Report: July 1, 2019 for the first year

- March 15 for all subsequent years

Where to Report: dfr.Oregon.gov/drugtransparency, iReg

Annual price increase reporting: Data elements

- Full trade name of the drug
- Full chemical or biologic product name of the drug
- 11-digit NDC for the drug product
- Price and dosage of the drug the manufacturer used to determine the cost $100 or more

Annual price increase reporting: Data elements

- The price of the drug at the beginning of the calendar year preceding the report
- The price of the drug at the end of the calendar year preceding the report
- The highest and lowest prices of the drug at any point during the calendar year preceding the report
- The increase in the price of the drug over the preceding calendar year, expressed as a percentage

Annual price increase reporting: Data elements

- The length of time the prescription drug has been on the market

- 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

- 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

Annual price increase reporting: Data elements

- The direct costs incurred and total dollars expended by the manufacturer in the previous calendar year:
  - To manufacture the prescription drug
  - 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
  - To distribute the prescription drug
  - For ongoing safety and effectiveness research associated with the prescription drug

Annual price increase reporting: Data elements

- 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
- The total sales revenue for the prescription drug during the previous calendar year
- The manufacturer's net profit attributable to the prescription drug during the previous calendar year
- The introductory price of the prescription drug when it was approved for marketing by the United States Food and Drug Administration

Annual price increase reporting: Data elements

- The net yearly increase by calendar year, in the price of the prescription drug during the previous five calendar years
- 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
- Any other information that the manufacturer deems relevant to the price increase

Annual price increase reporting: Data elements– Patient assistance programs

- The number of consumers residing in Oregon who participated in the patient assistance program over the previous calendar year
- The total dollar value of the coupons, discounts, copayment assistance or other reduction in costs provided to consumers in this state who participated in the program
- For each drug, the number of refills that qualify for the program
- If the program expires after a specified period of time, the time that the program is available to each consumer
- The eligibility criteria for the program and how eligibility is verified for accuracy

Information claimed to be trade secret

For information claimed to be trade secret within the report, the manufacturer will be prompted to provide a written explanation of why it is exempt by demonstrating all of the following:

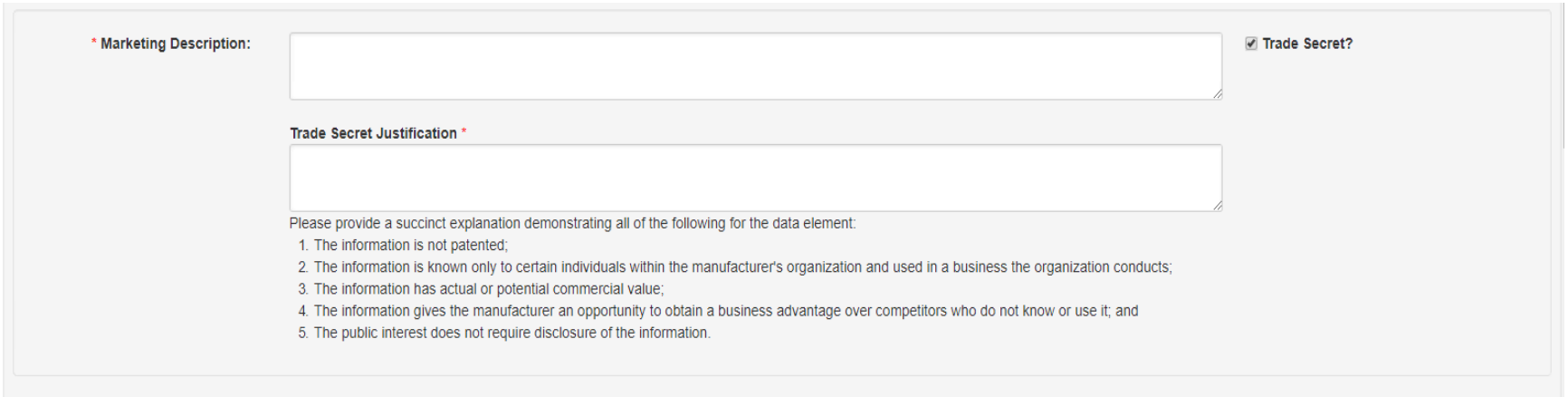
1. The information is not patented
2. The information is known only to certain individuals within the manufacturers organization and used in a business the organization conducts
3. The information has actual or potential commercial value
4. The information gives the manufacturer an opportunity to obtain a business advantage over competitors who do not know or use it
5. The public interest does not require disclosure of the information

Information claimed to be trade secret

- If the manufacturer asserts that disclosure of any information provided in a report is prohibited by state or federal law, the manufacturer must clearly indicate:
  - Relevant information
  - Explain the basis of the assertion, including any citations of the applicable state and federal law

- The burden of proof to establish information as conditionally exempt from disclosure as a trade secret is on the manufacturer submitting the filing.

Information claimed to be trade secret



Information claimed to be trade secret: Review process

- The department shall review the manufacturer's explanations and make a determination on a case-by-case basis.
  - The department will notify the manufacturer and provide a written explanation, if it is determined that any information claimed to be trade secret must be disclosed
  - Within 15 days of receiving the notification for disclosure, the manufacturer may submit an appeal letter to the director of DCBS and request reconsideration.

Information claimed to be trade secret: Review process

- The director or director's designee will review the appeal and issue an appeal determination within 15 days, or within a time period necessary to obtain legal review, of receiving an appeal letter.

- If the director's determination would result in the disclosure of information claimed to be trade secret, the department will notify the manufacturer of the director's decision at least 21 days in advance of disclosing the information.

Information claimed to be trade secret: Review process

- If the department exempts information from disclosure provided by a manufacturer, the department will post an explanation for exempting the information and a general description of the information.

- A person may petition the Attorney General, as provided in ORS 192.411, to review a decision made by the department to exempt information from disclosure.

Report timelines: Additional information requests

Within 60 calendar days of receiving a report from a prescription drug manufacturer, the department may submit a written request for supporting documentation or additional information to:

- Clarify or substantiate the previously reported material
- Enable an analysis of factors affecting drug prices for the purpose of providing recommendations to the Oregon State Legislature.

Manufacturers will receive an alert on their iReg account.

Report timelines: Additional information requests

Within 60 calendar days of receiving a request for information, a prescription drug manufacturer must provide a full and complete written response to the department's request

All information claimed to be a trade secret must be clearly identified and accompanied with an explanation as specified under OAR 836-200-540. Any requested information that is unavailable to the manufacturer must include a written explanation as specified by 836-200-0525.

Report timelines: Additional information requests

- Within 15 calendar days of receiving a request for more information, a manufacturer may request up to an additional 30 days to respond to the information request
  - The request for additional time must explain the grounds for the request and the need for additional time, submitted in writing on the iReg system

- The department shall respond in writing, within 15 days of receiving the manufacturer's request explaining the decision to grant the request, deny the request, or grant with an amount less than requested.

Report timelines: Public disclosure

Timeframes for disclosure	Action
As soon as practicable after receiving a filing	The department shall post to its website the name of the manufacturer and the prescription drug that is the subject of the filing
No later than 90 days after receiving a filing from a manufacturer	The department shall post to its website the information provided by the prescription drug manufacturer in the filing
No later than 60 days after receiving a response to a request for additional information from a manufacturer	The department shall post the response to its website

Report timelines: Public disclosure

Information claimed to be trade secret in a report filing, additional information response, or correspondence will not be posted until a final determination has been made by the department or the director.

Any information claimed to be trade secret determined by the department to be exempt from disclosure will not be posted to the department's website.

Assessments

There are two primary assessments for the Drug Price Transparency program:

1. Annual assessment paid by all prescription drug manufacturers and
2. Reporting assessment paid by prescription drug manufacturers who file a report(s) during the current reporting year

Billing for all assessments will occur by October 1st each year.

Assessments

Annual Assessment

- Prescription drug manufacturers who meet the requirements of a reporting manufacturer, as defined in OAR 836-200-0505, will be required to pay an annual assessment of $400.

Reporting Assessment

- Reporting manufacturers that file reports are required to pay an additional report assessment for each report filed. The amount of the report assessment will vary depending on the number of reports the department receives each year.

Civil penalties

	Missing, inaccurate, or incomplete data	Untimely responses for additional information	Failure to submit required report
First violation	$500 per day maximum for first 30 days $1,000 per day maximum after 30 days	$1,500 per day maximum for first 30 days $3,000 per day maximum after 30 days	$2,500 per day maximum for first 30 days $5,000 per day maximum after 30 days
Subsequent violations	$1,000 per day maximum	$3,000 per day maximum	$5,000 per day maximum

Program Contacts

Info on Oregon's Drug Price Transparency Program:

- Visit dfr.oregon.gov/drugtransparency
- Email rx.prices@oregon.gov
- Call 503-947-7200

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