



# Manufacturer User Guide Trade Secret Supplement

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## Drug Price Transparency Program



Dated June 24, 2025.

This guide relates specifically to information claimed trade secret reported to Oregon's Drug Price Transparency Program.

## **Agency information and Oregon laws and rules**

### **About DCBS:**

The Department of Consumer and Business Services (DCBS) is Oregon's largest consumer protection and business regulatory agency. For more information, visit <https://www.oregon.gov/dcbs/>.

### **About Oregon DFR:**

The Division of Financial Regulation (DFR) protects consumers and regulates insurance, depository institutions, trust companies, securities, and consumer financial products and services, and is part of DCBS. Visit [dfr.oregon.gov](http://dfr.oregon.gov).

### **About the Drug Price Transparency (DPT) Program:**

Oregon's DPT Program provides accountability for prescription drug pricing through the notice and disclosure of specific drug costs and price information from pharmaceutical manufacturers, health insurers, and consumers. Visit <https://dfr.oregon.gov/drugtransparency> and the webpage for manufacturers at <https://dfr.oregon.gov/drugtransparency/Pages/manufacturers.aspx>.

### **Laws and rules for trade secret claims:**

Oregon Revised Statutes – [ORS 646A.689\(10\)](#)

Oregon Administrative Rules – [OAR 836-200-0540](#)

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## I. Overview

- The Oregon [Prescription Drug Price Transparency Act](#) requires reporting manufacturers to file prescription drug price reports and pay an annual assessment to DCBS. The department reviews the reports and displays all information to the public that is not exempt from disclosure under ORS 192.345.
- The [Manufacturer User Guide](#) encompasses all areas of Oregon's DPT Program. The purpose of this Trade Secret Supplement is to help reporting manufacturers understand trade secret claims and procedures when submitting reports.
- Reporting manufacturers may request specific information provided to DCBS be conditionally exempt from disclosure under [ORS 192.345](#) as a trade secret. This is done by changing the trade secret box next to a data element in iReg to "Yes" and identifying the specific information claimed as trade secret.
- Making a trade secret claim does not excuse a manufacturer from providing required information. The information must be reported, even if claiming a trade secret.
- Some drug manufacturers employ third-party companies to handle some or all of their state-required drug reporting in Oregon. Drug manufacturers ultimately bear the responsibility for accurate and complete reporting, as well as any errors, including proper designation of trade secret claims and failure to claim data as trade secret.
- Reporting manufacturers are responsible for submitting appropriate justification for each trade secret claim. Detailed requirements for appropriate justification are included in this document. Information for each data element must be clearly identified to claim the information in that data element as trade secret.
- Once submitted, all information or data not claimed as trade secret is published on the data transparency site for public viewing. Correspondence not claimed as trade secret is published after the report has the status of "filing complete" or "closed as filed."
- Terms and acronyms used and defined in this Trade Secret Supplement are listed in the [last section](#) of this document.
- Compliance tips
  - These annotations are provided as a message from the compliance staff of the Oregon DPT Program.
  - The annotations are not official regulatory guidance.
  - The annotations are not legal advice.

## II. Trade secret claims

Oregon DPT revised administrative rules are effective April 1, 2025. Rule changes have been incorporated into this document. Note that we also plan to make iReg changes in the future.

**Compliance tip:**

- Know your trade secret claims.
- Prepare your trade secret justification for each individual claim.

**1. Not all data elements may be claimed trade secret**

This list contains report data DCBS does not consider as trade secret because these items are publicly available or known outside the company:

- National Drug Code (NDC)
- Trade name
- Chemical name
- Generic name(s)
- Wholesale Acquisition Cost (WAC)
- Dosage
- Date of market entry or available in the U.S.
- U.S. Food and Drug Administration (FDA) priority or breakthrough
- Public funding for R&D
- Subscription service information like Medi-Span, First Databank, and IQVIA

**2. Trade secret claims**

If a manufacturer asserts that disclosure of any information provided in a report is prohibited by state or federal law, the manufacturer must clearly indicate the relevant information and explain the basis of the assertion, including citations of the applicable state and federal laws.

Information that is publicly available is not a trade secret. Information that is common industry knowledge or practice is generally not a trade secret.

The burden of proof to establish information as conditionally exempt from disclosure as a trade secret is on the manufacturer submitting the drug report. DCBS will review the manufacturer's explanations and make a determination on a case-by-case basis as outlined in [OAR 836-200-0540](#).

If DCBS exempts a manufacturer's information from disclosure, it will post an explanation of the basis for exempting the information and a general description of the nature of the information to the data transparency website.

A person may petition the Oregon attorney general, as provided in [ORS 192.411](#), to review a decision made by DCBS to exempt information from disclosure.

### 3. *Know the requirements*

Reporting manufacturers may request specific information be conditionally exempt from disclosure under [ORS 192.345](#) as a trade secret.

- Submit the required information.
- Select “Yes” for “Trade Secret?” if claiming trade secret.
- **IMPORTANT NOTE:** Asserting a trade secret claim does not excuse a manufacturer from providing the required information. Asserting a trade secret claim without providing the required information is noncompliant and may result in penalties for the manufacturer.

### 4. *Proper justification of trade secret claims*

For each data element, a manufacturer must explain how the information claimed as trade secret meets the criteria listed in [OAR 836-200-0540](#).

iReg uses the term “justification” for the explanation that is required. A justification must assert *which information* in the related data element is trade secret and *why* it is exempt from disclosure by demonstrating all of the following criteria in [OAR 836-200-0540](#)(1)(b):

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

To claim information as trade secret, change the trade secret drop-down to “Yes” next to a data element to access its trade secret justification field. The following screenshot from iReg shows the data element and its accompanying trade secret justification field.

\* Pricing Trade Secret? Yes

Methodology:

Trade Secret Justification \*

Please provide a succinct explanation demonstrating all of the following for the data element:

1. The information is not patented;
2. The information is known only to certain individuals within the manufacturer’s 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; and
5. The public interest does not require disclosure of the information.

## 5. *Insufficient trade secret claims may be denied*

Trade secret claims may be denied for failure to provide an explanation for each of the elements listed in OAR 836-200-0540(1)(b). Here are some examples of insufficient trade secret justifications.

**Scenario 1** – Justification submitted fails to cover all of the requirements.

*This communication contains proprietary, confidential and competitively sensitive information, and company could be harmed if the information was publicly disclosed. The company is providing this information in reliance on the State of Oregon commitment to treat this communication as confidential.*

**Scenario 2** – Justification submitted also fails to cover all of the requirements.

*The confidential information has not been publicly disclosed. This information constitutes company trade secrets and are exempt from disclosure under the relevant laws and regulations. The confidential information is not the type of information that has been available in the past (a) on a publicly available website operated by company or its affiliates, or (b) in a publicly available document, including publicly available filings with the FDA, U.S. Securities and Exchange Commission (SEC), or any other state or federal regulatory agency. This information constitutes company's trade secrets and are exempt from disclosure under the relevant laws and regulations.*

### **Compliance tip:**



It may be acceptable to submit a justification in paragraph form, but the paragraph(s) must cover the requirements listed in OAR 836-200-0540.

**Scenario 3** – Justification submitted repeats the requirements without any details.

*Company is providing the following explanation to give support to its stance that this required information is considered trade secret and therefore exempt from reporting under ORS 192.345.*

- A. The information is not patented.*
- B. The information is known only to certain individuals within the manufacturer's organization and used in a business the organization conducts.*
- C. The information has actual or potential commercial value.*
- D. The information gives the manufacturer an opportunity to obtain a business advantage over competitors who do not know or use it.*
- E. The public interest does not require disclosure of the information.*



### **Compliance tip:**

Listing the requirements of OAR 836-200-0540, without providing an explanation of how they are applicable is insufficient justification.

**Scenario 4 – Justification submitted for wrong drug or different data element.**

*Company is providing the following explanation to give support to its stance that the information for wrong drug name is considered trade secret and therefore exempt from reporting under ORS 192.345. ...*

**Compliance tip:**

Copying an explanation from another drug or data element is insufficient justification. Each justification must discuss why that particular information is being claimed as a trade secret.

**6. Initial steps of DPT trade secret review process**

- a. Oregon DPT sends an email requesting the drug manufacturer employees designate the recipients of any trade secret determination information. The email is sent when no trade secret contacts have previously been designated or the designations are outdated.
  - i. This email is only sent to drug manufacturer's direct employees listed as iReg "Contacts" for the account. The email requests the drug manufacturer designate its trade secret contacts.
  - ii. Only a drug manufacturer direct employee may designate trade secret contacts for trade secret determination letters. While an employee can include a third party as trade secret contact, third parties may not designate themselves nor can they be the only trade secret contact.
- b. The drug status is changed to "Trade secret review in progress."

**Compliance tip:**

Oregon DPT laws are directed toward drug manufacturers and also apply to any third parties they employ to handle some or all of their state-required drug reporting in Oregon. Drug manufacturers ultimately bear the responsibility for accurate and complete reporting.

**III. Trade secret determinations**

Step 1: A trade secret determination letter (determination) is issued when Oregon DPT plans to disclose any of the information claimed as trade secret.

- a. A message is posted in iReg correspondence, stating that DCBS has issued a determination.
- b. A determination is sent only to company-designated trade secret contacts.
- c. A determination is sent through secure Biscom transmittal.
- d. The status of the drug report containing the trade secret claim changes to "Trade secret determination issued."



A determination discloses how the information claimed as trade secret will be published on the data transparency website. Here is an example from a determination:

Data element	Claimed trade secret information that the department has determined to disclose (“Information to be Disclosed”) <sup>1</sup>
Marketing Description	<p>Date this NDC was introduced to the U.S. market: <u>06/15/2025</u>.</p> <ol style="list-style-type: none"> <li>1. Consumer marketing: <ul style="list-style-type: none"> <li>• Consumer marketing spending – four quarters prior to launch: <b>[monetary number]</b>.</li> <li>• Consumer marketing spending – four quarters after launch: <b>[monetary number]</b>.</li> </ul> </li> <li>2. Health care providers (HCP) marketing spending: <ul style="list-style-type: none"> <li>• HCP marketing spending – four quarters prior to launch: <b>[monetary number]</b>.</li> <li>• HCP marketing spending – four quarters after launch: <b>[monetary number]</b>.</li> </ul> </li> </ol> <p>Public information - marketing activities.</p> <ol style="list-style-type: none"> <li>3. Marketing activities targeting consumers: <ul style="list-style-type: none"> <li>• Marketing materials focused on disease state education to patients</li> <li>• Consumer website, including paid search</li> <li>• TV, social media, radio, mobile applications</li> <li>• Online display ads, magazines, blogs, or billboards</li> </ul> </li> <li>4. Marketing activities targeting HCPs: <ul style="list-style-type: none"> <li>• Contracted sales force</li> <li>• Materials for physician visits to inform and educate physicians on efficacy and safety profile</li> <li>• Industry conference presence and contracted speakers</li> <li>• Social media and journal advertising directed at HCPs</li> </ul> </li> </ol>

<sup>1</sup> The language in the brackets will be disclosed in lieu of the information claimed to be a trade secret.

Oregon law requires DPT to describe the nature of the information withheld and redacted when excluded from disclosure on our website. In the example above, the dollar amounts reported for marketing spending have been replaced with **[monetary number]**. DCBS uses bolded text to show the redacted information in the determination, but iReg does not allow for bolded text and will display the information in plain text for the transparency website once the report is final.

Step 2: If no appeal is posted in iReg correspondence within 15 days of the determination, the determination becomes final.

- a. A message will be posted in iReg correspondence stating that the determination is final.
- b. The status of the drug report will be changed to “Final trade secret determination.”

Step 3: The drug report will remain in the status “Final trade secret determination” for 21 days.

Step 4: Following the 21-day waiting period, the drug report containing the trade secret claim will be published to the drug transparency website in the manner shown in the determination (as provided in the example of a determination on [Page 9](#)). The status of the report will change to “Filing Complete.”

#### **IV. Notification of agreement with trade secret claims**

When a drug manufacturer claims specific information as trade secret, and DCBS’ review of a trade secret claim is in agreement with the claim, DCBS will send a notification email to the trade secret contacts. When DCBS is in agreement with the trade secret claim, it means that the information submitted and claimed as trade secret appears to meet the requirements to be exempt from disclosure under ORS 646A.689(10).

The drug report containing the specified and agreed trade secret claim will be published to the drug transparency website in a manner similar to the example of a determination on [Page 9](#). The status of the report will change to “Filing Complete.”

#### **V. Appeal procedure – denial of trade secret claim**

When a drug manufacturer disagrees with the determination, an appeal may be filed.

- a. An appeal must be filed within 15 days of the determination date.
- b. An appeal should be filed in iReg correspondence, in the same manner as any other correspondence that attaches to the drug report and should be claimed as trade secret to prevent the appeal information from publishing to the transparency website when the report is final.

- c. An appeal should clearly indicate what specific part of the determination is being appealed and requested for reconsideration.
- d. An appeal to a determination for insufficient trade secret justification must sufficiently explain and justify the trade secret claim as required by OAR 836-200-0540.

Step 1: The reporting manufacturer files an appeal to the determination in iReg correspondence within 15 days of the determination.

Step 2: DCBS posts an acknowledgement of the appeal in iReg correspondence. The status of the drug report related to the determination being appealed changes to “Under appeal.”

Step 3: DCBS reviews the appeal information.

## **VI. Final trade secret determination and notifications**

When an appeal to a determination is filed within 15 days of the determination date, and DCBS’ review of the appeal information is complete, a final trade secret determination letter (final determination) is issued.

- a. A message is posted in iReg correspondence, stating that DCBS has issued a final determination.
- b. The final determination is sent through secure Biscom transmittal only to company-designated trade secret contacts, in the same manner as the determination.
- c. The status of the drug report containing the trade secret claim will change to “Final trade secret determination.”
- d. The drug report will remain in the status “Final trade secret determination” for 21 days.
- e. Following the 21-day waiting period, the drug report containing the trade secret claim will be published to the data transparency website in the manner shown in the final determination, and provided in the example of a determination on [Page 9](#). The status of the report will change to “Filing Complete.”

## VII. When information claimed as trade secret is published

Once a report status is filing complete, all data and correspondence is published to the transparency website. Any information claimed to be trade secret that is determined by DCBS to be exempt from disclosure will not be posted to the data transparency website.

Here is an example of an iReg drug report. This example is used only for instructional purposes, to show how information may be displayed following a final determination.

Marketing description
<p>Date this NDC was introduced in the U.S. market: <u>06/15/2025</u>.</p> <ol style="list-style-type: none"> <li>Consumer marketing: <ul style="list-style-type: none"> <li>Consumer marketing spending – four quarters prior to launch: [monetary number].</li> <li>Spending for consumers planned or budgeted for four quarters after launch: [monetary number].</li> </ul> </li> <li>HCP marketing: <ul style="list-style-type: none"> <li>HCP marketing spending – four quarters prior to launch: [monetary number].</li> <li>Spending for HCPs planned or budgeted for four quarters after launch: [monetary number].</li> </ul> </li> </ol> <p>Public information - marketing activities.</p> <ol style="list-style-type: none"> <li>Marketing activities targeting consumers: <ul style="list-style-type: none"> <li>Marketing materials focused on disease state education to patients</li> <li>Consumer website, including paid search</li> <li>TV, social media, radio, mobile applications</li> <li>Online display ads, magazines, blogs, or billboards</li> </ul> </li> <li>Marketing activities targeting HCPs: <ul style="list-style-type: none"> <li>Contracted sales force</li> <li>Materials for physician visits to inform and educate physicians on efficacy and safety profile</li> <li>Industry conference presence and contracted speakers</li> <li>Social media and journal advertising directed at HCPs</li> </ul> </li> </ol>

## VIII. Filing statuses for reports with trade secret claims

The following are the filing statuses in iReg that are relevant to reports with trade secret claims. See the [Manufacturer User Guide](#) for the full list of filing statuses.

Note: The [data transparency website](#) does not display all of these filing statuses, but users will see them when viewing the manufacturer account in iReg.

iReg filing status	Description of status
Trade secret claim	The report has trade secret claims that need review.
Trade secret review in progress	Staff members are reviewing the report's trade secret claims.
Review complete	The report has been reviewed and is pending being assigned the next appropriate status.
Trade secret determination issued	DCBS does not agree with all or part of the trade secret claims made on the report, and a trade secret determination was issued in Biscom. A message is also posted in iReg stating that the determination was sent in Biscom. This status is used for 15 calendar days while the manufacturer has the option to appeal the determination. No determination is issued if DCBS agrees with all trade secret claims on a report. Biscom information can be found on the <a href="#">webpage for manufacturers</a> .
Under appeal	DCBS received a timely appeal to the trade secret determination. The report remains in this status while DCBS reviews the appeal.
Final trade secret determination	A trade secret determination is final if there is no timely appeal. If there is a timely appeal, a final trade secret determination is issued in Biscom after review of the appeal. This status is maintained for 21 calendar days.
Filing complete	All reviews are complete and any appeal or waiting periods have expired. All report data and correspondence are published to the data transparency website (per a final trade secret determination, if applicable).

## IX. Terms and acronyms used in this document

- DCBS means Oregon Department of Consumer and Business Services.
- DFR means Oregon Division of Financial Regulation.
- DPT means drug price transparency and refers to the Oregon DPT Program.
- iReg means the DFR system for submitting reporting online.
- HCP means health care providers and physicians. When reporting marketing spending costs, this term also applies to insurance carriers, pharmacists, pharmacy benefit managers, and all others in the health care industry.
- Trade secret, in this document means information exempt from disclosure in accordance with [ORS 192.345](#) and [OAR 836-200-0540](#).
- Justification, in this document means to appropriately explain *which information* is trade secret and *why* it is exempt from disclosure by demonstrating all of the criteria listed in [OAR 836-200-0540](#).
- Determination, in this document means “trade secret determination letter.”
- Final determination, in this document means “final trade secret determination letter.”
- Exempt from disclosure as a trade secret means the information meets the requirements for nondisclosure in accordance with [ORS 192.345](#) and [OAR 836-200-0540](#).
- Filing or drug filing means drug report.
- Report status means the status of the report in iReg in the table on [Page 13](#) of this document.