

Manufacturer User Guide

Drug Price Transparency Program



Updated March 28, 2024. This guide has the following updates:

- New instructions for completing the revised annual price increase report and when the report is required.
- Clarification of expectations for marketing expense and dosage.
- Added details about billings and collections.
- Reminders about making a trade secret claim and how non-trade secret data is published directly to our data transparency site.
- New pictures in the iReg walk-through section, pages 28-60.

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.

About the Drug Price Transparency program:

Oregon's Drug Price Transparency 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:

Oregon Revised Statutes – [ORS 646A.680 to 646A.692](#)

- Definitions
- Registration requirements
- Reporting requirements
- Fees
- Penalties

Oregon Administrative Rules – [OAR 836-200-0500 through 836-200-0560](#)

- Definitions
- Registration requirements
- Reporting requirements and expectations
- Additional information requests
- Trade secret claims
- Public disclosure of reports
- Consumer notifications
- Fees
- Penalties

ATTENTION: This manufacturer guide has been updated with changes from the recent court ruling regarding annual price increase reporting. Read [DFR Bulletin No. 2024-3](#) for more information.

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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 will review the reports and disclose any non-trade-secret information to the public.

The purpose of this guide is to help reporting manufacturers comply with the transparency requirements for Oregon's Drug Price Transparency program. The department uses the [iReg system](#) for the filing of prescription drug price reports and for the billing of fees assessed by the department to reporting manufacturers.

II. Accounts, users, and contacts

All manufacturer reporting for Oregon's Drug Price Transparency program will occur through the [iReg system](#). The iReg system provides the reporting mechanism, secure correspondence between the department and filers, and billing for the program assessments. Refer to the [iReg walk-through](#) for examples.

Account creation: Prescription drug manufacturers that meet the definition of a reporting manufacturer are required to have an account (register) and pay an annual assessment. Pursuant to OAR 836-200-0505, a reporting manufacturer is defined as an entity that meets all of the following:

- Required to be registered with the [Oregon Board of Pharmacy](#) as a drug manufacturer.
- Engaged in manufacturing prescription drugs as defined by [ORS 646A.689](#).
- That sets or changes the wholesale acquisition cost (WAC) of its drugs.

Reporting manufacturers include entities that identify as virtual manufacturers or contract to another entity the act of manufacturing. Each entity that is a reporting manufacturer (even subsidiaries of a parent company that is also a reporting manufacturer) are required to create their own separate account with the department. If a parent company is setting the price, then the account creation and reporting responsibility is with the parent company.

All reporting manufacturers are required to have an account regardless of whether they must file any reports.

To create an account, go to the webpage for manufacturers at <https://dfr.oregon.gov/drugtransparency/Pages/manufacturers.aspx>. Click on "Register a reporting manufacturer" and complete the form. For those that already have an account, there is a form to request company name, address, or other updates to the account.

ATTENTION: If the marketing date shows the entity should have been previously registered, we will set up billing for the annual fee owed for prior years. Any previously due reports should be filed as soon as possible.

Once the department receives the registration request, an account will be set up in iReg. The person on the registration will be set up as a user and contact on the account and receive a confirmation email. This is usually done within two business days.

Users and contacts: Manufacturers are responsible for keeping their information up to date. If you do not keep this information up to date, you may miss important due dates and appeal deadlines. Make sure your email system is not blocking or quarantining communications from iReg emails ending with .gov. If there is a change to the company's name, address, federal employer identification number (FEIN), labeler names, or other updates, use the "Update an existing account" form on the webpage for manufacturers to send us the changes.

Due to the large number of companies registered with the program, we ask manufacturers to manage access for users whenever possible. For every manufacturer account, there should be at least one employee with the appropriate permissions to manage users. Certain notices are only received by those listed as a contact. It is also important to have the correct users designated as contacts.

The manufacturer is responsible for keeping contact information current and maintaining at least two users or contacts. There are detailed iReg instructions on management of users and contacts in Section X ([iReg walk-through](#)). Manufacturers are solely responsible for ensuring that users maintain the confidentiality of their accounts and passwords and for using reasonable efforts to prevent unauthorized access to their iReg accounts. User login credentials and passwords should not be shared or used by more than one user.

If a manufacturer is using a third party to submit its Oregon Drug Price Transparency program reports, there must be a user who is an employee of the manufacturer in addition to the third party. The manufacturer is responsible for compliance and for any unpaid debts.

Notices: Billing and general information notices are located in iReg, where you can view prior notices sent. Go to the "Contacts" tab and select "Contact History." Select "Show History for ALL Contacts" for the messages sent for that account. Note that some messages to users and contacts may not be available here or may have been directly emailed to users or contacts instead.

III. Assessments and collections

ATTENTION: In accordance with [Senate Bill 192 \(2023\)](#), there will be a different fee process for 2024 and forward. This guide will be updated once those details are finalized. The information below relates to billings for periods before Aug. 1, 2023.

Currently, there are two assessments (fees) for the Drug Price Transparency program:

- Annual assessment paid by all reporting manufacturers
- Reporting assessment paid by reporting manufacturers who file one or more reports during the billing year

The billing year is Aug. 1 of the prior year through July 31 of the current year. The annual assessment and any applicable reporting assessment are due on **Oct. 1** of the current year. Funds collected from the assessments are solely used for expenses incurred by the department for administration of the program.

Contacts will be notified of the annual billing with a demand to pay notice sent through email by Sept. 1, which is due Oct. 1. This will be the amount owed for the billing year that ended July 31 of that year. Unpaid fees are sent to collections and will incur an interest rate of 9 percent per year.

Example: The 2023 billing year is from Aug. 1, 2022, through July 31, 2023. Annual billing notices will be emailed Sept. 1, 2023, for the amount due Oct. 1, 2023. After Oct. 1, 2023, unpaid annual billings are sent to collections and will incur interest of 9 percent per year.

Annual assessment

Reporting manufacturers are required to pay an annual assessment of \$400.

Reporting assessment

Reporting manufacturers that file reports during the billing year are required to pay an additional fee for each report filed. The amount of the reporting assessment varies depending on the number of reports the department receives each year. This assessment is calculated by dividing the amount of revenue needed to cover the department's program expenses by the total number of these filings, subtracting the amount of revenue collected through the annual assessment.

$$\text{Annual expenses} - (\$400 \times \# \text{ of reporting manufacturers})$$

Total reports

Billing and collections

Manufacturers owe an assessment each year as described above. Manufacturers are sent the demand to pay and reminders by email to the contacts or users on the account 30 days before the due date.

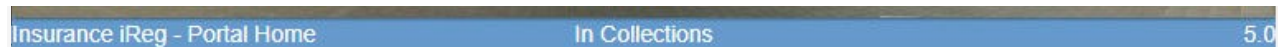
View a list of assessments by going to the “Billings” tab in iReg. You can then select a billing and click on “Details” or “Fiscal Details” for additional information. The billing status is pending when posted and then complete when the full payment is received and posted. The details page for a billing shows some information about the billing and allows a user to print the payment coupon (voucher). The fiscal details for a billing show the payments received. See pictures in Section X ([iReg walk-through](#)).

Our agency mailing addresses and Form W-9 is in the billings and collections information on our [webpage for manufacturers](#). You may pay by check or by credit or debit card. To pay by credit or debit card, call our cashiering staff at 503-947-7891 during the hours of 8 a.m. to 4 p.m. (Pacific time), Monday through Friday. You may need a copy of the voucher. We do not have online or electronic payment options.

If paying by check, include a copy of the voucher so your payment is processed correctly. If paying for multiple manufacturer accounts, include all vouchers with the check.

If not paid by the due date, debts are sent to our agency’s Accounts Receivable (AR) unit and have a billing status of “in collections (AR).” Then, as required by Oregon law, AR sends debts to the Department of Revenue – Other Agency Accounts.

Manufacturer accounts with unpaid billings sent to collections will show a banner message when users view the account in iReg. The “In Collections” message will display in the blue bar near the top of the page. Here is what it looks like:



The billings tab in iReg will show which debts are in collections. For debts in collections, iReg generally will not reflect the correct balance owed.

If a debt is in collections and has been sent to the Department of Revenue, contact its Other Agency Accounts (OAA) unit at oa.help@dor.oregon.gov or 503-945-8199. The webpage is <https://www.oregon.gov/dor/payments>. You will need to provide your company information. If you have questions about a debt, email us at rx.prices@dcbs.oregon.gov.

IV. New drug reporting

Reporting manufacturers are required to submit a report within 30 days of introduction of new prescription drugs for sale in the United States at a price exceeding \$670 for either a 30-day supply or a course of treatment lasting less than one month.¹ The manufacturer setting the drug's WAC is responsible for reporting.

A new specialty drug report is only required when a National Drug Code (NDC) that meets the WAC threshold is first marketed based on U.S. Food and Drug Administration (FDA) approval of a new drug application (NDA), abbreviated new drug application (ANDA), or biologics license application (BLA).

If a drug was previously marketed by one company and then is later marketed by another company based on a purchase or licensing/marketing agreement, a new specialty drug report was only required by the first company. If a drug is manufactured, but never actively marketed by the first company, then a new drug report is required by the company that is first marketing the drug.

Reportable data elements

ATTENTION: Trade secret claims are defaulted to “Not set” for data elements that have the option to claim the response as a trade secret per ORS 192.345. You must either select:

- “Yes” to claim the response as a trade secret, or
- “No” to claim that the response is not a trade secret.

Once submitted, all data not claimed as trade secret are published on the data transparency website for public viewing. Correspondence not claimed as trade secret is published after the report has the status of “filing complete” or “closed as filed.”

Provide succinct descriptions. Do not provide reports or documents that contain information that is not required. You may provide information and include a website link; however, a website link alone is not a compliant response.

New drug reports include the following data elements:

- 1. National Drug Code (NDC):** Enter the NDC in the 11-digit configuration. This identifies the labeler, product, and trade package size by unique code for the FDA and the manufacturer.

Manufacturers are required to separately report each NDC that meets the reporting threshold.

¹ The threshold for new drug reporting is established by the Centers for Medicare and Medicaid Services (CMS) for specialty drugs in the Medicare Part D program; \$670 is the amount specified in OAR 836-200-0505 for the minimum Part D specialty tier eligibility in the [2018 Final Call Letter from CMS](#).

Note: Use the 11-digit National Council for Prescription Drug Programs (NCPDP) format in iReg. Most common conversions:

NDC (FDA)	11-character NDC (NCPDP)
4-4-2 (9999-9999-99)	5-4-2 (09999999999)
5-3-2 (99999-999-99)	5-4-2 (99999099999)
5-4-1 (99999-9999-9)	5-4-2 (99999999909)

2. **Trade name:** Provide the full trade name that is the exclusive name of the drug product owned by the reporting company under trademark law. If the trade name is the same as the chemical name, enter the chemical name in this field. Do not enter the brand name for the drug if the brand name is not the product being reported.
3. **Chemical name:** Provide the full chemical or biologic product name. This is the nonproprietary name of the drug product, usually the active ingredients.
4. **Marketing description:** Provide the dollar amount of any spending or planned spending on marketing to *consumers* in the U.S. for the:
 - First 12 months after launch; and
 - Any spending before the launch date.

Provide the dollar amount of any spending or planned spending on marketing to *physicians and other health care professionals* in the U.S. for the:

- First 12 months after launch; and
- Any spending before the launch date.

Provide a description of how the above amounts for marketing were or will be used in the introduction of the new prescription drug, including:

- Direct-to-consumer media advertisements on platforms, such as TV, magazines, radio, social media, blogs, billboards, mobile applications, or other web-based media.
- Direct-to-consumer promotional incentives, such as free trial offers, rebates, coupons, and other utilization incentives if different from the patient assistance program.
- Promotion of the drug to physicians or other health professionals, such as professional detailing, free drug samples, sponsorships for continuing education for health professionals, gifts, conference events, seminars, or other promotional activities.
- Other paid advertising or promotion to consumers or health care providers.

Also include the date the drug was introduced to the market if there was a delay from the FDA approval date to the start of marketing.

Compliance tip: Marketing description must include *information* and *dollar amounts* about the company's spending on marketing for both marketing to consumers *and* marketing to physicians and other health care professionals. For a generic or biosimilar drug, if there was no marketing for the drug, report there was no marketing. If the company marketed the generic or biosimilar drug, report the amount spent on marketing.

- 5. Wholesale acquisition cost (WAC):** Enter the WAC for the reporting year that was used to determine if the price exceeded the reporting threshold of \$670 for either a 30-day supply or a course of treatment lasting less than one month.

Enter the package WAC, not the unit or monthly price. WAC is defined by [42 U.S.C. 1395w-3a\(c\)\(6\)\(B\)](#). All reported WAC prices are package prices, not unit prices.

- 6. Dosage:** Enter the recommended dosage for this product. This is the amount and frequency prescribed, as would be explained to a patient taking the drug as recommended. If there is more than one such recommended dosage, the largest recommended total dosage will be considered for the purpose of determining the course of treatment. Examples: 2 pills per day, 30 mg every 4 hours as needed, 50 ml once per week, etc.

Compliance tip: When reporting, think “amount,” “strength,” and “frequency” and report each. Do not refer to a package insert or another document.

- 7. Pricing methodology:** Describe the methodology used to establish the price (WAC) of the new prescription drug, including a narrative description and explanation of all major financial and nonfinancial factors that influenced the decision to set the price of the drug.

Include an explanation of any cost-based pricing, quality-adjusted pricing, value-based pricing, or other models and strategies used to establish the price. Include the description of any fixed costs, variable costs, quality measures, utilization estimates, and other relevant information.

For generic or biosimilar drugs, specify in detail what percentages were applied in pricing this particular drug or confirm that no percentage difference or comparison to brand name or other generic equivalents was used in determining the price. Include the drug trade name and manufacturer/labeler of the comparison product.

Compliance tip: Report clear and specific information. If the company did not use any drug comparisons for determining the price, clearly confirm in writing that no comparison was used, *and* report what the company did to set the price.

- 8. FDA priority or breakthrough:** Indicate “yes” if there was a breakthrough designation or priority review granted and then attach any support documentation. Otherwise, indicate “no” if neither of these conditions existed. This refers to the expedited reviews given to drugs intended to treat a serious condition by demonstrating the drug may provide substantial improvement to the safety or efficacy in treatment of the serious condition.
- 9. Acquisition cost and date:** If the drug was not developed by the reporting manufacturer, enter the price paid for acquisition of the new prescription drug² and the date purchased. Otherwise, leave blank. Note: If the drug was part of a purchase of a company or other drugs or assets, and the cost to acquire the drug being reported cannot be provided, list the cost of the entire purchase and provide an explanation in the documents section of the report to explain what else was included in the acquisition.

Compliance tip: Acquisition cost and date do not apply to the acquisition of inventory for relabeling and repackaging.

- 10. Estimated average number of patients per month:** Estimate the average number of patients who will be prescribed the new prescription drug each month in the U.S. Include a description of any epidemiologic studies or analyses on incidence and prevalence of the conditions the drug targets and other relevant information used to estimate the average number of patients.

Compliance tip: Brand-name drugs are expected to have an estimate of the number of patients per month; “0” and “1” are not acceptable for reporting this information. To provide more information regarding how the company arrived at the estimate, use the next data field (“Patients Per Month Description”) to report the information.

- 11. R&D costs using public funds:** Enter the amount of public funds used for research and development costs associated with the new prescription drug. Specify all sources of public funds provided by national, state, local, or foreign government entities used in the basic or applied research for the drug, preclinical trials, and clinical trials. In the “Public funds sources and uses” box, enter the following for each type of public funds: Dates of R&D project, name of project, and location of project. If more than one R&D project using public funds, list each separately. Enter “0” (zero) in the amounts if no public funds were used and provide a statement to that effect in the description box.

Compliance tip: If reporting “0” for public funds, do not mark as a trade secret.

² Applies only if the new prescription drug was acquired and not developed by the manufacturer.

Manufacturers may claim part or all of the information reported for certain data elements as a trade secret. The department will review information claimed to be a trade secret to determine whether the information will be disclosed. Refer to [Section VII](#) and OAR 836-200-0540 for more information before making any trade secret claims on the filing.

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

Manufacturers are required to certify the information reported to the program is accurate and complies with state law and regulations. When a report is certified, it is expected that manufacturers have made a good-faith effort to report required information or respond to a request for additional information. Failure to comply may result in civil penalties.

Refer to the [iReg walk-through](#) for pictures of the system and other information.

V. Annual price increase reporting

ATTENTION: This guide has been updated with changes from the recent court ruling regarding these reports. Read [DFR Bulletin No. 2024-3](#) for more information.

Annual price increase reports are required for prescription drugs that have the following:

- A patient assistance program available in Oregon (whether or not there were Oregon participants).
- A wholesale acquisition cost (WAC) of \$100 or more.
- An increase in the weighted average WAC of 10 percent or more in the year that just ended (reporting year) when compared to the previous year (comparison year).

Reporting is required whether or not there were any Oregon patients who actually received assistance during the reporting year. Other data may also be reported.

These reports can be filed starting Jan. 1, and the deadline to report this information is March 15. **Note:** For reports due in 2024, the due date has been extended to May 15.

Reporting for annual price increases will be through the iReg system. Annual price increase reports should be submitted for each National Drug Code (NDC) that meets the reporting threshold.

The weighted average price in the reporting year is compared to the weighted average price in the comparison year to determine if the price increase is 10 percent or more.

The formula for determining the weighted average price is the number of days spent at each price multiplied by that price, which are then added together and divided by the total number of days in the year. The formula for the net increase percentage is the difference in the weighted average price of the reporting year and the comparison year divided by the weighted average price of the comparison year.

Example 1: During the comparison year (2022) the weighted average price for Drug A was \$700. During the reporting year (2023), the weighted average price was \$850 and there were patient assistance programs available in Oregon.

The increase of the weighted average price is greater than 10 percent, the price exceeds \$100 per month, and patient assistance is available in Oregon, so an annual price increase report is required by May 15, 2024, to report patient assistance data for 2023.

Example 2 shows calculations and a leap year: Drug Z has a WAC of \$500 for the first 100 days of 2023 and \$600 for the remainder of the year. The weighted average price for 2023 (comparison year) is \$572.60.

$$\text{2023 weighted average price: } \frac{(100 \times \$500) + (265 \times \$600)}{365} = \$ 572.60$$

On Jan. 25, 2024, the WAC is increased to \$640, and there is a patient assistance program available in 2024. The weighted average for 2024 (reporting year) is \$637.38.

$$2024 \text{ weighted average price: } \frac{(24 \times \$600) + (342 \times \$640)}{366} = \$ 637.38$$

This is a difference of \$64.78. As shown below, the increase for 2024 is 11.3 percent (rounded), so a report will be required by March 15, 2025.

$$2024 \text{ increase percentage: } \frac{(\$637.38 - \$572.60)}{\$572.60} \times 100 = 11.31 \%$$

Required reportable data elements

ATTENTION: The iReg system has these changes for annual price increase reports for data elements with the option to claim the response as a trade secret per ORS 192.345:

- Trade secret claims for patient assistance data are defaulted to “Not set.”
- Trade secret claims for voluntary data elements are defaulted to “No.”
- You must select “Yes” to claim a response as a trade secret.

Once submitted, all data not claimed as trade secret are published on the data transparency website for public viewing. Correspondence not claimed as trade secret is published after the report has the status of “filing complete” or “closed as filed.”

Provide succinct descriptions. Do not provide reports or documents that contain information that is not required. You may provide information and include a website link; however, a website link alone is not a compliant response.

Annual price increase reports **must** include the following data elements:

1. **Filing year:** Enter the year the weighted average price increased as compared to the prior year.
2. **National Drug Code (NDC):** Enter the NDC in the 11-digit configuration. This identifies the labeler, product, and trade package size by unique code for the FDA and the manufacturer.

Note: Use the 11-digit National Council for Prescription Drug Programs (NCPDP) format in iReg. Most common conversions:

NDC (FDA)	11-character NDC (NCPDP)
4-4-2 (9999-9999-99)	5-4-2 (099999999999)
5-3-2 (99999-999-99)	5-4-2 (99999099999)
5-4-1 (99999-9999-9)	5-4-2 (99999999909)

3. **Trade name:** If this does not automatically populate, provide the full trade name that is the exclusive name of the drug product owned by the reporting

company under trademark law. If the trade name is the same as the chemical name, enter the chemical name in this field. Do not enter the brand name for the drug if the brand name is not the product being reported.

4. **Chemical name:** If this does not automatically populate, provide the full chemical or biologic product name. This is the nonproprietary name of the drug product, usually the active ingredients.
5. **Generic name(s):** If applicable, enter names of any generic version of the prescription drug available on the market.
6. **Patient assistance programs:** If there are any patient assistance programs, select “Add assistance program” for each program. Add each patient assistance program offered by the manufacturer to consumers residing in Oregon for the reported prescription drug whether or not there were any Oregon participants. Each entry must provide the program name and type and the following data elements:
 - Number of participants: Enter the number of consumers residing in Oregon who participated over the previous calendar year.
 - Value of assistance: The total dollar value of the coupons, discounts, copayment assistance, or other reduction in costs provided to consumers in Oregon who participated over the previous calendar year.
 - Refills: If limited refills were allowed, enter the number of refills for this drug, or select “Other” and describe how refills were allowed if none of the options were accurate.
 - Time period: Specify the period of time that the program is available to each consumer.
 - Eligibility criteria and verification process: Describe the eligibility criteria and how eligibility is verified for accuracy.

Reporting manufacturers that provide funding for independent patient assistance programs must make a good-faith effort to secure this information.

Any bona fide independent charity patient assistance programs operating in full compliance with the guidance provided in the U.S. Department of Health and Human Services Office of the Inspector General’s Supplemental Special Advisory Bulletin are exempt from reporting in this section.

Voluntary reportable data elements

Annual price increase reports **may** include the following data elements:

7. **Net increase percent:** Enter the increase percentage in the weighted average WAC over the calendar year that just ended compared to the weighted average WAC over the previous calendar year. Do not file reports for increases that were less than 10 percent.
8. **Introductory price, Jan. 1 and Dec. 31:** Enter the price (WAC) when the product was first approved for marketing by the FDA. Enter the WAC on Jan. 1 and Dec. 31 of the year that just ended.
9. **Highest, lowest, and weighted average WAC:** Enter the highest, lowest, and daily weighted average WAC for the year that just ended. Note: If these are the same because the increase occurred on Jan. 1 of the reporting year or in the prior year, provide an explanation and include the date of the last increase in the “other relevant pricing information” data element.
10. **Dosage:** Enter the recommended dosage for this product. This is the amount of the drug that would be prescribed in a single prescription to a patient taking the drug as recommended. If there is more than one such recommended dosage, the largest recommended total dosage will be considered for the purposes of determining the course of treatment. Examples: 2 pills per day, 30 mg every 4 hours as needed, 50 ml once per week, etc.
11. **Date on market:** Enter the date the drug was first available for purchase.
12. **Increase factors:** Provide factors and their details that contributed to the price increase. Include an explanation of major financial and nonfinancial factors. Specify in detail what percentages or comparisons were applied in increasing the price for this particular drug or confirm that no percentage difference or comparison to brand name or other generic equivalents was used in determining the price increase. Include the drug trade name and manufacturer/labeler of the comparison product.

Compliance tip: Report clear and specific information. If company did not use any drug comparisons for determining the price increase, clearly confirm in writing that no comparison was used and report what the company did use for setting the increased price.
13. **R&D costs using public funds:** Enter the amount of public funds used for research and development costs associated with the prescription drug. Specify all sources of public funds provided by national, state, local, or foreign government entities used in the basic or applied research for the drug, preclinical trials, and clinical trials.

In the “Public funds sources and uses” box, enter the following for each type of public funds: Dates of R&D project, name of project, and location of project. If more than one R&D project using public funds, list each separately. Enter “0” (zero) in the amounts if no public funds were used and provide a statement to that effect in the description box.

Compliance tip: If reporting “0” for public funds do not mark as a trade secret.

14. Direct costs: Provide U.S. spending amounts in U.S. dollars for all fixed and variable costs incurred by the manufacturer during the previous calendar year:

- To manufacture the prescription drug
- To market the prescription drug, including direct-to-consumer marketing and paid promotion to physicians
- To distribute the prescription drug
- For ongoing safety and effectiveness research associated with the prescription drugs

Compliance tip: Provide direct cost information. Claiming information as exempt from disclosure due to a proprietary, confidential, or trade secret claim does not exempt a manufacturer from its duty to report that information to the department. Failure to report may result in civil penalties.

15. Total sales revenue: Enter the total gross sales revenue associated with the drug during the previous calendar year in the U.S. Revenue is defined consistent with generally accepted accounting principles.

16. Profit from drug: Enter the net profit that can be attributed to the prescription drug during the previous calendar year in the U.S. Net profit is defined as consistent with generally accepted accounting principles.

17. Other relevant pricing information: Enter any other information that the manufacturer deems relevant to the price increase. Note: Also use this field to provide an explanation of why the WAC amounts reported are identical and include the date of the last increase.

18. Non-U.S. prices: Enter the 10 highest prices paid for the prescription drug during the previous calendar year in any country other than the United States, or check the box if you only sell this product in the U.S.

For reporting prices in other countries, the price should be the WAC equivalent in that country, converted to U.S. dollars, and countries should not

be repeated (ex-manufacturer price, ex-factory, ex-wholesale). Price in other countries should be reported as an average for the previous calendar year.

- 19. Five-year net annual increases:** Enter the net yearly increase in WAC for the drug, by calendar year, during the previous five calendar years. Reminder: The net increase percentage for the year being filed is the same as the first entry on this five-year list. Therefore, if filing a 2021 report, the percentage for 2021 on this list is the same as reported above.

Net yearly increase means an increase in the average yearly WAC of a drug, calculated by dividing the average WAC of the drug over one calendar year by its average WAC over the previous calendar year.

Previous five calendar years means the past five years from the previous calendar year, which the iReg system will display on the form. If a drug came on the market during the five-year period, reporting for this data element would begin on the year it came to market and forward.

- 20. Documents:** Attach any documentation necessary to support the information reported.

All reported WAC prices, including the prices of the drug in other countries, are package prices, not unit prices.

Manufacturers may claim part or all of the information reported for a data element as a trade secret. The department will review information claimed to be a trade secret to determine whether the information will be disclosed. See [Section VII](#) and OAR 836-200-0540 for more information before making any trade secret claims on the filing.

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

Manufacturers are required to certify the information reported to the program is accurate and complies with state law and regulations. When a report is certified, it is expected that manufacturers have made a good-faith effort to report required information or respond to a request for additional information. Failure to comply may result in civil penalties.

See the [iReg walk-through](#) for pictures of the system and other information.

VI. 60-day price increase notice reporting

A report is required 60 days before a planned price increase when certain thresholds are met, subject to exceptions.

For each National Drug Code (NDC) for a *brand-name* prescription drug, a report is required when the planned price increase is 10 percent or more, or an increase of \$10,000 or more.

For each NDC for a *generic* prescription drug, a report is required when the planned price increase is 25 percent or more, and the increase is \$300 or more.

Example 1: A brand-name prescription drug's wholesale acquisition cost (WAC) is \$500, and there is a plan to increase it to \$600. This increase is more than 10 percent, so a report is filed at least 60 days before that price increase.

Example 2: A generic prescription drug's WAC is \$200, and there is a plan to increase it to \$300. This increase is more than 25 percent, but the increase is less than \$300, so a report is not filed.

There is more information on the report filing requirements in [Bulletin No. 2020-12](#).

Exceptions: No report is required if the prescription drug is manufactured by four or more companies and meets one of the criteria listed in [ORS 646A.683\(4\)](#).

Provide succinct descriptions. Do not provide reports or documents that contain excess information that is not required. You may provide the information and include a website link, but a website link only is not a valid response.

Reportable data elements

ATTENTION: Trade secret claims are defaulted to “Not set” for data elements that have the option to claim the response as a trade secret per ORS 192.345. You must either select:

- “Yes” to claim the response as a trade secret, or
- “No” to claim that the response is not a trade secret.

Once submitted, all data not claimed as trade secret are published on the data transparency website for public viewing. Correspondence not claimed as trade secret is published after the report has the status of “filing complete” or “closed as filed.”

Sixty-day notice price increase reports include the following data elements:

1. **National Drug Code (NDC):** Enter the NDC in the 11-digit configuration. This identifies the labeler, product, and trade package size by unique code for the FDA and the manufacturer.

NOTE: Use the 11-digit National Council for Prescription Drug Programs (NCPDP) format in iReg. Most common conversions:

NDC (FDA)	11-character NDC (NCPDP)
4-4-2 (9999-9999-99)	5-4-2 (09999999999)
5-3-2 (99999-999-99)	5-4-2 (99999099999)
5-4-1 (99999-9999-9)	5-4-2 (99999999909)

2. **Trade name:** If this does not automatically populate, provide the full trade name that is the exclusive name of the drug product owned by the reporting company under trademark law. If the trade name is the same as the chemical name, enter the chemical name in this field. Do not enter the brand name for the drug if the brand name is not the product being reported.
3. **Chemical name:** If this does not automatically populate, provide the full chemical or biologic product name. This is the nonproprietary name of the drug product, usually the active ingredients.
4. **Year available in U.S.:** Enter the year the product was first available for purchase in the U.S.
5. **Current price (WAC):** Enter the current price (WAC) for the prescription drug.
6. **New price (WAC):** Enter the expected price (WAC) for the prescription drug for the upcoming planned increase.

All reported WAC prices, including the prices of the drug in other countries, are package prices, not unit prices.
7. **Date increase effective:** Enter the date the planned price increase is expected to be in effect.
8. **Reasons for price increase:** There are three categories of reasons for the price increase: change, improvement, and other. Answer “yes” for the relevant fields and provide a description of the change, improvement, or other reasons for the price increase. If there were no changes or improvements to the product, choose “other” and provide an explanation for the increase.

Compliance tip: A 60-day price increase report must contain the reason for the price increase, and the explanation should be similar to what would be reported on an annual price increase report (which will generally also be required).

9. Other relevant information: Provide any additional information or details about the reasons, factors, consumers, or timing of this increase.

Manufacturers may claim part or all of the information reported for a data element as a trade secret. The department will review information claimed to be a trade secret to determine whether the information will be disclosed. See [Section VII](#) and OAR 836-200-0540 for more information before making any trade secret claims on the filing.

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

Manufacturers are required to certify the information reported to the program is accurate and complies with state law and regulations. When a report is certified, it is expected that manufacturers have made a good-faith effort to report required information or respond to a request for additional information. Failure to comply may result in civil penalties.

See the [iReg walk-through](#) for pictures of the system and other information.

VII. Information claimed to be trade secret

Reporting manufacturers may request specific information provided to the department 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 which specific information is claimed.

Reporting manufacturers are responsible for submitting appropriate justification for a trade secret claim. Refer to detailed requirements for appropriate justification below. Each data element must be clearly indicated by the manufacturer to claim the information in that field or attachment as trade secret.

Once submitted, all 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.”

ATTENTION: Making a trade secret claim does not exempt a manufacturer from providing that information. The information must be reported, even if claiming a trade secret.

For each field, item, or attachment claimed to be trade secret within the report, the manufacturer will be prompted to provide a written explanation. The explanation needs to detail *which information* in the related field or attachment is trade secret and *why* it is exempt from disclosure by demonstrating **all** of the following:

- 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.

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 the relevant information and explain the basis of the assertion, including citations of the applicable state and federal laws.

Note: 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 filing. The department will review

the manufacturer's explanations and make a determination on a case-by-case basis as outlined in OAR 836-200-0540.

1. If the department determines any information claimed to be a trade secret must be disclosed, the department will notify the manufacturer and provide a written explanation of the department's determination.
2. Within 15 days of receiving the notification for disclosure, the manufacturer may submit a letter to the director of DCBS to appeal the department's determination and request reconsideration. The letter must explain the grounds for the request.
3. The director or director's designee will review the appeal to the determination and issue a determination within 15 days, or within a time period necessary to obtain legal review, of receiving an appeal letter.
4. 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.

If the department exempts information from disclosure provided by a manufacturer, the department will post an explanation of the basis for exempting the information and a general description of the nature of the information to the department's website.

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.

VIII. Review, filing status, and disclosure of reports

Submitted reports will be placed in the appropriate filing status while staff members review the report for compliance issues and trade secret claims. Here is information about each filing status. Not all are used for each report, and some are only used for a period of time. The filing statuses in iReg are for tracking the review process.

iReg filing status	Description of status
In progress	The manufacturer is editing the report. If there are old reports in this status, they should be deleted if they were not required. Any report that is required should be completed even if it is after the due date.
Submitted	The report was certified by the manufacturer. Drug Price Transparency (DPT) staff members have not yet started review of the report.
Compliance review	Staff members are reviewing the report for compliance. A request for information (RFI) may be posted in iReg correspondence. If an RFI is posted, the report will remain in this stage until staff members review the RFI response or until the due date for the response has expired.
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	The department 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 the department agrees with all trade secret claims on a report. Biscom information can be found on the webpage for manufacturers .
Under appeal	The department received a timely appeal to the trade secret determination. The report remains in this status while the department reviews the appeal.
Final trade secret determination	A trade secret determination is final if there is no timely appeal. A final trade secret determination is issued in Biscom after review of a timely 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).

List of filing statuses continued on next page.

iReg filing status	Description of status
Not in compliance	<p>Staff members found the report to be noncompliant (e.g. when the response to an RFI is insufficient or there is no response). The manufacturer should contact DPT compliance staff to resolve the issue. The program may initiate enforcement action by sending a USPS letter of potential noncompliance (NC Letter) to the responsible manufacturer. The NC Letter is the first step in the enforcement process where the manufacturer may be subject to penalties.</p> <p>Note: The account will have “Enforcement Action” at the top banner until all noncompliant reports are resolved.</p>
Enforcement	<p>The report was sent to the Enforcement unit. The Enforcement unit may issue orders and penalties.</p> <p>Note: The account will have “Enforcement Action” at the top banner until all noncompliant reports are resolved.</p>
Judicial hold	The report is awaiting the outcome of a court action.
Closed as filed	<p>The report is not sufficient to qualify for the status of “Filing Complete.” All report data and correspondence are published to the data transparency website (upon a final trade secret determination, if applicable). Enforcement actions may be pursued in the future.</p>

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.

Review of submitted reports

The department’s review timeline, as described in OAR 836-200-0535, is outlined here:

<p>Within 60 calendar days of receiving a report</p>	<p>The director or director’s designee may submit a written request for supporting documentation or additional information to the manufacturer. The request is limited to information necessary to:</p> <ul style="list-style-type: none"> • Clarify or substantiate the previously-reported material or • Enable analysis of factors affecting drug prices for providing recommendations to the Oregon Legislature <p>Manufacturer contacts will receive an email that correspondence is posted in iReg. To see this, a user needs to log into iReg and go to the "Correspondence" tab under the "Drug Prices" heading. Then select the correspondence and click on “Details” to read the message. Click on “Original” to see the attachment.</p>
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Within 60 calendar days of receiving a request for information	The manufacturer must provide a full and complete written response. All information claimed to be a trade secret must be clearly identified and accompanied with an explanation as specified under OAR 836-200-0540. If any requested information is unavailable to the manufacturer, the manufacturer must provide a thorough explanation as specified by OAR 836-200-0525, including a description of the missing information and the circumstances contributing to the manufacturer's inability to provide it.
Within 15 calendar days of receiving a request for more information	Manufacturers may request up to an additional 30 days to prepare and submit a response to the director's request. The request must explain the grounds for the request and the need for additional time, submitted in writing in the iReg system.
Within 15 days of receiving a request for additional time	The director or director's designee will respond in writing through the iReg system specifying and explaining the decision to grant or deny the request, or grant an amount less than requested.

All data reporting and correspondence between the manufacturer and the department that includes information about a specific drug report will occur within the iReg system to maintain records associated with the report. Do not use iReg to ask questions or for general communication with staff. Instead email us at rx.prices@dcbs.oregon.gov.

If the department receives supplemental report information about a specific drug report filed by the manufacturer through other communication avenues, the manufacturer will be directed to submit the additional report information through the iReg system. If marking a correspondence message box, or an attachment, as trade secret, clearly identify which information is claimed as a trade secret.

Public disclosure of reported information

Once a drug report has been received, the department will post the name of the manufacturer and the prescription drug that is the subject of the filing to the program's data transparency website as soon as practicable.

Submitted drug reports will be posted to the data transparency website as soon as practicable, usually by the next day. Information on the report that is not claimed as trade secret is also posted at this time. Correspondence in iReg that is not marked as trade secret is posted to the data transparency website once the report has a status of "filing complete" or "closed as filed."

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 that is determined by the department to be exempt from disclosure will not be posted to the data transparency website.

IX. Civil penalties

Manufacturers violating state law and administrative rules may receive a civil penalty based on the type of violation. Outlined below are the types of violations and the associated civil penalties that may be imposed against prescription drug manufacturers.

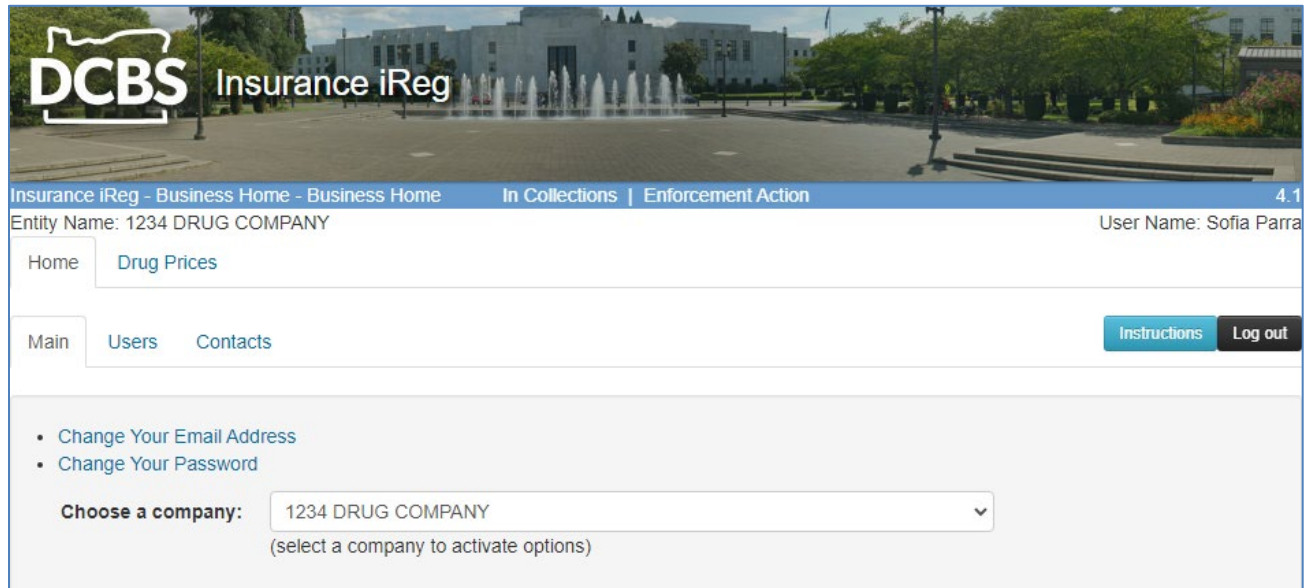
	Missing, inaccurate, or incomplete data	Untimely responses for more information	Failure to submit required report
First violation	\$500 per day maximum for first 30 days \$1,000 per day maximum after 30 days	\$1,500 per day maximum for first 30 days \$3,000 per day maximum after 30 days	\$2,500 per day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

For any other violations, including a breach of good-faith expectations, intent to obstruct implementation of the program, or other violations injurious to the public, the maximum civil penalty that may be imposed is \$10,000 per day of violation.

X. iReg walk-through

This section of the manufacturer user guide shows the different screens and elements within the reporting application.

- Figure 1 – [Home screen](#)
- Figures 2a-c – [Users and permissions](#)
- Figures 3a-e – [Contacts](#)
- Figures 4a-e – [New drug reports](#)
- Figures 5a-h – [Annual price increase reports and patient assistance](#)
- Figures 6a-b – [Documents: attaching and viewing](#)
- Figures 7a-d – [60-day price increase notices](#)
- Figure 8 – [Filing statuses in iReg](#)
- Figure 9 – [Trade secret claims](#)
- Figure 10 – [Certification of complete filing](#)
- Figures 11a-d – [Correspondence: starting correspondence and responding to request for information and noncompliance letters](#)
- Figures 12a-b – [Billings \(assessments\)](#)

Figure 1 – Home screen

Once a user has logged on to iReg, the home screen will display. The user can access the Main sub-tab, which has options for selecting the company for reporting. In the top right-hand corner of the screen, there are two buttons: “Instructions” and “Log out.” “Instructions” will go to the general iReg help website, and “Log out” will exit the user from the system.

An individual user may have access to multiple accounts and will be able to choose a manufacturer account on the main screen. If the login is different for the other manufacturers, the user will have to separately log in to access those accounts.

If we have started an enforcement action, you will see “Enforcement Action” in the banner at the top. Contact our compliance staff for questions about these issues.

If an unpaid billing has been sent to collections, you will see “In collections” in the banner at the top. See the [billing and collections information](#) in this guide or email us at rx.prices@dcbs.oregon.gov for questions about unpaid debts.

Figure 2a – Users: list of authorized users for account

The screenshot shows a web application interface for managing users. At the top, there are navigation tabs for 'Main', 'Users', and 'Contacts', along with 'Instructions' and 'Log out' buttons. On the left side, there are two menu options: 'User List' (highlighted in blue) and 'User Detail'. The main content area displays a table of users with the following columns: Logon ID, First Name, Last Name, Email Address, and Phone Number. A single user is listed with the Logon ID 'FLASTNAX', 'First &' as the first name, 'Last Name' as the last name, email 'rx.prices@dcbs.oregon.gov', and phone number '503-947-7200'. Below the table, it indicates 'Showing 1 to 1 of 1 entries' and provides navigation for 'Previous', '1', and 'Next'. At the bottom of the user list area, there are three buttons: 'Add User', 'Edit User', and 'Remove User'.

On the “Users” tab is a list of all users for a company/entity. Users who can manage other users can add, edit, or remove a user. Select the “User Detail” option on the left-hand side of the screen to see the user’s full profile for that account.

Figure 2b – Users: adding, editing, or removing users

The screenshot shows the 'User Detail' form. At the top, there are navigation tabs for 'Main', 'Users', and 'Contacts', along with 'Instructions' and 'Log out' buttons. On the left side, there are two menu options: 'User List' and 'User Detail' (highlighted in blue). The main content area has two tabs: 'New User' and 'Existing User'. The form contains several input fields: 'User Id' (required), 'First Name' (required), 'Middle Initial', 'Last Name' (required), 'Email Address' (required), and 'Phone' (with separate boxes for area code and extension, and an 'ext.' field, all required). Below these fields is a 'Mailing Address' section with a 'Line 1' input field. Red asterisks are placed to the right of the required fields to indicate they are mandatory.

Here is the screen to add a new user or edit a user’s information. The red asterisk shows required fields.

Section continued on next page.

Figure 2c – Users: access permissions

Application Access:

Financial Regulation

Registered Entities Administration

Registered Entities Submission

Registered Entities View

Manage Users

Application Information:
Includes Tax filings and other Financial Data
For Assistance Contact:
Financial Regulation Section
orinstax.ins@oregon.gov

Drug Prices

60-Day Increase Notice

Annual Drug Price Filings

New Specialty Drug Filings

Manage Users

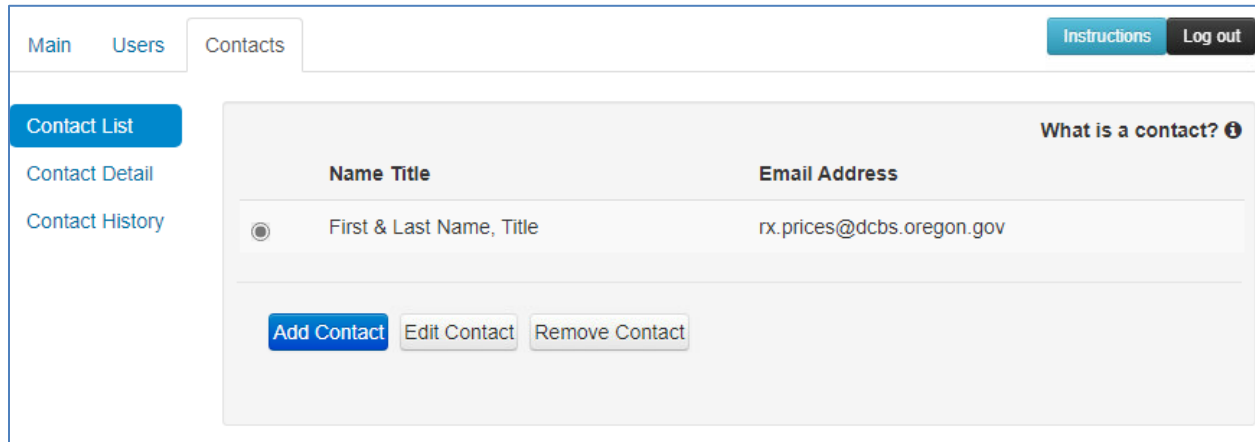
Application Information:
Drug Price reporting and correspondence by Pharmaceutical Manufacturers
For Assistance Contact:
Drug Price Transparency Program
rx.prices@oregon.gov
503-947-7200

Save **Cancel**

These are the user permission options. The Financial Regulation subsection is used for other entities regulated by the Division of Financial Regulation and is not applicable to pharmaceutical manufacturers.

New users can be delegated permissions to manage users, allowing the new user to create and edit users for the company account. Each user may also have permissions for the types of reports. This allows the user to view, create, edit, or submit reports for the specified categories. Do not give third-party users authority to manage users. Only manufacturer employees should have authority for who can access the account.

It is recommended that each account have at least two employees with access and at least one with authority to manage users. Be sure to keep all users and contacts up to date. Remember to click “Save” to confirm changes.

Figure 3a – Contacts: list of contacts receiving notices for account

The Contacts tab displays the people who have been identified as contacts for the company account. The difference between contacts and users is that contacts do not have permission to access the iReg system, but will receive emails regarding specified topics for the program.

All users have the option to “Add Contact,” “Edit Contact,” or “Remove Contact.” The primary user for the company should also be listed as a contact, as well as anyone else who should receive system notices. The “Edit Contact” button allows the user to edit or fill out the contact information. Contact History gives a list of the history of messages sent, which is explained in more detail later in this section.

Each account must have at least one contact because some notices may be sent to only contacts. Be sure to keep all users and contacts up to date.

Section continued on next page.

Figure 3b – Contacts: adding, editing, or removing contacts

The screenshot shows a web interface for managing contacts. At the top, there are navigation tabs: 'Main', 'Users', and 'Contacts'. On the right, there are links for 'Instructions' and 'Log out'. On the left, there is a sidebar with 'Contact List', 'Contact Detail' (highlighted), and 'Contact History'. The main content area is titled 'Contact Information:' and contains the following fields:

- Name and Title:** A text input field with the placeholder 'First & Last Name, Title'. A red asterisk is below the field, indicating it is required.
- Address Line 1:** A text input field.
- Address Line 2:** A text input field.
- City, State, ZIP:** Four separate input fields for city, state, ZIP, and a fourth field.
- Email Address:** A text input field with the placeholder 'rx.prices@dcbs.oregon.gov'. A red asterisk is below the field, indicating it is required.
- Telephone:** A text input field with the value '5039477200' and a separate 'Extension' input field.
- Cell/Mobile Number:** A text input field and a separate 'Extension' input field.
- Pager Number:** A text input field and a separate 'Extension' input field.
- Fax Number:** A text input field and a separate 'Extension' input field.

A red asterisk and the text '* Required' are located at the bottom right of the form area.

Users can edit the contact information for a specific contact within the company account. The next figure shows the types of emails the contact can receive.

Section continued on next page.

Figure 3c – Contacts: notice types

Receive Notices About:

Financial Regulation:

ADMIN ACTIONS *	<input checked="" type="checkbox"/>
REGISTERED ENTITIES *	<input checked="" type="checkbox"/>

Drug Prices:

Annual Drug Price Filings *	<input checked="" type="checkbox"/>
Billing/Invoicing *	<input checked="" type="checkbox"/>
Legal Affairs Contact *	<input checked="" type="checkbox"/>
New Specialty Drug Filings *	<input checked="" type="checkbox"/>
Other Countries Pricing	<input checked="" type="checkbox"/>
Patient Assistance Programs	<input checked="" type="checkbox"/>
Regulatory/Compliance Contact *	<input checked="" type="checkbox"/>

Pharmaceutical Sales Representative-PSR:

PSR Licensing *	<input checked="" type="checkbox"/>
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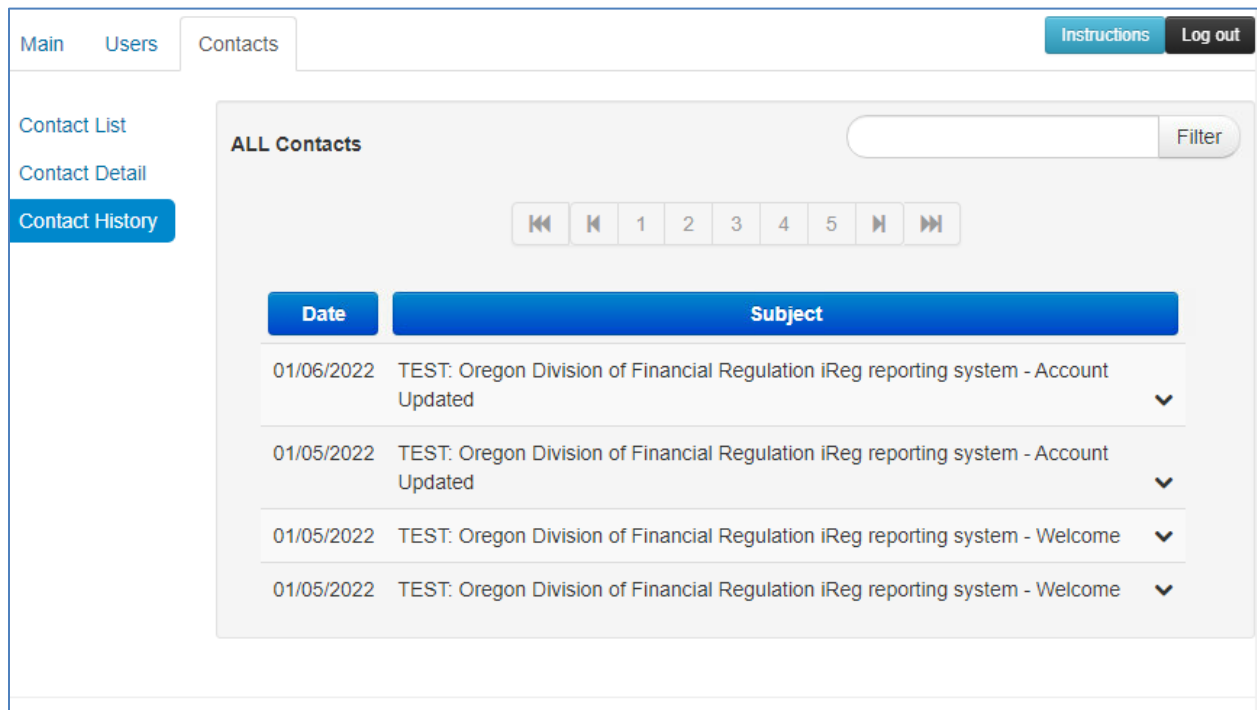
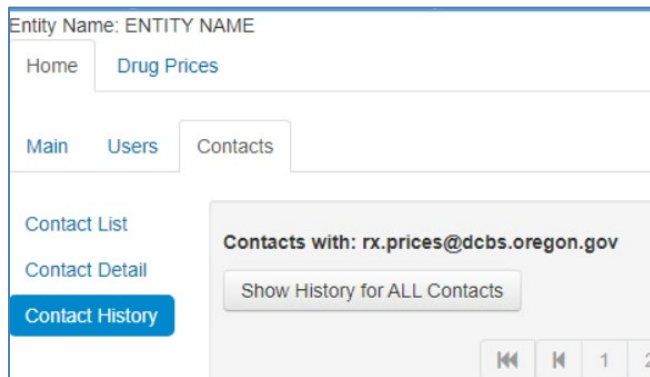
*At least one contact must subscribe to this notification

Selecting a notification will cause the contact to receive email notifications each time the specified event occurs for this entity.

There are several types of program topics a contact can receive. Note: At least one contact must be able to receive the required email notices from the department as indicated by the red asterisks. Click “Save” to confirm changes.

Section continued on next page.

Figures 3d and 3e – Contacts: history of emails



The Contact History screen displays the activity the specific contact has had on the account, such as establishing a new user and editing user information. Clicking on the button labeled “Show History for ALL Contacts” displays all history for the account.

Figure 4a – New drug reports

Insurance iReg - Drug Prices - New Drugs - Filings 9.0.1
Entity Name: ENTITY NAME User Name: First & Last Name

Home Drug Prices

New Drugs Annual Filings Correspondence 60-Day Billings Instructions Log out

Filings
Details

Show All

10 records per page Search:

▲ Create/Filing Date Trade Name NDC Status

No data available in table

Showing 0 to 0 of 0 entries ← Previous Next →

Create New Filing

All new drug reports created by the company display in the New Drugs sub-tab. Reports can be sorted by the categories on the list of filings. A report can be created by clicking the “Create New Filing” button. Users can edit filings that are in progress by clicking on a drug filing and then choosing “Details” on the left side. Once a report is submitted, it cannot be edited by users.

Figure 4b – New drug filing creating a report

Home Drug Prices

New Drugs Annual Filings Correspondence 60-Day Billings Instructions Log out

Filings
Details

Start New Drug Filing

NDC: *

Trade Name: *

Chemical Name: *

Next Cancel

When the “Create New Filing” button has been selected, the user must enter the National Drug Code (NDC), trade name, and chemical name to initiate the filing. Once this information has been reported, the filing is started and appears in the list of filings. The “Next” button navigates the user to the other data elements to be reported.

Section continued on next page.

Figure 4c – New drug filing details

Figures 4c to 4e show what the filing looks like in iReg. For more information and guidance on the data elements, see Section IV ([New Drug Reporting](#)) of this user guide. Each data field that can be claimed as trade secret has a check box next to it, which can be selected to claim the information reported as a trade secret under ORS 192.345. See Figure 9 and [Section VII](#) for information on trade secret claims.

Filing Details

Important Trade secret claims are defaulted to "Not Set" for data elements that have the option to claim the response as a trade secret per ORS 192.345. You must select "Yes" to claim the response as a trade secret or "No" to claim that the response is not trade secret. Once submitted, all data and correspondence not claimed as trade secret are published on the data transparency website for public viewing.
 Updated 03/31/2024

Filing Status: In Progress

* NDC:

* Trade Name:

* Chemical Name:

Pricing Information

* Marketing Description: Trade Secret? Not Set

* Wholesale Acquisition Cost (WAC): Trade Secret? Not Set

* Dosage: Trade Secret? Not Set

* Pricing Methodology: Trade Secret? Not Set

Section continued on next page.

Figure 4d – New drug filing details continued

* FDA Priority or Breakthrough:	<input type="text"/>	
Acquisition Cost:	<input type="text"/>	Trade Secret? Not Set
	Required if the drug was acquired	
Acquisition Date:	<input type="text"/>	Trade Secret? Not Set
	Required if the drug was acquired	
* Estimated Avg. Number of Patients per Month:	<input type="text"/>	Trade Secret? Not Set
Patients per Month Description:	<input type="text"/>	Trade Secret? Not Set
R&D Costs Using:		
* International Public Funds:	<input type="text"/>	Trade Secret? Not Set
* USA Federal Public Funds:	<input type="text"/>	Trade Secret? Not Set

Section continued on next page.

Figure 4e – New drug filing details continued

* All States Public Funds: Trade Secret? Not Set

* All Local Public Funds: Trade Secret? Not Set

* Public Funds Sources and Uses: Trade Secret? Not Set

Documents:

10 records per page Search:

Doc Type	Reason for Inclusion	TS?	Justification	Document
No data available in table				

Showing 0 to 0 of 0 entries

[← Previous](#) [Next →](#)

[Attach New Document](#)

[Continue To Certification](#) [Save Progress](#) [Cancel](#)
[Start/Open Correspondence](#) [Delete Filing](#)

“Save Progress” will save all information that has been entered into the report, but will not submit it. Click “Continue to Certification” when the report is finalized and ready for submission. See Figure 6 about attaching documents and Figure 10 for the certification screen.

Figure 5a – Annual price increase reports and patient assistance

ATTENTION: This guide has been updated with changes from the recent court ruling regarding these reports. Read [DFR Bulletin No. 2024-3](#) for more information.

Insurance iReg - Drug Prices - Annual Filings - Filings Enforcement Action 9
Entity Name: ENTITY NAME User Name: Sofia Pa

Home Drug Prices

New Drugs Annual Filings Correspondence 60-Day Labeler Names Billings Instructions Log o

Filings
Details

ATTENTION PLEASE

iReg is now updated for the revised filings. The due date for the required patient assistance program reporting has been extended to May 15, 2024. The additional information may be reported voluntarily. Please see [DFR Bulletin No. 2024-3](#) for information about this change related to the recent court ruling.

Updated 03/31/2024

Show All

10 records per page Search:

	Create/Filing Date	Filing Year	Trade Name	NDC	Status
<input checked="" type="radio"/>	01/03/2023	2022	Trade name	00111222333	In Progress
<input type="radio"/>	01/06/2022	2021	Brand name, if applicable	00112233445	Submitted
<input type="radio"/>	02/10/2022	2021	Idarubicin Hydrochloride	00143930601	Submitted

Showing 1 to 3 of 3 entries ← Previous 1 Next →

Create New Filing

All annual price increase reports created by the company will display in the “Annual Filings” tab. Reports can be sorted by the categories on the list of filings. A report can be created by clicking the “Create New Filing” button. Users can edit filings that are in progress by clicking on a drug filing and then choosing “Details” on the left side. Once a report is submitted, it cannot be edited by users.

Figure 5b – Annual price increase filing creating a report

The screenshot displays the iReg software interface for creating an annual drug filing report. The top navigation bar includes 'New Drugs', 'Annual Filings', 'Correspondence', '60-Day', 'Labeler Names', 'Billings', and 'Instructions'. The 'Annual Filings' section is active, with a 'Details' button highlighted. A prominent red alert box titled 'ATTENTION PLEASE' contains the following text: 'iReg is now updated for the revised filings. The due date for the required patient assistance program reporting has been extended to May 15, 2024. The additional information may be reported voluntarily. Please see DFR Bulletin No. 2024-3 for information about this change related to the recent court ruling. Updated 03/31/2024'. Below the alert, the 'Start Annual Drug Filing' section is visible, featuring four required input fields: 'Filing Year', 'NDC', 'Trade Name', and 'Chemical Name', each marked with a red asterisk. At the bottom of this section are 'Next' and 'Cancel' buttons.

When the “Create New Filing” button has been selected, the user must enter the year for which they are filing and the NDC to initiate the filing. If not automatically populated, the trade name and chemical name must also be entered. Once this information has been reported, the filing is started and appears in the list of filings. The “Next” button navigates the user to the other data elements to be reported. Section continued on next page.

Figure 5c – Annual price increase filing details

Figures 5c to 5h show what the filing looks like in iReg. For more information and guidance on the data elements, refer to Section V ([Annual Price Increase Reporting](#)) of this user guide.

ATTENTION: Trade secret claims are defaulted to “Not set” or “No” for data elements that have the option to claim the response as a trade secret per ORS 192.345. You must select “Yes” to claim the response as a trade secret. Once submitted, all data and correspondence not claimed as trade secret are published on the data transparency website for public viewing.

Drug Price Increase Filing Details

Important Trade secret claims are defaulted to "No" for data elements that have the option to claim the response as a trade secret per ORS 192.345. You must select "Yes" to claim the response as a trade secret. Once submitted, all data and correspondence not claimed as trade secret are published on the data transparency website for public viewing.

Updated 03/31/2024

Filing Status: In Progress

* Filing Year:

* NDC:

* Trade Name:

* Chemical Name:

Generic Name(s):

Patient Assistance Programs:

10 records per page Search:

Program Name	Participant Count	Value of Assistance
No data available in table		

Showing 0 to 0 of 0 entries

When adding patient assistance, the details screen will open as shown in Figure 5d. Section continued on next page.

Figure 5d – Annual price increase filing details continued

All fields are required for each patient assistance program being reported. Add each program available in Oregon, even if there are no Oregon participants.

The screenshot shows a web form titled "Add Assistance Program". It contains several required fields, each marked with an asterisk (*). The fields are: "Program Name" (text input), "Program Type" (dropdown menu), "Number of Participants" (text input), "Value of Assistance" (text input), "Refills" (dropdown menu), "Time Period" (text area), "Eligibility Criteria" (text area), and "Eligibility Verification Process" (text area). To the right of each text input or text area is a "Trade Secret?" label followed by a yellow dropdown menu currently set to "Not Set". The form is contained within a window with a close button (X) in the bottom right corner.

Section continued on next page.

Figure 5e – Annual price increase filing details continued

Patient Assistance Programs:

10 records per page Search:

Program Name	Participant Count	Value of Assistance	View/Edit	🗑️
Drugs 4 U	100	2000.00	View/Edit	🗑️
More Assistance Program	<i>trade secret</i>	<i>trade secret</i>	View/Edit	🗑️

Showing 1 to 2 of 2 entries ← Previous 1 Next →

[Add Assistance Program](#)

For the NDC:

Net Increase Percent:

Introductory Price: Trade Secret? No ▼

Price on January 1st:

Price on December 31st:

Highest Wholesale Acquisition Cost (WAC):

Lowest Wholesale Acquisition Cost (WAC):

Average Wholesale Acquisition Cost (WAC): Trade Secret? No ▼

Dosage: Trade Secret? No ▼

Section continued on next page.

Figure 5f – Annual price increase filing details continued

Date on Market:	<input type="text"/>	
Increase factors:	<input type="text"/>	Trade Secret? No ▼
R&D Costs Using:		
International Public Funds:	<input type="text"/>	Trade Secret? No ▼
USA Federal Public Funds:	<input type="text"/>	Trade Secret? No ▼
All States Public Funds:	<input type="text"/>	Trade Secret? No ▼
All Local Public Funds:	<input type="text"/>	Trade Secret? No ▼
Public Funds Sources and Uses:	<input type="text"/>	Trade Secret? No ▼
Direct Costs:		
Manufacturing:	<input type="text"/>	Trade Secret? No ▼
Marketing:	<input type="text"/>	Trade Secret? No ▼
Distribution:	<input type="text"/>	Trade Secret? No ▼
Safety and Effectiveness:	<input type="text"/>	Trade Secret? No ▼

Section continued on next page.

Figure 5g – Annual price increase filing details continued

Total Sales Revenue:	<input type="text"/>	Trade Secret?	No <input type="button" value="v"/>
Profit from Drug:	<input type="text"/>	Trade Secret?	No <input type="button" value="v"/>
Other Relevant Pricing Information:	<input type="text"/>	Trade Secret?	No <input type="button" value="v"/>

Non US Prices:

We only sell in the US Trade Secret? No

	Country	Price
Country 1:	<input type="text"/>	<input type="text"/>
Country 2:	<input type="text"/>	<input type="text"/>
Country 3:	<input type="text"/>	<input type="text"/>
Country 4:	<input type="text"/>	<input type="text"/>
Country 5:	<input type="text"/>	<input type="text"/>
Country 6:	<input type="text"/>	<input type="text"/>
Country 7:	<input type="text"/>	<input type="text"/>
Country 8:	<input type="text"/>	<input type="text"/>
Country 9:	<input type="text"/>	<input type="text"/>
Country 10:	<input type="text"/>	<input type="text"/>

5-Year Net Annual Increases:

	% Increase	<input type="checkbox"/> Not on Market
2023	<input type="text"/>	<input type="checkbox"/> Not on Market
2022	<input type="text"/>	<input type="checkbox"/> Not on Market
2021	<input type="text"/>	<input type="checkbox"/> Not on Market
2020	<input type="text"/>	<input type="checkbox"/> Not on Market
2019	<input type="text"/>	<input type="checkbox"/> Not on Market

Trade Secret? No

Section continued on next page.

Figure 5h – Annual price increase filing details continued

Documents:

10 records per page Search:

Doc Type	Reason for Inclusion	TS?	Justification	Document
No data available in table				

Showing 0 to 0 of 0 entries ← Previous Next →

[Attach New Document](#)

[Continue To Certification](#) [Save Progress](#) [Cancel](#) [Start/Open Correspondence](#) [Delete Filing](#)

“Save Progress” will save all information that has been entered into the report, but will not submit it. Click on “Continue to Certification” when the report is finalized and ready for submission. Refer to Figure 6 about attaching documents and Figure 10 for the certification screen.

Figure 6a – Documents: attaching and viewing

Add Document

Attach Supporting Document

Important Trade secret claims are defaulted to "Not Set" for data elements that have the option to claim the response as a trade secret per ORS 192.345. You must select "Yes" to claim the response as a trade secret or "No" to claim that the response is not trade secret. Once submitted, all data and correspondence not claimed as trade secret are published on the data transparency website for public viewing.

Updated 03/31/2024

Document Type: Other Supporting Document: ▾ *

Reason for Inclusion: *

Document: Choose File BiscomNon...Guide_v2.pdf *

* Trade Secret? Not Set ▾

If a document is needed to explain a data element for a new drug or an annual price increase report, click the “Attach New Document” button. Identify the document type with the section of the report or choose “Other Supporting Documentation.” Describe what is being attached and the reason.

Note: The “Reason for Inclusion” information will appear on the transparency site that is viewable by the public.

Then upload the file. Once the file is uploaded, the user can make a trade secret claim and provide the proper explanation for why the document is a trade secret. The reporting system will accept all types of document types to upload. The user may upload multiple documents to a single report.

Note: Do not upload excessive or unnecessary documents.

Section continued on next page.


Figure 6b – Documents: uploaded

Documents:

10 records per page Search:

Doc Type	Reason for Inclusion	TS?	Justification	Document
Other Supporting Documentation	Description and reason for document	No		<input type="button" value="View Info"/> <input type="button" value="View Original"/> <input type="button" value="Trash"/>

Showing 1 to 1 of 1 entries 1

Once a document has been attached to a filing, the screen will close and the document will be displayed in the table. If multiple documents are uploaded, they can be sorted by several categories or deleted from the report using the trash can icon  before the report is submitted.

There are two buttons for an attached document: “View Info” and “View Original.” “View Info” provides the same information displayed in the documents table along with the size of the file, date and time uploaded, and MD5 hash (the attachment identification code). “View Original” lets users see the document as it was uploaded. Exception: If a document is marked trade secret, it will not be viewable.

Note: The “Reason for Inclusion” is posted to the transparency website even if the document is claimed as a trade secret.

Figure 7a – 60-day price increase notices

All 60-day notice price increase reports display in the 60-Day tab. Reports can be sorted by the categories on the list of filings. A report can be created by clicking the “Create New Filing” button. Users can edit filings that are in progress by clicking on a drug filing and then choosing “Details” on the left-hand side of the screen. Once a report is submitted, it cannot be edited.

Figure 7b – 60-day price increase filing creating a report

When the “Create New Filing” button has been selected, the user must enter the NDC and the effective date of the increase to initiate the filing. If not automatically populated, the trade name and chemical name must also be entered. Once this information has been reported, the filing is started and appears in the list of filings. The “Next” button navigates the user to the other data elements to be reported.

Section continued on next page.

Figure 7c – 60-day price increase filing details

Figures 7c and 7d show what the filing looks like in iReg. For more information and guidance on the data elements, refer to Section VI ([60-day Price Increase Notice Reporting](#)) of this user guide.

Filings
Details

60-Day Price Increase Notice Details

Important Trade secret claims are defaulted to "Not Set" for data elements that have the option to claim the response as a trade secret per ORS 192.345. You must select "Yes" to claim the response as a trade secret or "No" to claim that the response is not trade secret. Once submitted, all data and correspondence not claimed as trade secret are published on the data transparency website for public viewing.

Updated 03/31/2024

Filing Status: In Progress

* NDC:

* Trade Name:

* Chemical Name:

Pricing Information

* Year Available in US:

* Current Price (WAC):

Price Increase for this NDC

* New Price (WAC): <input type="text"/>	Trade Secret? Not Set ▼
* Date Increase Effective: <input type="text" value="7/19/2023"/> <input type="button" value="📅"/>	Trade Secret? Not Set ▼

Section continued on next page.

Figure 7d – 60-day price increase filing details continued

Reason for Price Increase

Change: No A chemical change was made.

Improvement: Yes A functional improvement was made.

* Description: Trade Secret? Not Set

Other: Yes Use this when the price increase is due to reasons not identified above.

Description: Trade Secret? Not Set

Other Relevant Information: Trade Secret? Not Set

Continue To Certification
Save Progress
Cancel

Start/Open Correspondence
Delete Filing

“Save Progress” will save all information that has been entered into the report, but will not submit it. Click “Continue to Certification” when the report is finalized and ready for submission to the department. See Figure 10 for the certification screen.

Figure 8 – Filing statuses in iReg

The picture below shows the list of the filing statuses used in iReg. The filing statuses in iReg were updated to track where the report is in the review process.

Not all filing statuses are used for each report and some are only used for a period of time. For example, the status “Trade secret determination issued” would only display for 15 days after the determination is sent in Biscom.

Go to [Section VIII](#) for more details about these filing statuses. Note that the filing statuses on the data transparency site are more general.

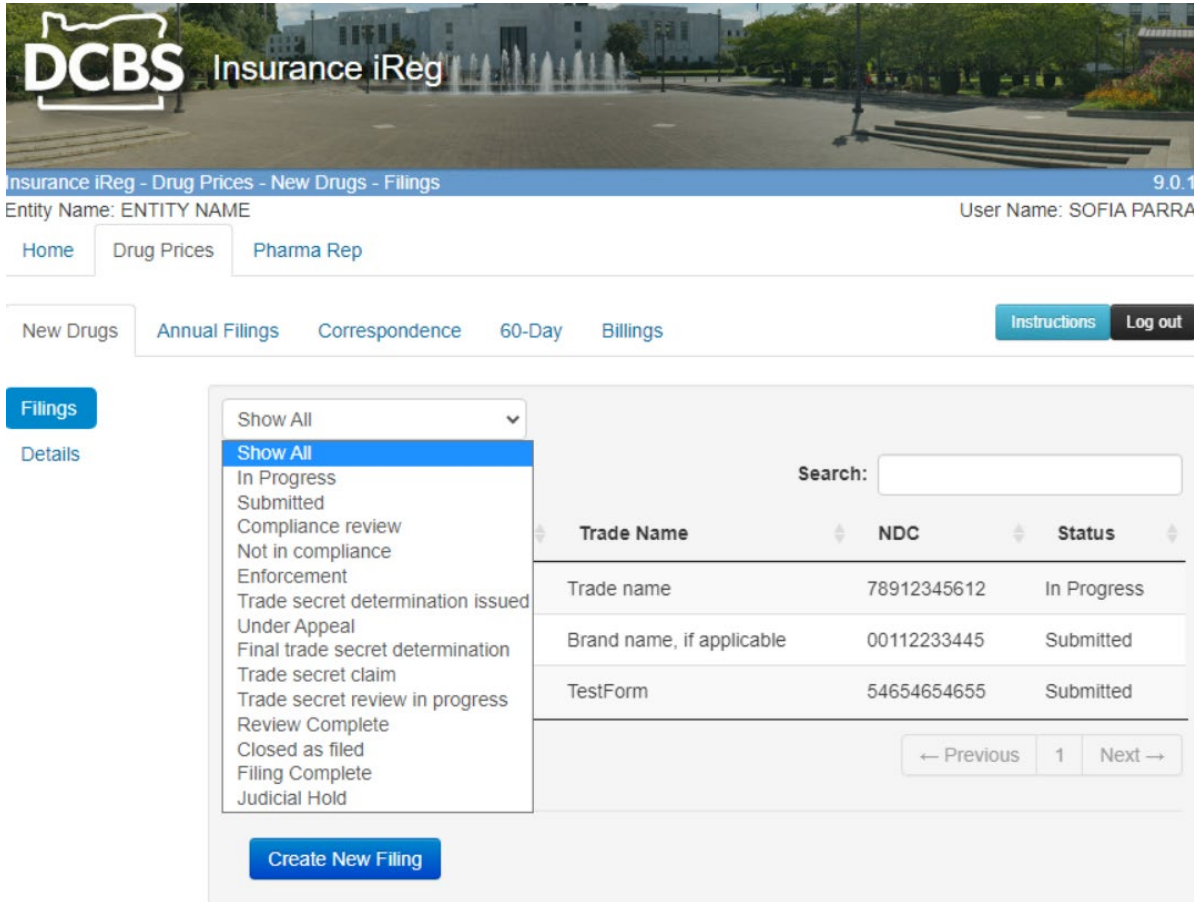


Figure 9 – Trade secret claims

* 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.

Users may claim information as trade secret by changing the trade secret dropdown to “Yes” next to a data element where the option is available and identifying which specific information is claimed. For more information on the trade secret claims, see the [Information Claimed to be Trade Secret](#) in Section VII of this guide.

For each data element or information claimed to be a trade secret, the manufacturer will be prompted to provide a written explanation as to why the information is exempt from disclosure, 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.

The department will review the manufacturer’s explanations and make a determination on a case-by-case basis as outlined in OAR 836-200-0540.

Figure 10 – Certification of complete filing

Certify Filing

Chemical Name:

Important Trade secret claims are defaulted to "No" for data elements that have the option to claim the response as a trade secret per ORS 192.345. You must select "Yes" to claim the response as a trade secret. Once submitted, all data and correspondence not claimed as trade secret are published on the data transparency website for public viewing.

Updated 03/31/2024

Certification

Certifier's Name: *

I, the undersigned authorized filer, hereby certify that the filing submitted complies with the applicable State law and regulations, Bulletins, filing requirements and reporting guidance set forth on the Department of Consumer and Business Services' web site. I further certify the filing is not false or misleading in any material respect and that I am authorized to sign and submit this certificate on behalf of the Company identified (hereinafter Company).

I understand that the Department of Consumer and Business Services will rely on this certificate and, should it be determined that this filing is materially false or misleading, appropriate action including civil penalties, as authorized by law, will be taken by the Department of Consumer and Business Services against the Company.

When a report is complete and ready to submit, click the “Certify” button. Users enter their full name and check the box to officially certify the report. Clicking the “Certify” button completes the process of filing a report. If there are any blank or required boxes that have not been completed, an error message will prompt the user to correct the issue before they can certify the report.

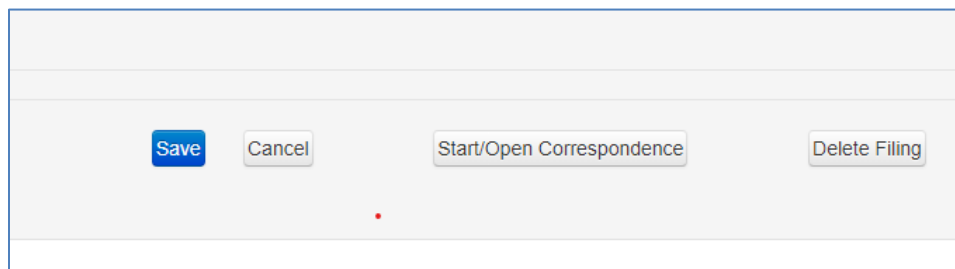
Figure 11a – Correspondence: list of correspondence

Start Date	Status	Filing Type	Trade Name	NDC	Rcvd/Sent/New	Attn Date	Attn Party
01/06/2022	Submitted	increase	Brand name, if applicable	00112233445	1 / 1 / 0	02/25/2022	Manufacturer
01/06/2022	Submitted	annual	Brand name, if applicable	00112233445	1 / 0 / 1		DFR

Correspondence is a way to communicate information specific to the report. Program staff will use the correspondence function to communicate information about the report and issue request for additional information letters. This information is available to the public once a report is in the “filing complete” or “closed as filed status.”

By selecting the correspondence thread and then clicking “Details” on the left-hand side of the screen, users can see the details of the selected correspondence.

Do not post messages not directly related to the information required for the report. Email DPT staff at rx.prices@dcb.oregon.gov for all other communications, such as questions about the program, the status of a report, enforcement actions, billings, etc.

Figure 11b – Correspondence: starting correspondence and responding to request for information and noncompliance letters

A correspondence thread must be associated with a report. It can be started from within the report by clicking on the “Start/Open Correspondence” button at the bottom of a report. You can also respond to one that was already started from the list of correspondence.

Section continued on next page.

Figures 11c and 11d – Correspondence: adding correspondence

Chemical Name:	Generic name
<hr/>	
01/06/2022 - parrase Reply Due: 02/25/2022	Other Viewed On: 01/27/2023
Message:	Testing
<hr/>	
01/06/2022 - flastnax	Request for Additional Information Viewed On: 01/06/2022
Message:	Testing
<hr/>	
<input type="button" value="Add Correspondence"/>	

New Correspondence

Important Trade secret claims are defaulted to "Not Set" for data elements that have the option to claim the response as a trade secret per ORS 192.345. You must select "Yes" to claim the response as a trade secret or "No" to claim that the response is not trade secret. Once submitted, all data and correspondence not claimed as trade secret are published on the data transparency website for public viewing.
Updated 03/31/2024

Correspondence Type: *

Message: * Trade Secret?

Supporting Document: BiscomNonDcbsUserGuide_v2.pdf Trade Secret?

Select “Add Correspondence” to post a response or provide additional information for the report. Users may choose a correspondence type from the categories provided and enter in the main message they want to communicate and add an attachment if needed.

Either the message box or attachment (or both) can be marked as trade secret if needed. Follow the guidelines in [Section VII](#) when making trade secret claims.

Section continued on next page.

Figure 11e – Correspondence: viewing agency correspondence to manufacturer

The screenshot displays a web application interface for viewing correspondence. At the top, there are navigation tabs: "New Drugs", "Annual Filings", "Correspondence" (selected), "60-Day", and "Billings". On the right, there are buttons for "Instructions" and "Log out".

On the left side, there is a "Thread List" section with a "Details" button highlighted in blue.

The main content area is titled "Annual Drug Filing". Below the title, it states: "Correspondence thread opened on 01/06/2022. Manufacturer: ENTITY NAME".

There are four input fields for drug information:

- Filing Year:** 2021
- NDC:** 00112233445
- Trade Name:** Brand name, if applicable
- Chemical Name:** Generic name

Below the input fields, there is a message section:

- Date:** 01/06/2022 - parrase
- Reply Due:** 03/07/2022
- Request for Additional Information:** Not Viewed
- Message:** Here's a request for information. The response is due in 60 days.
- Supporting Document:** View Info, original

When a user receives an email that we have attached correspondence, it should be viewed as soon as possible. There are deadlines for responding to our requests that are available in the correspondence details.

There are two buttons for an attached document: "View Info" and "View Original." "View Info" provides the same information that is displayed in the documents table along with the size of the file, date and time uploaded, and MD5 hash. "View Original" lets users see the document as it was uploaded. For requests, a formal letter will be attached explaining exactly what is being requested.

To reply to our request, refer to Figure 11c above about adding correspondence.

Figure 12a – Billings: list of assessments

Note: There will be a different fee process for 2024 and forward. This guide will be updated once those details are finalized. The information here relates to billings for periods before Aug. 1, 2023.

Year	Status	Amount Billed	Due Date
2023	PENDING	5000.00	10/01/2023
2022	IN COLLECTIONS (A.R.)	400.00	10/01/2022
2021	COMPLETED	400.00	10/01/2021
2020	COMPLETED	17876.00	10/01/2020

The Billings tab shows the amounts assessed each year. To view the details and print a voucher, select the year, and select “Details” on the left-hand side of the screen. You can only print a voucher when the status is “Pending,” so contact us if you need a copy of a voucher for a billing with a different status. To view payments and financial entries, select “Fiscal Details.” Unpaid billings will be sent to collections and forwarded to the Oregon Department of Revenue. When that happens, the payment information in iReg is not going to be complete. The payment must be made through the Department of Revenue’s [Other Agency Accounts](#).

Section continued on next page.

Figure 12b – Billings: details and printing a voucher

Year:

Billing Status: *

Annual Assessment Billed: *

Report Assessment Billed: *

Total Amount Billed:

Due Date: *

10 records per page

NDC	Trade Name	Chemical Name	Filing Type
00002143461	p_trade_name	p_chemical_name	New Specialty I
00002143461	p_trade_name	p_chemical_name	New Specialty I
00002143461	p_trade_name	p_chemical_name	New Specialty I

Showing 1 to 10 of 145 entries

To view the details of the billing and print the voucher, go to “Details.” You can see the annual assessment and reporting assessment. You will also see the list of reports associated with the reporting assessment.

To get the voucher, scroll down and select “Print Payment Coupon.” Mailing instructions will be on the voucher.

ATTENTION: Include a copy of the coupon with the payment for the payment to be processed correctly.

Refer to the [billing and collections information](#) in this guide for additional information. Email rx.prices@dcbs.oregon.gov for questions about billings or unpaid debts.