Manufacturer User Guide

Drug Price Transparency Program

DCBS | Department of Consumer and Business Services

Updated Feb. 12, 2026. This guide has the following updates posted Jan. 9 and Feb. 12 as well as some other minor updates:

- **IMPORTANT:** Reinstating required annual price increase reporting for reports due Apr. 15, 2026 (extended from Mar. 15 for 2026 only).
- Changes in iReg for new prescription drug reports related to the 2025 administrative rules, pages 12 and 13.
- Updates to marketing description template for new prescription drug reports, page 14.
- Guidance for identifying type of prescription drug, page 15.
- Clarification that reasons for inclusion are published when attaching documents. See figures 7a and 7b, pages 52 and 53.
- Updates in the iReg walk-through section, pages 31-64.

Reminder that trade secret information and process moved to the Trade Secret Supplement.

Agency information, Oregon laws and rules, and definitions

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 Oregon's DPT Program: Oregon's Drug Price Transparency (DPT) Program is part of DFR and provides accountability for prescription drug pricing through the notice and disclosure of specific drug costs and price information from pharmaceutical manufacturers, health insurers, pharmacy benefit managers, and consumers. Visit https://dfr.oregon.gov/drugtransparency. Webpage for manufacturers: https://dfr.oregon.gov/drugtransparency/Pages/manufacturers.aspx.

Laws and rules

Oregon Revised Statutes – ORS 646A.680 to 646A.692

Oregon Administrative Rules – OAR 836-200-0500 through 836-200-0560

Definitions

Dosage: The highest amount, strength, and frequency that a patient would take of a drug as recommended by its prescribing label as approved by the FDA.

FDA: The United States Food and Drug Administration (https://www.fda.gov/).

iReg: The Oregon DFR reporting system. Manufacturers are required to submit reports using iReg and maintain current users and contacts on accounts. "User" refers to someone who is listed and authorized to access the manufacturer account in iReg. Users can review and submit reports, add correspondence, view labeler names and numbers, and view billing information and transactions. "Contact" refers to someone who is listed on the manufacturer account in iReg to receive notices by email and who DFR may communicate with about the account. Contacts cannot log into an iReg account unless they are also listed as users.

Net yearly increase: An increase in the wholesale acquisition cost (WAC) of a drug over the course of a calendar year dividing the average WAC of the drug over the course of a calendar year by the average WAC over the course of the previous calendar year.

New prescription drug: A prescription drug that has received initial approval either through an original new drug application (NDA) under 21 U.S.C. 355(b); through an abbreviated new drug application (ANDA) under 21 U.S.C. 355(j); or through a biologics license application (BLA) under 42 U.S.C. 262. Each unique national drug code (NDC) will be considered a new prescription drug when that NDC enters the market.

A new prescription drug's *introduction date* is the FDA start marketing date or the date the product is first available for purchase in the United States, whichever is later.

A new prescription drug does not include a product that is only for use under an emergency use authorization (EUA); or a product with a change in the NDC or labeler name that has been previously marketed by the same or a different manufacturer; or a reformulated vaccine that replaces a vaccine that has the same name, application number, manufacturer, and labeler.

One-month supply: The total dosage of a prescription drug recommended by its prescribing label as approved by the FDA for 30 days or for a course of treatment lasting less than one month.

Reporting manufacturer: An entity meeting all the following characteristics:

- Required to be registered with the Oregon Board of Pharmacy as a drug manufacturer.
- Engages in the manufacture, directly or indirectly, including through contracts with other entities, of prescription drugs available for sale in this state, as defined by ORS 646A.689(1)(d), that are approved by the FDA under a new drug, an abbreviated new drug, or a biologics license application.
- Sets or changes the WAC of the FDA approved drugs it manufactures.

A reporting manufacturer does not include those that only manufacture prescription drugs as a registered 503B facility (section 503B of the Federal Food, Drug, and Cosmetic Act; 21 USC 353b).

Wholesale acquisition cost (WAC): Is the term in 42 U.S.C. 1395w-3a(c)(6)(B).

Table of Contents

I. Overview

The Oregon Prescription Drug Price Transparency Act requires reporting manufacturers to file prescription drug price reports and pay an annual assessment to DCBS. The department reviews the reports and discloses nontrade secret information to the public.

The purpose of this guide is to help reporting manufacturers comply with the transparency requirements for Oregon's DPT Program. The department uses the iReg system for the filing of manufacturer prescription drug price reports and for the billing of fees assessed by the department to reporting manufacturers. Refer to the Trade Secret Supplement that discusses trade secret claims and processes.

II. Accounts: registration, users, contacts, labelers, and notices

All manufacturer reporting for Oregon's DPT Program will occur through the iReg system. The iReg system provides the mechanism to submit reports, allows correspondence between the department and filers that is linked to a report, publish reports and correspondence to the data transparency site, list labeler names and numbers related to the account, and display billing assessments. Refer to the iReg walk-through for examples of the iReg system.

Once a report is submitted, each data element not claimed as trade secret is published on the data transparency website for public viewing. Report correspondence in iReg that is not claimed as trade secret is published after the report has the status of "filing complete" or "closed as filed."

Data elements and correspondence flagged with a claim for trade secret are first reviewed to determine if we agree with the claim. Refer to Trade Secret Supplement and OAR 836-200-0540 for more information before making any trade secret claims on the filing.

Registration and account creation

Prescription drug manufacturers that meet the definition of a *reporting manufacturer* as defined in OAR 836-200-0505 are required to have an account (register) and pay an annual assessment. 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 is required to create its own separate account with the department, unless pricing is decided by another reporting manufacturer who has its own account (such as a parent or sibling company). If a parent or other related company is setting the price for more than one reporting manufacturer, then the account creation and reporting responsibility is with that company and the account needs to include all FDA labeler names and numbers.

Consistent with OAR 836-200-0510, all reporting manufacturers are required to have an account regardless of whether they must file any reports. Registration is required within 30 days of becoming a reporting manufacturer or 10 days before a reporting deadline.

For example, Drug Company Z has its first FDA approved NDC with a marketing start date of 4/1/2025 in the FDA NDC directory. Because Z is preparing to launch this first product, the NDC will not be available for sale in the United States until 6/1/2025. If no report is required, Z is required to register by 7/1/2025, within 30 days of becoming a reporting manufacturer. If the NDC meets the reporting threshold, a report would be due 7/1/2025 and Z would be required to register 10 days before (by 6/20/2025).

To register, complete the "Register a reporting manufacturer" form on our webpage for manufacturers. We process registrations usually within two business days and set up an account in iReg. We will set up the manufacturer's employee on the registration as a user and contact on the account and send a confirmation email. There will also be automated emails from our iReg system.

To make changes to an account, use the "Update an existing account" form.

For late registrations, we will set up billings for the annual fees owed for prior years. Prior year reports (required under current laws) should be filed as soon as possible.

Users and contacts

Reporting manufacturers are responsible for keeping users and contacts up to date. You must designate as a user at least one manufacturer employee who manages access to the account and receives trade secret determinations.

ATTENTION: If you do not keep this information up to date, you may miss important due dates and appeal deadlines, potentially incurring penalties.

Make sure your email system is not blocking or quarantining communications from iReg (or any 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 in iReg whenever possible. For every manufacturer account, there should be at least one employee with the appropriate permissions to manage users. Because certain notices are only received by contacts, we recommend that all users are also designated as contacts. You may also wish to have a shared email that is frequently monitored as a contact, so that important notices are not missed.

Refer to the iReg walk-through for pictures of the user and contact tabs. Manufacturers are solely responsible for ensuring that users maintain the confidentiality of their passwords and for using reasonable efforts to prevent unauthorized access to their iReg accounts. User login credentials and passwords should not be shared.

Third-party compliance or legal assistance

If a manufacturer is using a third party to submit its reports or help with other compliance or trade secret claims, there must be a user who is an employee of the manufacturer in addition to the third party. Third-party users cannot have authority to manage users as that authority is only for manufacturer employees. The manufacturer is responsible for its company's compliance and paying fees and penalties.

If you are a third-party compliance or legal company, you may update contacts on client accounts as needed. If you need changes to your company's user profiles, we can help you.

IMPORTANT reminders if authorizing a third party on the manufacturer account:

- According to Oregon law, manufacturers are required to report certain information and the manufacturer is responsible for all actions taken on their behalf.
- When a third-party company is hired to represent the manufacturer, the manufacturer is responsible for the third party's actions, compliance with all reporting requirements, and payment of assessments and penalties.
- Everyone submitting reports or representing a manufacturer is expected to be familiar with applicable Oregon law and follow DPT guidance. The relationship between the manufacturer and the third party should not hinder DPT Program operations or require repetitive communications with the program staff about program requirements and expectations.
- Manufacturers are responsible for maintaining current users and contacts on the account with at least one manufacturer employee (we recommend at least two), regardless of whether they are using a third-party company.
- Conflicts between a manufacturer and a third party regarding DPT guidance and program compliance should be handled without requiring DPT intervention. While staff are available to provide technical assistance, manufacturers bear ultimate responsibility for program reporting.

FDA labeler names and numbers

Each active account has FDA labeler names and numbers listed in iReg. These can be found on the Labeler Names subtab under the Drug Prices tab. These are used for annual assessments and report compliance. Only DPT staff can make updates to labeler information, so use the update an existing account form to provide any corrections or updates.

Notices

For report correspondence, the iReg system only emails a notice that correspondence is available to view and users must log in to view the correspondence. You can view copies of billing and informational notices in iReg that were emailed to contacts on the account. 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 may not be available here or may have been directly emailed to users or contacts instead. Let us know if you have any questions about prior communications.

III. Assessments and collections

Billing periods are calendar years and the assessment is issued in the year following that calendar year. The 2025 billing was owed by companies who were reporting manufacturers at any time during the billing period of Jan. 1 to Dec. 31, 2024. Note that the 2024 billing had a short billing period from Aug. 1 to Dec. 31, 2023, to cover the change in billing periods.

The annual assessment owed by manufacturers covers the costs for both the Oregon Prescription Drug Affordability Board (PDAB) and the Drug Price Transparency (DPT) Program. Each year, the amounts vary because they are based on the total amount that must be collected and the number of reporting manufacturers in each size category. Size categories are as follows:

- Small is for reporting manufacturers with 10 or fewer NDCs. The manufacturers in this category will collectively pay 7 percent of the program costs.
- Medium is for reporting manufacturers with 11 to 39 NDCs. The manufacturers in this category will collectively pay 31 percent of the program costs.
- Large is for reporting manufacturers with 40 or more NDCs. The manufacturers in this category will collectively pay 62 percent of the program costs.

*Exception: A manufacturer qualifies for an exception if **every** NDC used for billing purposes as shown in the FDA's NDC directory:*

- *Has a marketing category of ANDA (abbreviated new drug application), or*
- *Has a marketing category of NDA AUTHORIZED GENERIC (new drug application for an authorized generic of a brand name drug), or*
- *Is a biosimilar where the proprietary and nonproprietary name are the **same** with a marketing category of BLA (biologics license application) – biosimilars with a different proprietary name disqualify the manufacturer from the exception.*

Manufacturers who qualify for the exception have two size categories: medium (40 or more NDCs) and small (39 or fewer NDCs).

The initial list of the size categories each year is posted on the webpage for manufacturers to review. Manufacturers are notified by email and have 30 days to submit the form to request a change and provide information if they do not agree with their size category. When submitting a size change request, it is important to identify any sample packages or NDCs that were removed from the market during the billing period and include any documentation to support the claims, so we can compare this information to what we have.

After the 30-day period to submit requests for changes to size categories, the program will finish reviewing timely requests and finalize size categories. Those who submitted timely requests or were affected by the request of another will be notified of the results of the review. Billing amounts will be calculated based on the final number of manufacturers in each size category. Once calculated, the amount for each size category is set for that year's billing and billings are posted in iReg.

When the demand to pay notice is issued, the manufacturer will have 30 days to pay. Refer to Billings and Collections below for more details about paying a billing.

The amounts vary each year depending on the total that must be collected and the number of reporting manufacturers in the size category. For reference, here are the amounts owed by each manufacturer based on their size category for 2024 and 2025:

Year	Small	Medium	Large
2025	$ 725	$ 6,525	$ 19,505
2024	$ 680	$ 6,570	$ 16,145

If a manufacturer registers late and owes an assessment for a prior billing period, they will be notified of their initial size category by email and have 30 days to review their size category before it is final. They will owe the amount for their size for that billing. Funds collected from late registrations reduce program costs for future billings.

Example: Company RST registered in July 2025 but should have been registered in November 2023. Upon registration, the company was sent a size category review notice for the 2024 and 2025 billings. Once the size categories were final, the billings for 2024 and 2025 were added to the account. Then demand to pay notices were sent allowing at least 30 days to pay the prior year debts for both billing years.

2023 and prior assessments

For periods before Aug. 1, 2023, according to OAR 836-200-0555, the annual assessments were $400 per year and there was a variable fee owed by those who submitted reports during the billing period to cover the remaining program costs. These billing periods were from Aug. 1 of the prior year through July 31 of the billing year and the assessments were due Oct. 1 of the billing year.

Those who register late will owe the $400 annual assessment for prior years when they should have registered. Funds collected from assessments originally due 2019 through 2023 are for DPT Program expenses and will reduce program costs for future billings.

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 on the account at least 30 days before the due date.

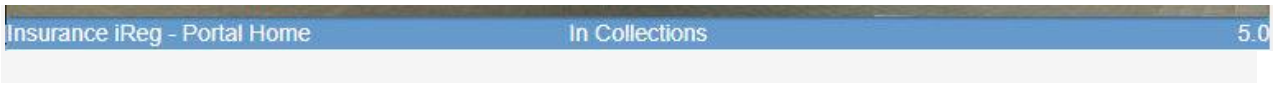
View assessments by logging into iReg and going to the “Billings” tab. You can then select a billing and select “Details” or “Fiscal Details” for additional information. The billing status is pending when posted and then complete when the full payment is received and posted. The details page for a billing shows some information about the billing and allows a user to print the payment coupon (voucher). The fiscal details for a billing show the amount assessed, any adjustments, and payments credited. Refer to pictures in the iReg walk-through.

Our agency mailing address 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)” in iReg for that year’s billing.

Accounts with unpaid billings sent to collections will show the “In Collections” message in the blue bar near the top of the page when logged into the account in iReg:



The billings tab in iReg will show which debts are in collections. For debts in collections, iReg does not reflect interest accrued or additional fees or penalties.

If a debt remains unpaid, it is sent to the Oregon Department of Revenue, Other Agency Accounts unit, as required by Oregon law. Unpaid assessments will be charged an interest rate of 9 percent per year and could incur additional fees and penalties.

If a debt is in collections and has been sent to the Department of Revenue, contact the Other Agency Accounts unit at oaa.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 or need information for the unit to locate the debt, email DPT staff at rx.prices@dcbs.oregon.gov.

IV. New prescription 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 that exceed $950 for a one-month supply.[1] The manufacturer setting the drug's WAC is responsible for reporting. Note: Drugs introduced before Jan. 1, 2025, used the previous threshold of $670.

A new prescription drug report is required when a National Drug Code (NDC) that meets the WAC threshold is first marketed based on FDA approval of a new drug application (NDA), abbreviated new drug application (ANDA), or biologics license application (BLA). Additional NDCs that meet the threshold also require reporting within 30 days of when the NDC entered the market, whether they are FDA approved at the same time as the first NDC or later.

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 prescription 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 for a new prescription drug report

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

- "Yes" to claim the information provided as a trade secret, or
- "No" to claim that the response is not a trade secret.

Once a report is submitted, each data element not claimed as trade secret is published on the data transparency website for public viewing. Report correspondence in iReg that is not claimed as trade secret is published after the report has the status of "filing complete" or "closed as filed." Data elements and correspondence flagged with a claim for trade secret are reviewed to see if we agree with the claim.

Refer to Trade Secret Supplement and OAR 836-200-0540 for more information before making any trade secret claims on the filing.

Reporting manufacturers should 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.

[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; $950 is the amount specified in OAR 836-200-0505 for the minimum Part D specialty tier eligibility in the 2024 Final Call Letter from CMS.

New data elements (♦) and other changes have been made in iReg. New prescription 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. 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 (proprietary) name for the NDC being reported (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. This should match the FDA NDC directory.

   After the name, enter the strength and package size for the NDC being reported.

   Do *not* enter the brand name for the drug unless that is the NDC being reported.

3. **Chemical name:** Provide the full chemical or biologic name. This is the nonproprietary name of the drug product, usually the active ingredients.

4. ♦ **FDA labeler name for NDC:** Provide the labeler name (company name) from the package for the NDC. This should match the FDA NDC Directory.

5. ♦ **FDA start marketing date:** Provide the FDA start marketing date. This should match the FDA NDC Directory.

6. ♦ **Date first available for purchase in U.S.:** Enter the date this NDC entered the U.S. market. If there was not a delay to market entry, enter the FDA start marketing date.

7. ♦ **Is this a generic or biosimilar:** Answer yes or no. A generic or biosimilar is a medication created to be the same as an already marketed drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use.

8. ♦ **Marketing spending:** Amounts spent on marketing activities, including expenses incurred prior to the launch date while preparing to market the product.

♦ **Consumer marketing spending ($) – four quarters prior to launch:** Enter the amount the company spent on marketing to consumers in the four quarters prior to launch (date first available for purchase in U.S.).

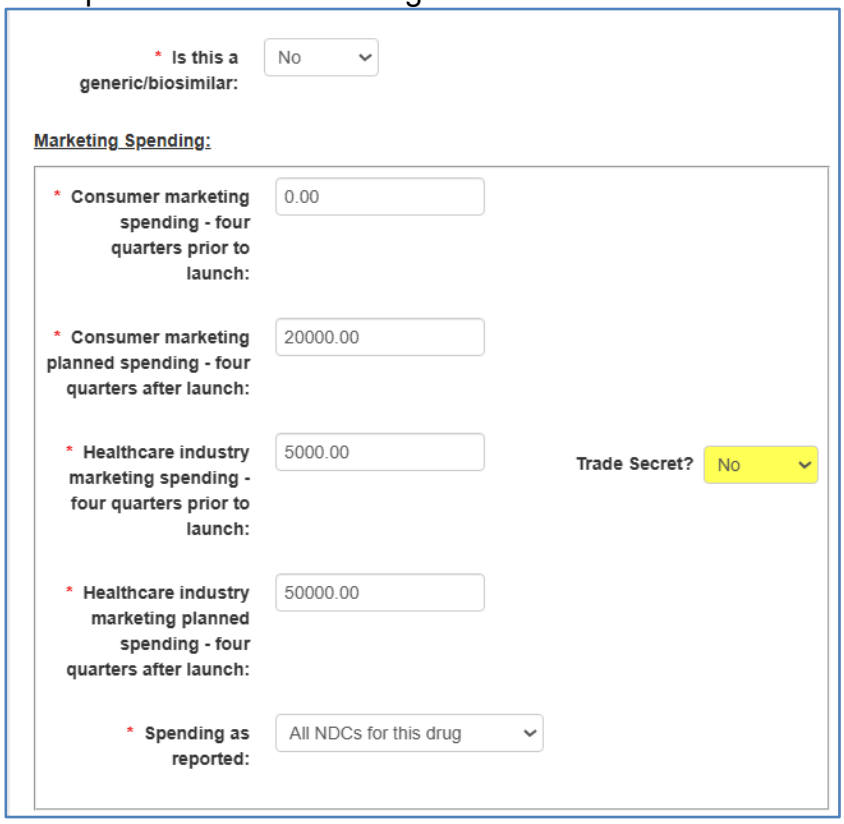
♦ **Consumer marketing spending ($) – four quarters after launch:** Enter the amount the company plans to spend on marketing to consumers for the four quarters after launch.

♦ **Healthcare industry marketing spending ($) – four quarters prior to launch:** Enter the amount the company spent on marketing to healthcare professionals in the four quarters prior to launch.

♦ **Healthcare industry marketing spending ($) – four quarters after launch:** Enter the amount the company plans to spend on marketing to healthcare professionals for the four quarters after launch.

♦ **Spending as reported:** Select whether the above amounts are just for this NDC on the report or whether it includes the total spending for all NDCs for this drug.

Example of new fields in iReg:



9. Marketing description – marketing activities:

Provide a description of the most costly marketing activities targeting consumers, 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.

Provide a description of the most costly marketing activities targeting healthcare industry, including:

- 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.

Limit responses for this data element to 2,000 characters or less.

Compliance tip: If there was no marketing, report there was no marketing and identify whether this applies to marketing for consumers or the healthcare industry. This will save you a compliance inquiry. This marketing description reporting template is optional and may help with compliant reporting.

Marketing description template

Public information – marketing activities.
1. Marketing activities targeting consumers:
•
•
•
•
2. Marketing activities targeting healthcare industry:
•
•
•
•

10. Wholesale acquisition cost (WAC) ($): Enter the WAC for this NDC being reported (price used to determine if it exceeded the reporting threshold of $950 for a one-month supply). Note that the reporting threshold was $670 for NDCs that launched before Jan. 1, 2025.

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

11. **Dosage – highest amount, strength, and frequency as recommended in prescribing label:** Report the dosage of this NDC used to determine the price of a one-month supply. According to OAR 836-200-0505, dosage is the highest amount, strength, and frequency that a patient would take the drug as recommended by its prescribing label as approved by the FDA. Examples: 2 pills per day, 75 mg every 4 hours as needed, 50 ml once per week, or 120 mg per day for avg. adult weight (weight-based dosing).

12. **Pricing methodology:**

    Identify this NDC type using the following guidance:
    - Brand name (NDA with different proprietary name)
    - Branded generic (ANDA with different proprietary name)
    - Authorized generic (NDA authorized generic)
    - Generic (NDA or ANDA with same proprietary and nonproprietary name)
    - Biologic (BLA with different proprietary name and first of kind)
    - Branded biosimilar (BLA with different proprietary name and not first of kind)
    - Biosimilar (BLA with same proprietary and nonproprietary name)

    For biosimilars, also state whether or not the NDC is an interchangeable product.

    Report factors used in determining the price of this NDC, such as prices of other prescription drugs or costs to manufacture. Include any appropriate explanation as needed. Refer to section (4) of OAR 836-200-0531 for examples of factors.

    If pricing methodology is based on comparison to another product, include the methodology and identify the comparison brand name, labeler name, NDC, and WAC used for the methodology.

    Limit response for this data element to 2,000 characters or less.

13. **FDA priority or breakthrough:** Indicate “yes” if there was a breakthrough designation or priority review granted. 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.

14. **Acquisition cost and date:** If the drug was not developed by the reporting manufacturer, enter the price paid for acquisition of the new prescription drug[2] and the date purchased. Otherwise, leave blank and select “No” for the trade secret claim response.

    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 cost.

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

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

15. **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 United States. You may 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. Otherwise, leave the description field blank and select "No" for the trade secret claim response.

    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. If you want to provide information regarding how the company arrived at the estimate, use "Patients Per Month Description" to report this optional information.

16. **Research and development (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 international public 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 used 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: Public funding is not considered a trade secret.

17. **Documents:** Only attach documentation necessary to support the information reported. Note: A document's "Reason for Inclusion" is posted to the transparency website and viewable by the public even if the document is claimed as trade secret. It is appropriate to state "*see document"* when attaching a document claimed as trade secret, rather than entering justification information as the reason for inclusion.

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 Trade Secret Supplement 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 and trade secret claims reported to the program are accurate and comply 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. 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

Annual price increase reporting is required per ORS 646A.689(3) and temporary rule OAR 836-200-0530. DFR Bulletin No. 2024-3 is withdrawn. Though Bulletin 2024-3 no longer applies, annual price increase information remains voluntary for 2023 and 2024 reports and patient assistance information remains required for those years.

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

- A wholesale acquisition cost (WAC) of $100 or more for a one-month supply.
- 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*).

For filings due in 2026, a 2025 report is required if the weighted average WAC for 2025 is 10 percent or more above the weighted average WAC for 2024 and the WAC is $100 or more for a one-month supply. If there was no price increase in 2024 or 2025, then no report is required in 2026.

These reports can be filed starting Jan. 1, and the deadline to report is March 15. For 2026, the iReg system was not available for submitting these reports until February 2026. For 2025 reports due in 2026, the due date has been extended to **Apr. 15, 2026**.

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 (2024) the weighted average price for Drug A was $700. During the reporting year (2025), the weighted average price was $850.

The increase of the weighted average price is greater than 10 percent and the price exceeds $100 per month, so an annual price increase report is required for reporting 2025 data.

Example 2 shows calculations and a leap year: Drug Z has a WAC of $500 for the first 100 days of 2024 and $600 for the remainder of the year. The weighted average price for 2024 (comparison year) is $572.68.

$$\text{2024 weighted average price: } \frac{(100 \times \$500) + (266 \times \$600)}{366} = \$\ 572.68$$

On Jan. 25, 2025, the WAC is increased to $640. The weighted average for 2025 (reporting year) is $637.37.

$$\text{2025 weighted average price: } \frac{(24 \times \$600) + (341 \times \$640)}{365} = \$\ 637.37$$

This is a difference of $64.78. As shown below, the increase for 2025 is 11.3 percent (rounded), so a report is required to be submitted in 2026 for reporting 2025 data.

$$\text{2025 increase percentage: } \frac{(\$637.37 - \$572.68)}{\$572.68} \times 100 = 11.30\ \%$$

For acquired products previously marketed by another company, a manufacturer is expected to have the price history and file if the threshold is met whether they set the prices or another company set the prices.

Required reportable data elements for an annual price increase drug report

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

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

Once a report is submitted, each data element not claimed as trade secret is published on the data transparency website for public viewing. Report correspondence in iReg that is not claimed as trade secret is published after the report has the status of “filing complete” or “closed as filed.” Data elements and correspondence flagged with a claim for trade secret are reviewed to check if we agree with the claim.

Refer to Trade Secret Supplement and OAR 836-200-0540 for more information before making any trade secret claims on the filing.

Reporting manufacturers should 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 identifying the labeler, product, and trade package size by unique code for the FDA and the manufacturer. 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)

3. **Trade name:** Provide the full trade (proprietary) name for the NDC being reported (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 NDC 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:** Refer to Section VI for details about reporting patient assistance program data.

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.

   Compliance tip: Pricing compendium information is not a trade secret.

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:** Report the dosage of this NDC used to determine the price of a one-month supply. According to OAR 836-200-0505, dosage is the highest amount, strength, and frequency that a patient would take the drug as recommended by its prescribing label as approved by the FDA. Examples: 2 pills per day, 75 mg every 4 hours as needed, 50 ml once per week, or 120 mg per day for avg. adult weight (weight-based dosing).

    Compliance tip: Information that is publicly available is not a trade secret.

11. **Date on market:** Enter the date the drug was first available for purchase.

12. **Increase factors:** Report major financial and nonfinancial factors used in determining the price increase for this NDC, such as prices of other prescription drugs or costs to manufacture. Include any appropriate explanation as needed.

    If pricing was increased based on comparison to another product, include the methodology and identify the comparison brand name, labeler name, NDC, and WAC used for the methodology.

    Limit response for this data element to 2,000 characters or less.

    Compliance tip: Report clear and specific information. If company did not use any drug comparisons for determining the price increase, clearly confirm no comparison was used and report what the company did use for setting the increased price.

13. **Research and development (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 international public 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: Public funding is not considered 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 United States. 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 United States. 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 United States.

    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.

    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, 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.

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 2025 report, the percentage for 2025 on this list is the same as reported above.

20. **Documents:** Attach any documentation necessary to support the information reported. Note: A document's "Reason for Inclusion" is posted to the transparency website and viewable by the public even if the document is claimed as a trade secret.

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. Refer to Trade Secret Supplement 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 and trade secret claims reported to the program are 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. Failure to comply may result in civil penalties.

Refer to the iReg walk-through for pictures of the system and other information.

VI. Patient assistance program reporting

Patient assistance program data is currently reported as part of the annual price increase report. If there are any patient assistance programs, select "Add assistance program" for each program. Add each patient assistance program available 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 those consumers in Oregon who participated over the previous calendar year.

- Refills: Options are limited, unlimited, no refills, and other. If limited refills were allowed, enter the number of refills for this drug. If none of the options are accurate, select “Other” and describe how refills were allowed.
- 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.

Compliance tip: Information that is publicly available is generally not a trade secret.

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.

VII. 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. This includes any drug sold under a brand name, including drugs that are branded generics or biosimilars.

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. For acquired products, a

manufacturer is expected to have the price history and file if the threshold is met whether they set the prices or another company set the prices.

Reportable data elements for a 60-day notice drug report

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

- "Yes" to claim the information provided as a trade secret, or
- "No" to claim that the response is not a trade secret.

Once a report is submitted, each data element not claimed as trade secret is published on the data transparency website for public viewing. Report correspondence in iReg that is not claimed as trade secret is published after the report has the status of "filing complete" or "closed as filed." Data elements and correspondence flagged with a claim for trade secret are reviewed to see if we agree with the claim.

Refer to Trade Secret Supplement and OAR 836-200-0540 for more information before making any trade secret claims on the filing.

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 (proprietary) name for the NDC being reported (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 NDC 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 United States.

5. **Current price (WAC):** Enter the current price (WAC) for the prescription drug.

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

6. **New price (WAC):** Enter the expected price (WAC) for the prescription drug for the upcoming planned increase. All reported WAC prices are package prices, not unit or monthly 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:** If desired, provide any additional information or details about the reasons, factors, consumers, or timing of this increase. Otherwise, leave blank and select “No” for the trade secret claim response.

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. Refer to Trade Secret Supplement 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 and trade secret claims reported to the program are 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. Failure to comply may result in civil penalties.

Refer to the iReg walk-through for pictures of the system and other information.

VIII. Review, filing status, and disclosure of reports

Submitted reports will be placed in the appropriate filing status for tracking through the review process. Not all statuses are used for each report. Refer to Trade Secret Supplement and OAR 836-200-0540 for more information about trade secret claims.

iReg filing status	Description of status
In progress	The manufacturer is editing the report. If old reports are in this status, they should be deleted if not required. DPT staff members will put the report back to this status if a manufacturer must resubmit due to noncompliance.
Submitted	The report was certified by the manufacturer. DPT staff members may be reviewing the report for compliance.
Compliance review	Staff members are reviewing the report and may ask for clarification or additional details. If needed, a request for additional information (RFI) may be added to iReg correspondence and the report will remain in this stage until staff members review the RFI response or the due date 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. If there is a timely appeal, a final trade secret determination is issued in Biscom after review of the appeal. This status is maintained for 21 calendar days.
Filing complete	All reviews are complete and any appeal or waiting periods have expired. All report data and correspondence are published to the data transparency website (per a final trade secret determination, if applicable).

List of filing statuses continued on next page.

iReg filing status	Description of status
Not in compliance	Staff members found the report to be noncompliant (for example, when required data is missing, or there is no or insufficient response to an RFI). The manufacturer should contact DPT compliance staff to resolve the issue. The program may initiate enforcement action by sending a U.S. Postal Service 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. Note: The account will have “Enforcement Action” at the top banner until all noncompliant reports are resolved.
Enforcement	The manufacturer account was sent to the Enforcement unit. The Enforcement unit may issue orders and penalties. The account will have “Enforcement Action” at the top banner until all noncompliant reports are resolved or if an enforcement order is still in effect even if all reports are now in compliance.
Judicial hold	The report is awaiting the outcome of a court action.
Closed as filed	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 (per a final trade secret determination, if applicable). Enforcement actions may be pursued in the future.

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

Drug reports are expected to contain all required data at the time they are submitted. The department will not issue additional information requests for missing data. The department’s review timeline, as described in OAR 836-200-0535, is outlined here:

Within 60 calendar days of receiving a report	The director of DCBS or the 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: • Clarify or substantiate the previously-reported material or • Enable analysis of factors affecting drug prices for providing recommendations to the Oregon Legislature 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 select “Details” to read the message. Select “Original” to see the attachment.

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 and be submitted in writing in the iReg system. Timely requests are automatically granted, so DPT staff members will no longer issue a decision on this request.

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 members. Instead email 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 may 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, 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. Refer to Trade Secret Supplement and OAR 836-200-0540 for more information about trade secret claims.

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 (ORS 646A.692; OAR 836-200-0560).

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

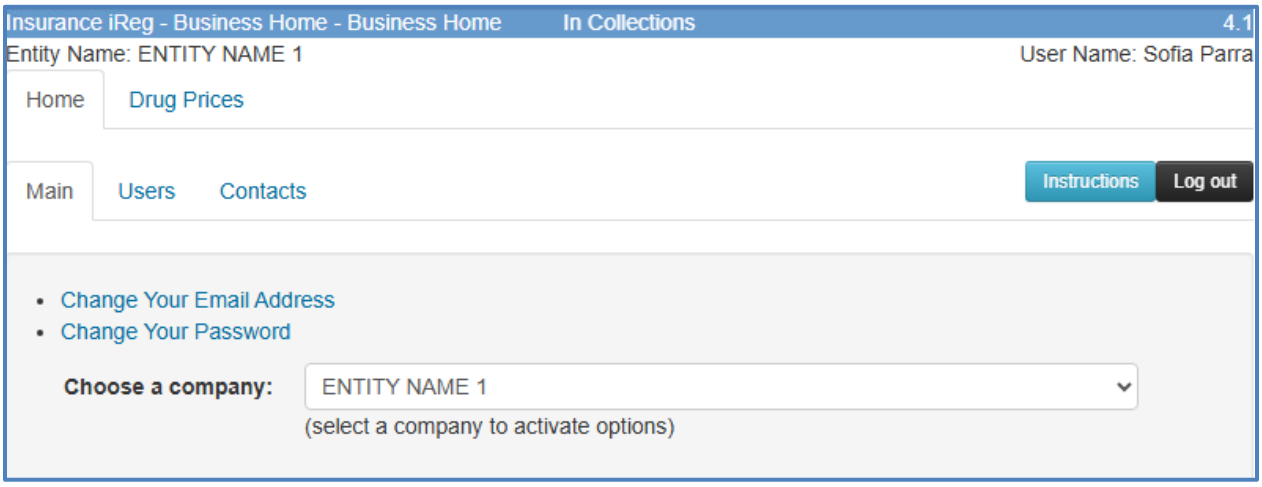
For any other violations, the maximum civil penalty that may be imposed is $10,000 per day of violation, which includes the following:

- Failure to register and create an online account.
- A breach of good-faith expectations.
- Intent to obstruct implementation of the program.
- Other violations injurious to the public.

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



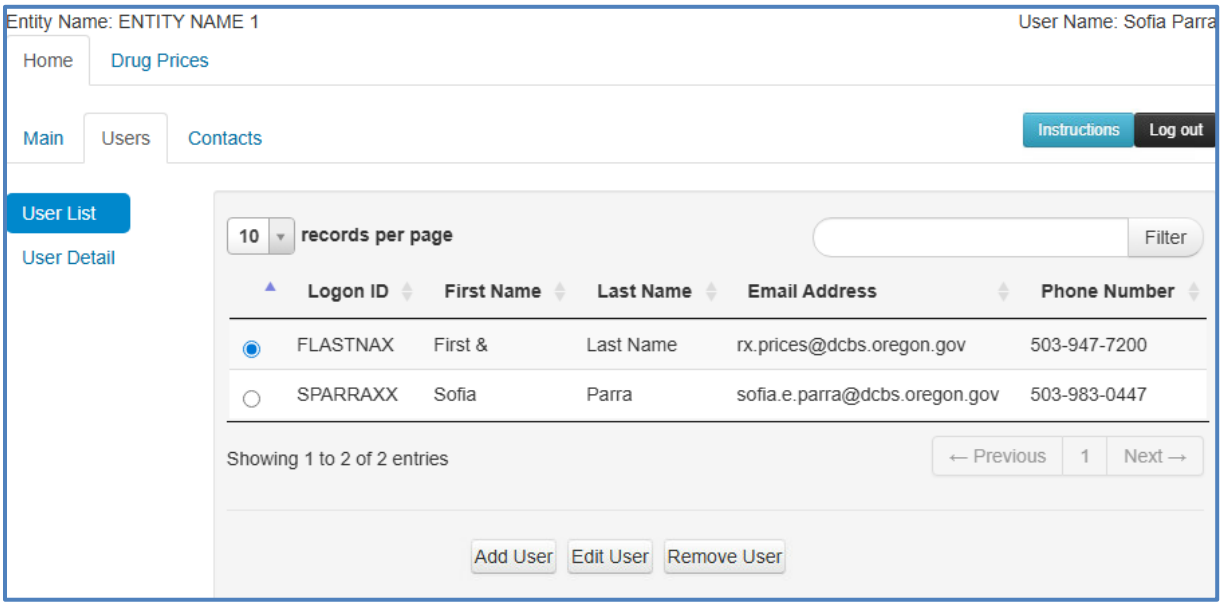
Once a user has logged on to iReg, the home screen will display. The user can access the “Main” sub-tab, which has options for selecting the company for reporting. In the top right-hand corner of the screen, there are two buttons: “Instructions” and “Log out.” “Instructions” will go to the general iReg 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 the program has started an enforcement action, “Enforcement Action” will appear in the top banner. Contact our compliance staff for questions about these issues.

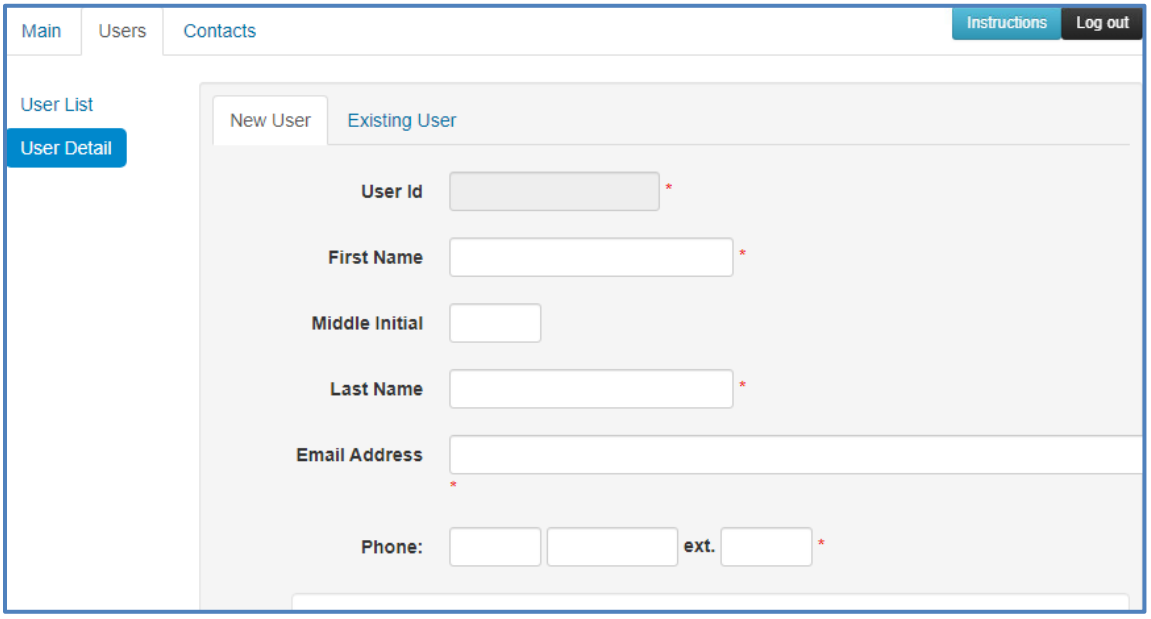
If an unpaid billing has been sent to collections, “In collections” will appear in the top banner. Refer to the billing and collections information in this guide or email the program at rx.prices@dcbs.oregon.gov for questions about unpaid debts.

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



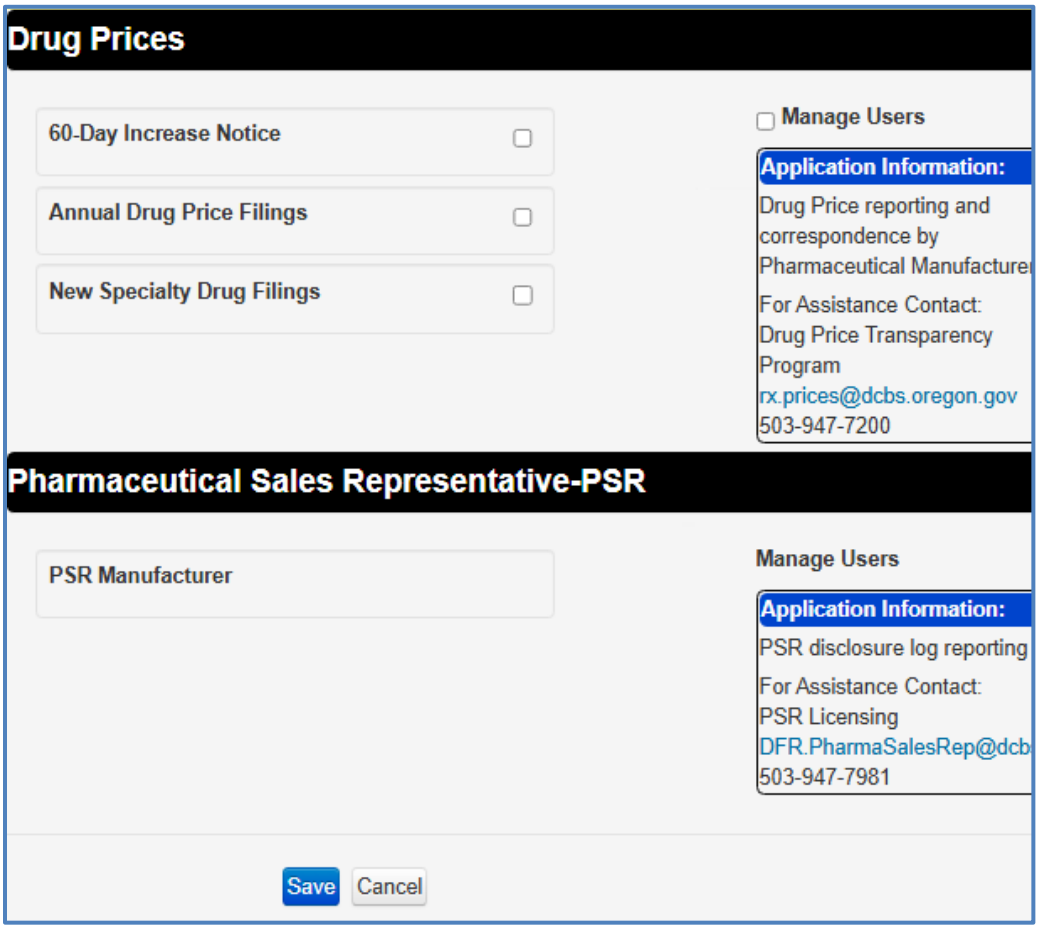
On the "Users" sub-tab is a list of all users for a company/entity. Users who can manage other users can add, edit, or remove a user. Select the "User Detail" option on the left-hand side of the screen to bring up the user's full profile for the account. Only those who have authority to manage users will see the add, edit, and remove options.

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



Selecting the "User Detail" option brings up the screen where the user can add a new user or edit an existing user's information. A red asterisk indicates a required field.
Section continued on next page.

Figure 2c – Users: access permissions

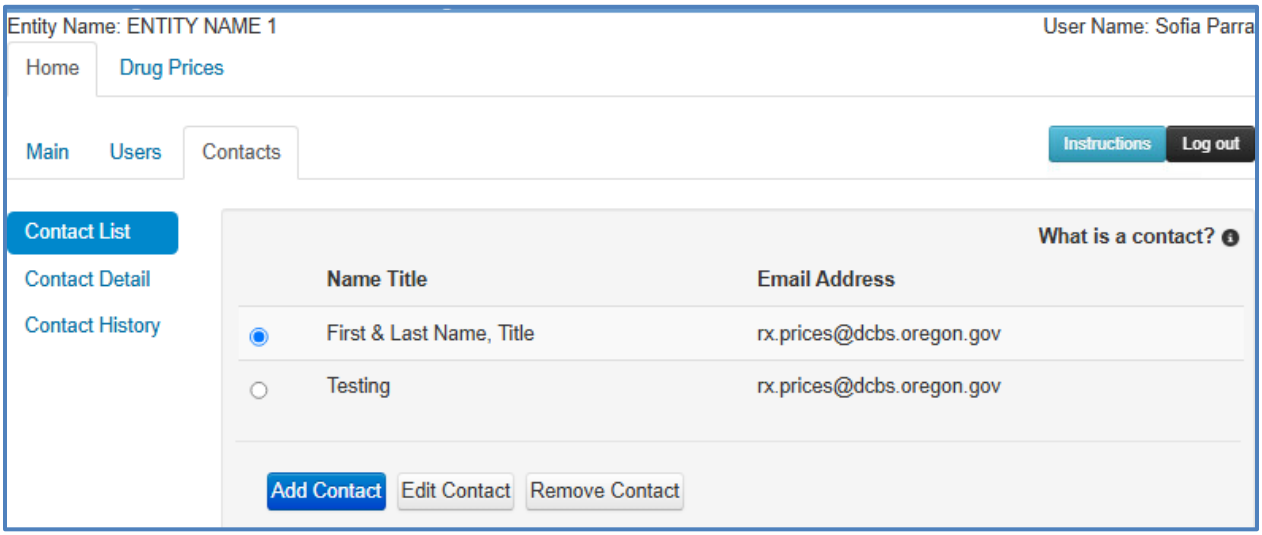


These are the user permission options. New users can be delegated permissions to manage users, allowing the new user to create and edit users for the company account. Each user may also have permissions for the types of reports. This allows the user to view, create, edit, or submit reports for the specified categories. Do not give third-party users authority to manage users. Only manufacturer employees should have authority over who can access the account. Pharmaceutical Sales Representative (PSR) access is a separate program and only for manufacturers who submit PSR licensing reports on behalf of licensees.

It is recommended that each account has 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.

Third-party companies: If you need to be added to an account, the manufacturer employee must initially add you. Once your company is added to the account, we can help you with any additions, changes, or removals to user profiles for your staff.

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



The “Contacts” sub-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.

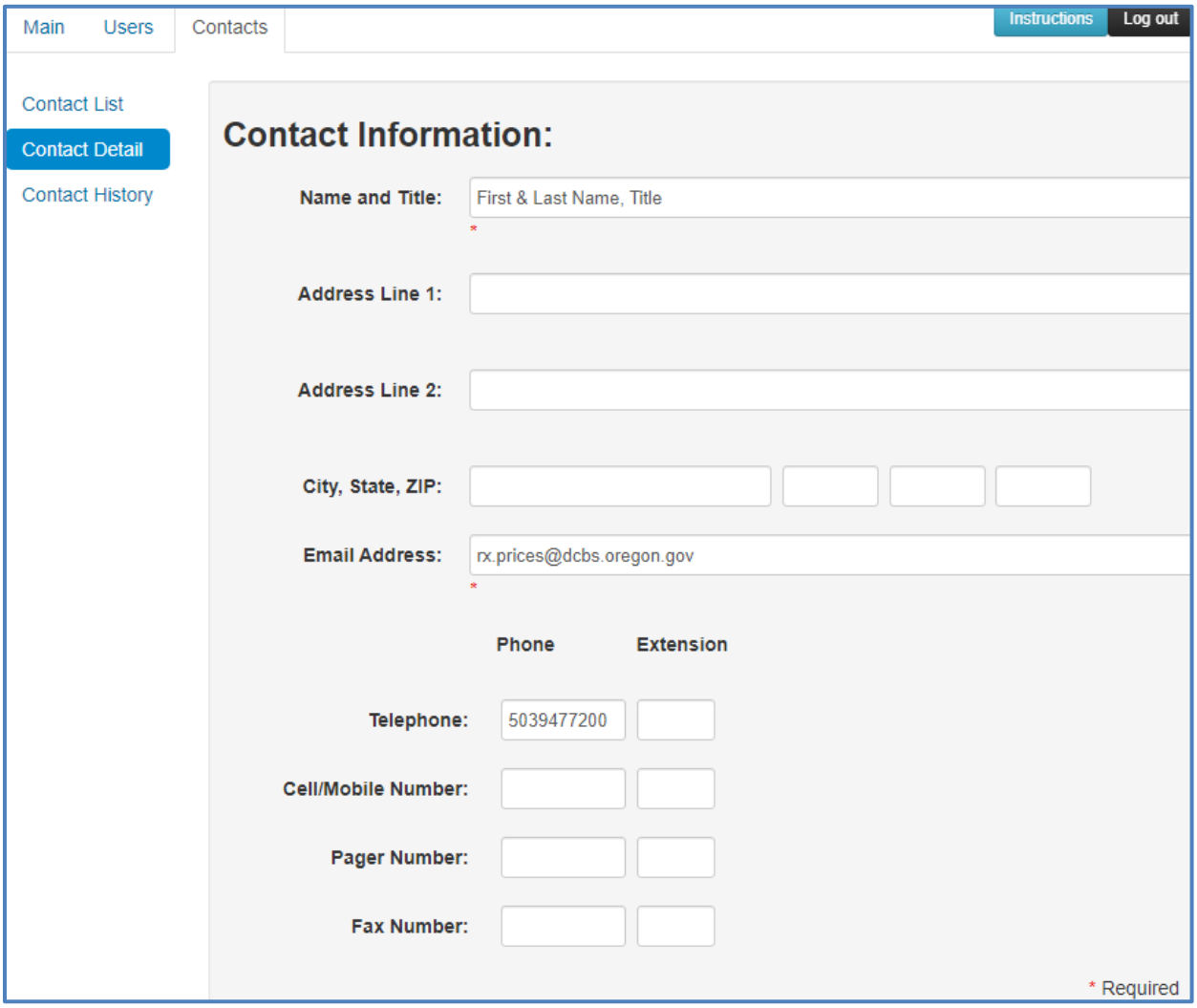
All users have the option to “Add Contact,” “Edit Contact,” or “Remove Contact.” The primary user for the company should also be listed as a contact, as well as anyone else who should receive system notices. The “Edit Contact” button allows the user to edit or fill out the contact information. The “Contact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

Tip: You may have a shared email that is frequently monitored as a “Contact” so that important notices are not missed. We recommend that all users are also contacts.

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

Section continued on next page.

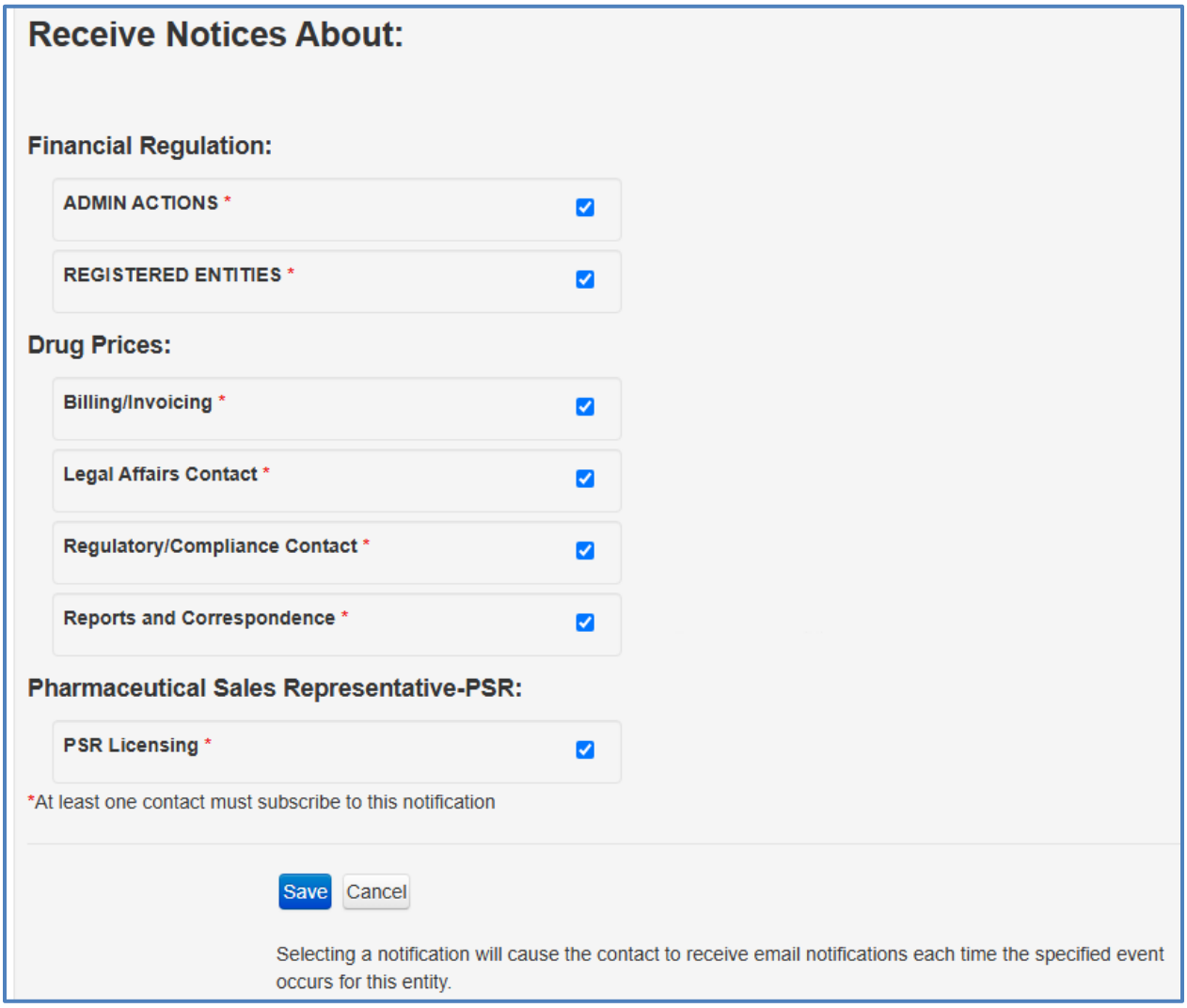
Figure 3b – Contacts: adding, editing, or removing contacts



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.

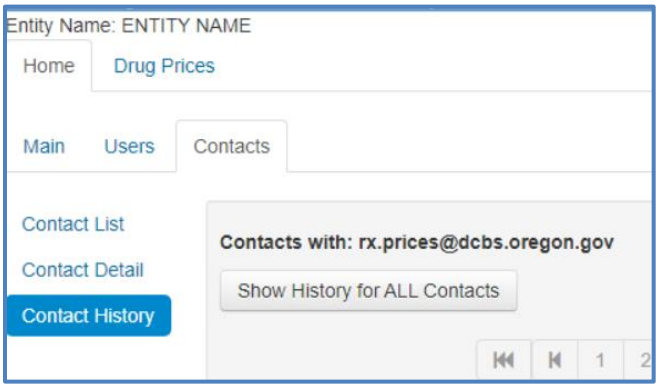
Figure 3c – Contacts: notice types

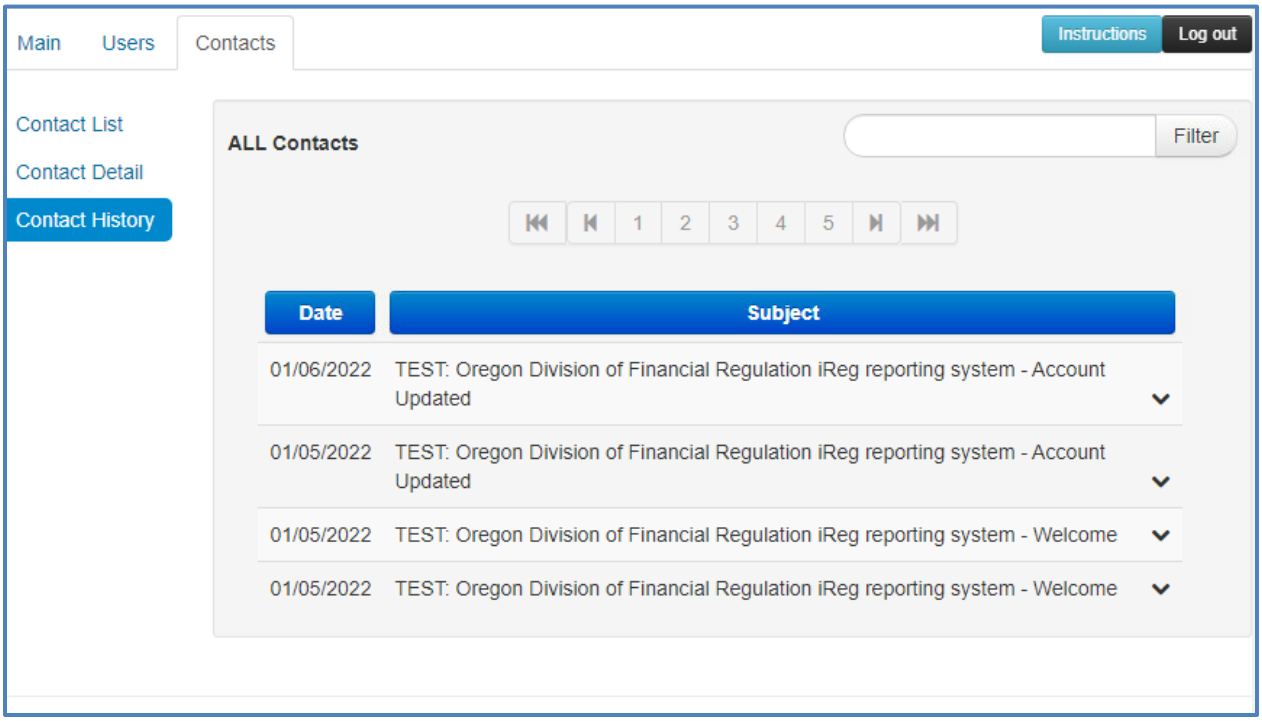


There are various types of program topics a contact can receive. Note: At least one contact must be able to receive the required email notices from the department as indicated by the red asterisks. Select “Save” to confirm changes.

Section continued on next page.

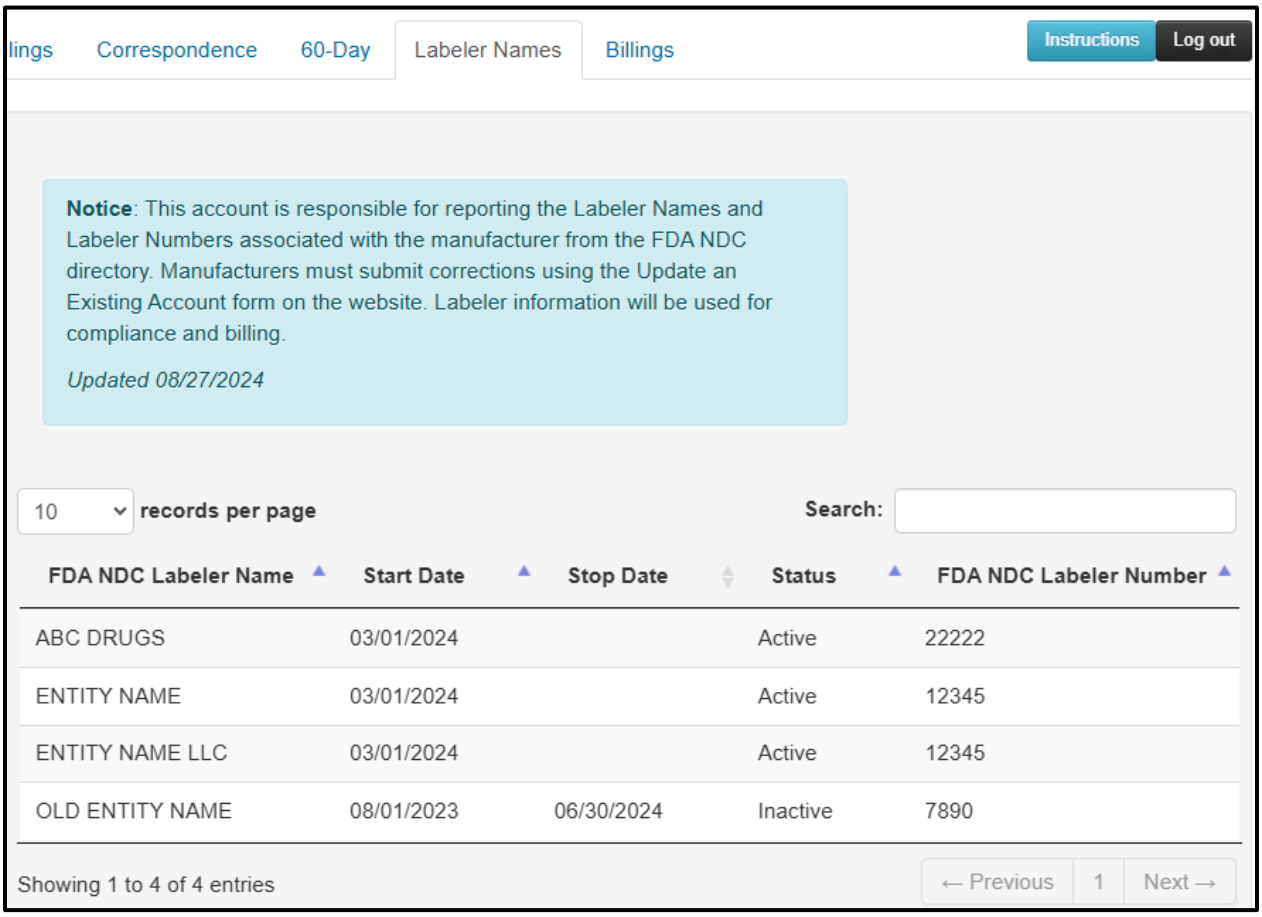
Figures 3d and 3e – Contacts: history of emails





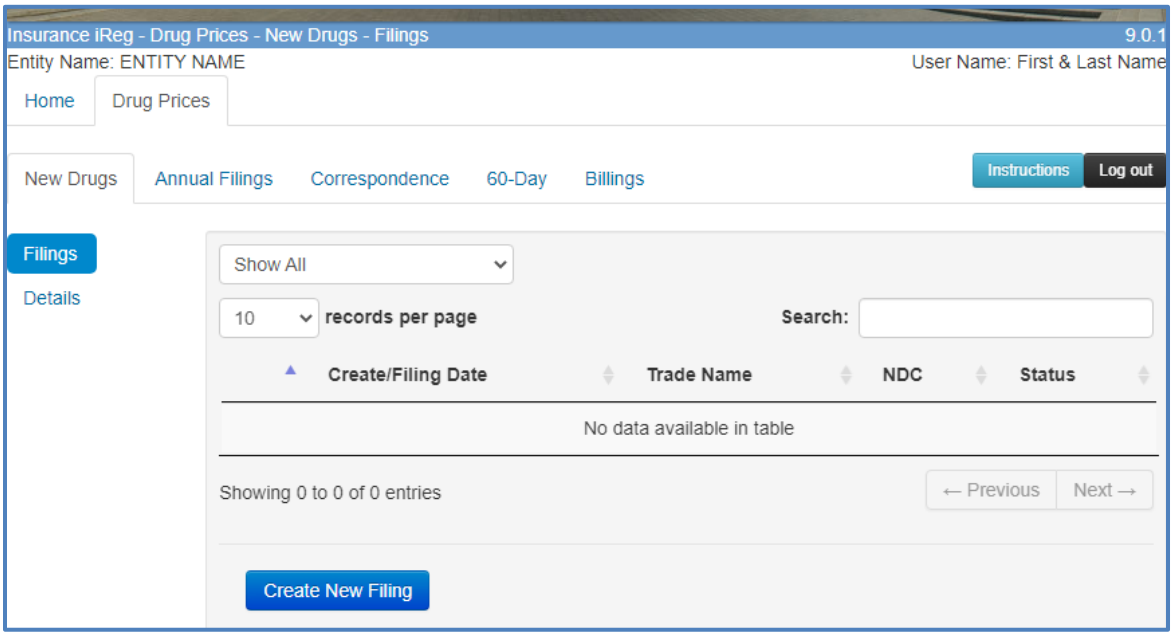
The “Contact History” screen displays the activity a specific contact has had on the account, such as establishing a new user and editing user information. Selecting the button labeled “Show History for ALL Contacts” displays all history for the account.

Figure 4 – Labeler names and numbers



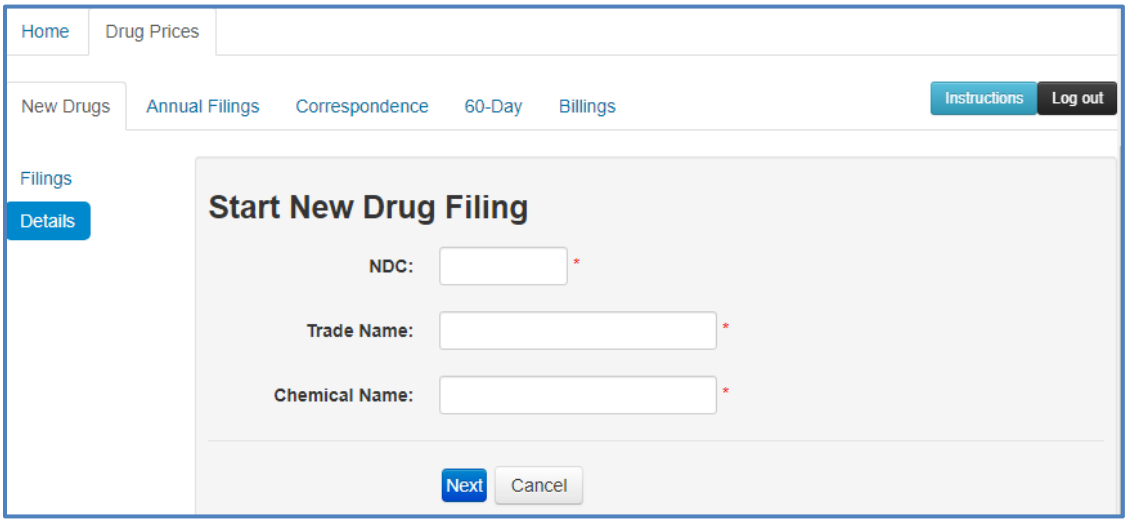
Under the “Labeler Names” sub-tab, users can find the FDA labeler names and numbers associated with the account. The names and numbers will be used for reporting compliance and the annual assessment. Only DPT staff members can update this information, so notify the program if any corrections are needed.

Figure 5a – New drug reports



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 selecting 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 can only be edited by DPT staff members.

Figure 5b – New drug filing creating a report

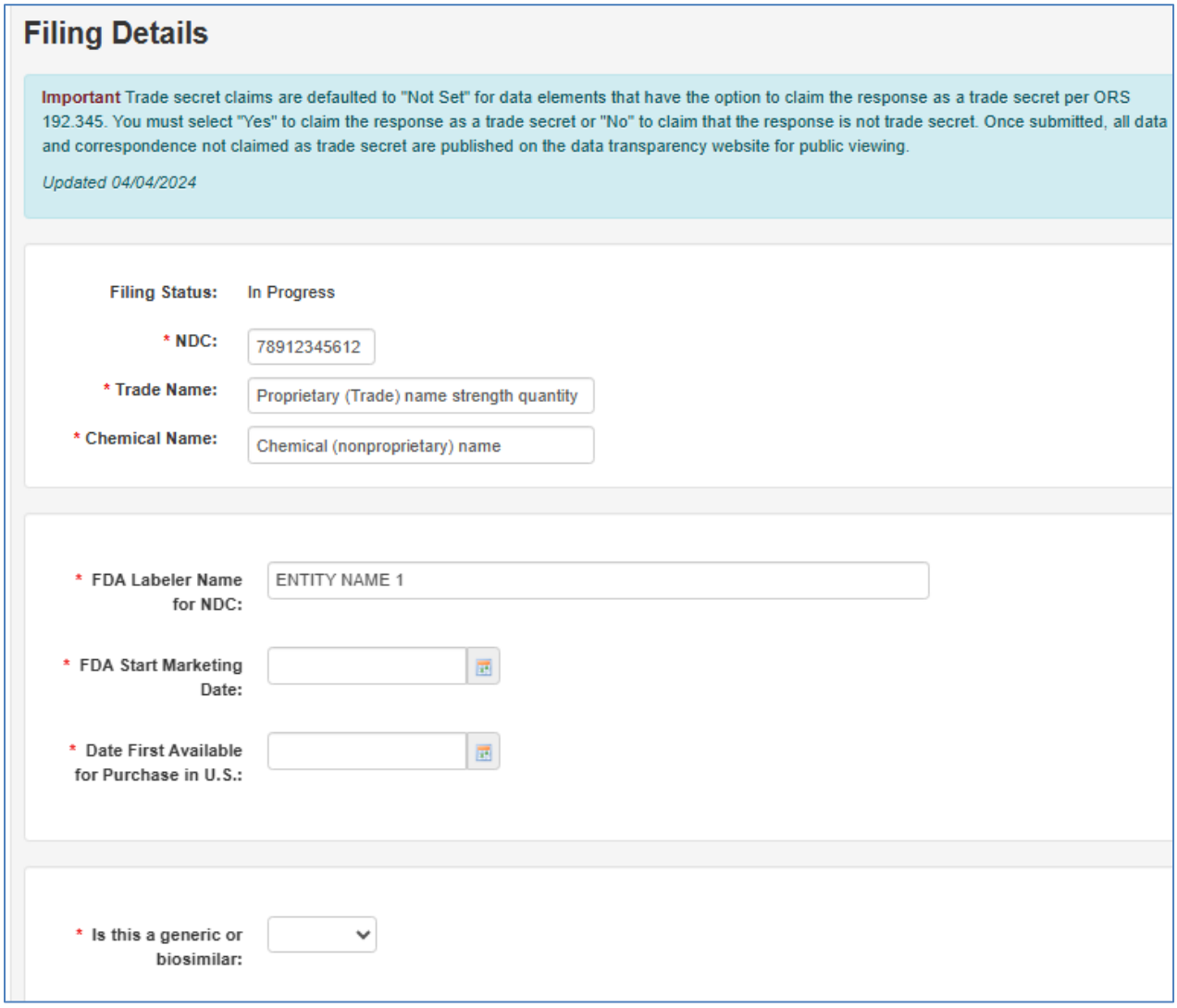


When the “Create New Filing” button has been selected, the user must enter the National Drug Code (NDC), trade name, and chemical name to initiate the filing. Once this information has been reported, the filing is started and appears in the list of filings. The “Next” button navigates the user to the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

Section continued on next page.

Figure 5c – New drug filing details

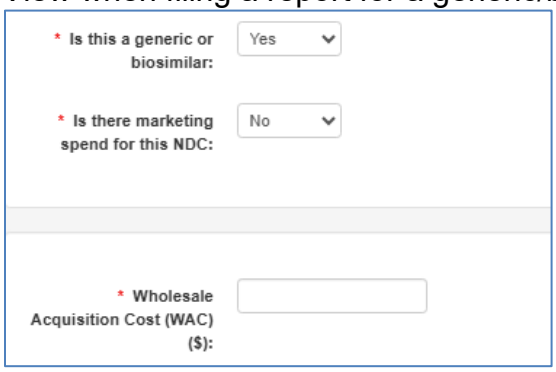
Figures 5c to 5g show how the filing appears in iReg. This includes recent changes. For more information and guidance on the data elements, refer to Section IV (New prescription drug reporting) of this user guide. Each data field that can be claimed as trade secret has a check box next to it, which can be selected to claim the information reported as a trade secret under ORS 192.345. Once a report is submitted, each data element not claimed as trade secret is published on the data transparency website for public viewing. Check out Figure 10 and refer to the Trade Secret Supplement and OAR 836-200-0540 for more information before making any trade secret claims on the filing.



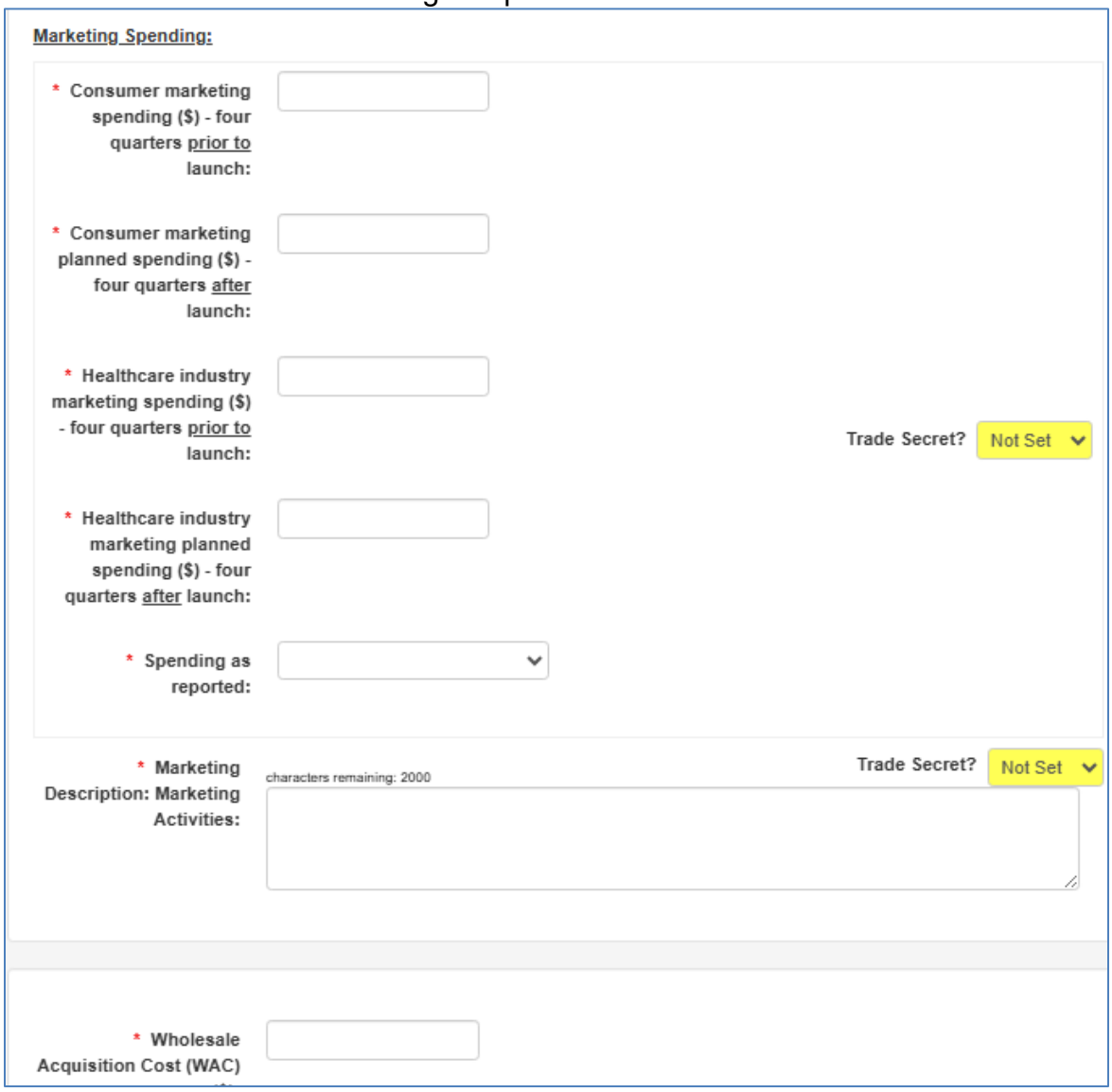
Section continued on next page.

Figure 5d and 5e – New drug filing details continued

View when filing a report for a generic/biosimilar that isn't being marketed:

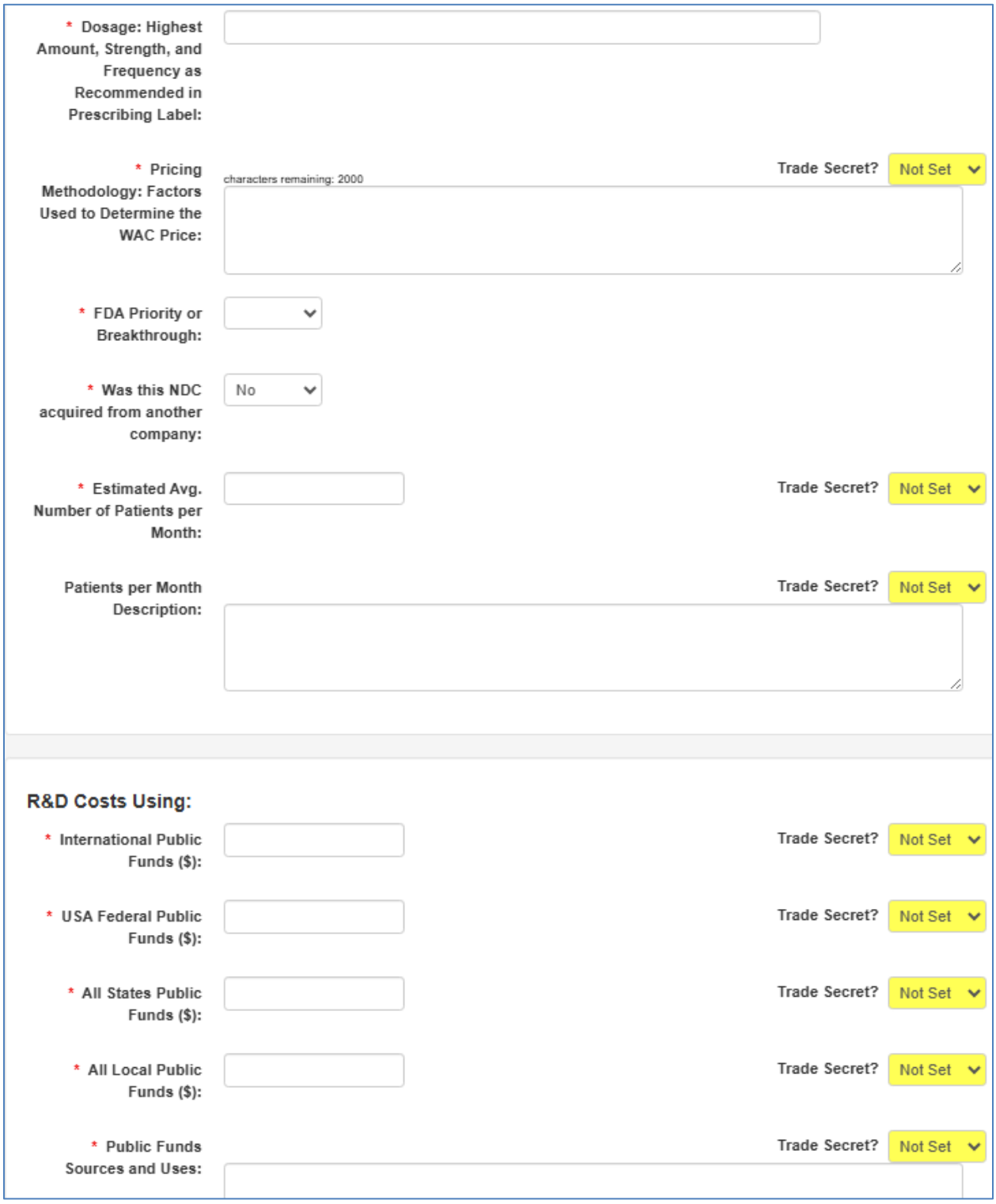


Additional fields about marketing this product:



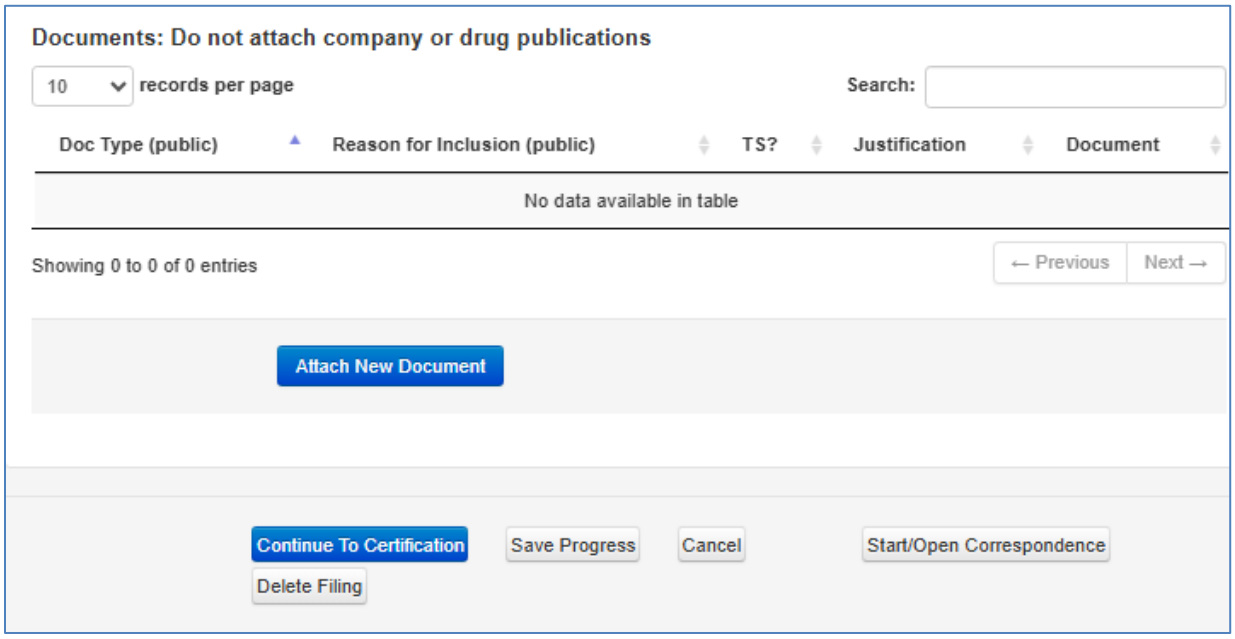
Section continued on next page.

Figure 5f – New drug filing details continued



Section continued on next page.

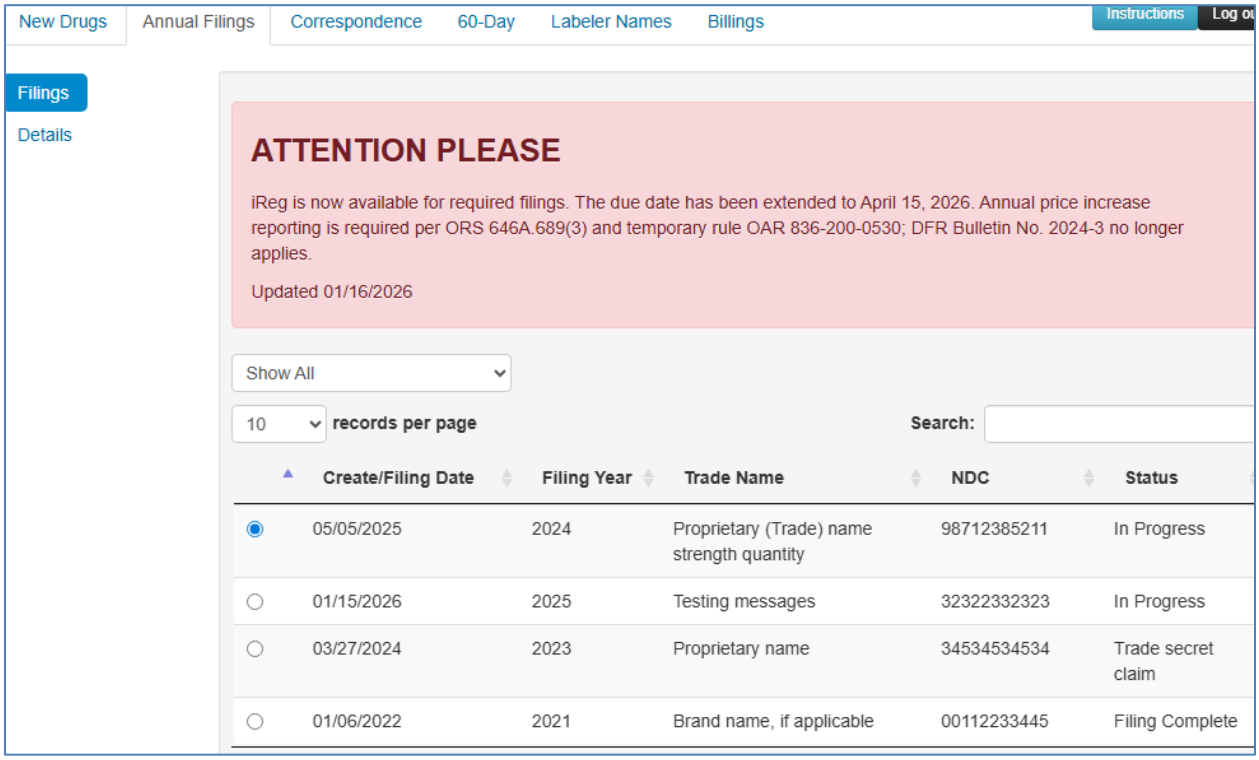
Figure 5g – New drug filing details continued



"Save Progress" will save all information that has been entered into the report but will not submit it. Select "Continue to Certification" when the report is finalized and ready for submission. Refer to Figure 7 about attaching documents and Figure 11 for the certification screen.

Figure 6a – Annual price increase reports and patient assistance

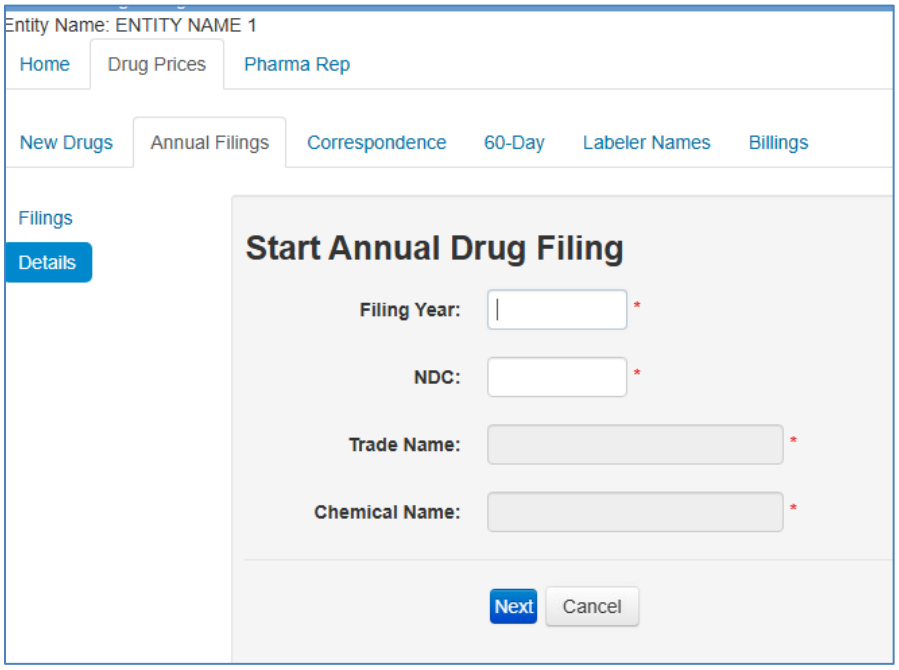
ATTENTION: DFR Bulletin No. 2024-3 was rescinded and no longer applies. Annual price increase reporting is required per ORS 646A.689(3) and temporary rule OAR 836-200-0530.



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 selecting the “Create New Filing” button. Users can edit filings that are in progress by selecting a drug filing and then choosing “Details” on the left side of the page. Once a report is submitted, it cannot be edited by users.

Section continued on next page.

Figure 6b – Annual price increase filing creating a report



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.

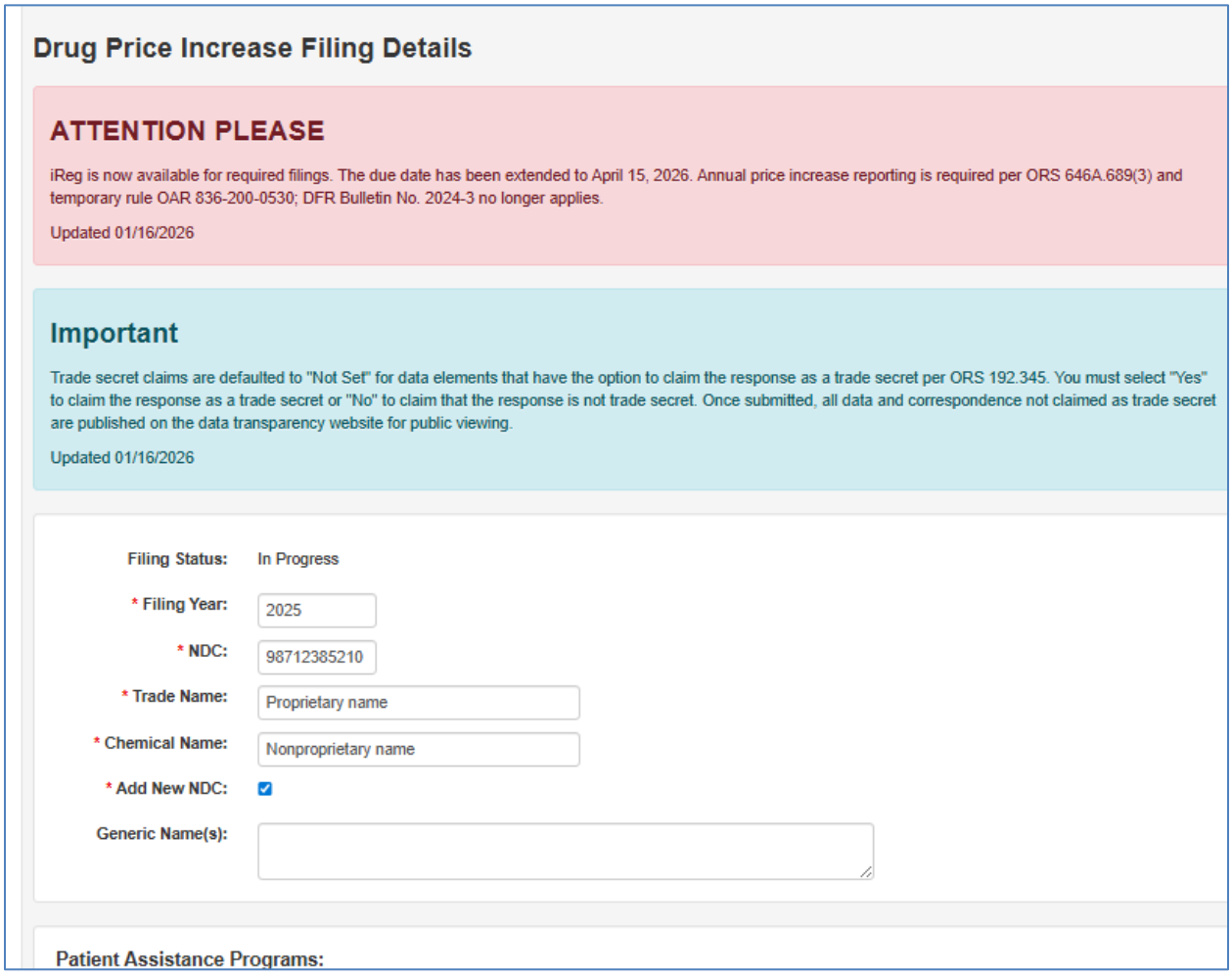
Figure 6c – Annual price increase filing details

Figures 6c to 6g show how the filing appears 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” for data elements that have the option to claim the information provided as a trade secret per ORS 192.345. You must either select:

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

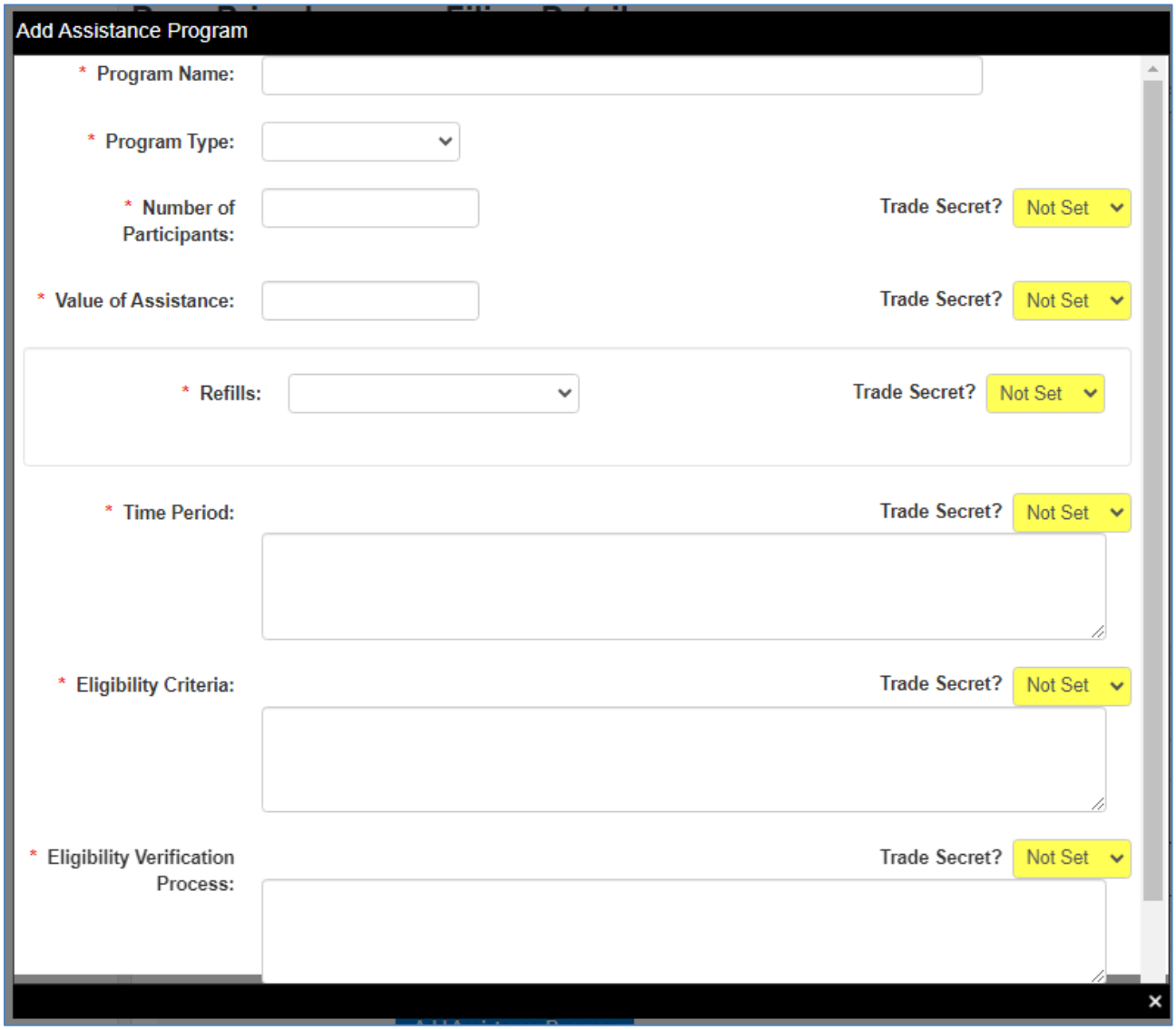
Once a report is submitted, each data element not claimed as trade secret is published on the data transparency website for public viewing. Check out Figure 10 and refer to Trade Secret Supplement and OAR 836-200-0540 for more information before making any trade secret claims on the filing.



When adding patient assistance, the details screen will open as they appear in Figure 6d. *Section continued on next page.*

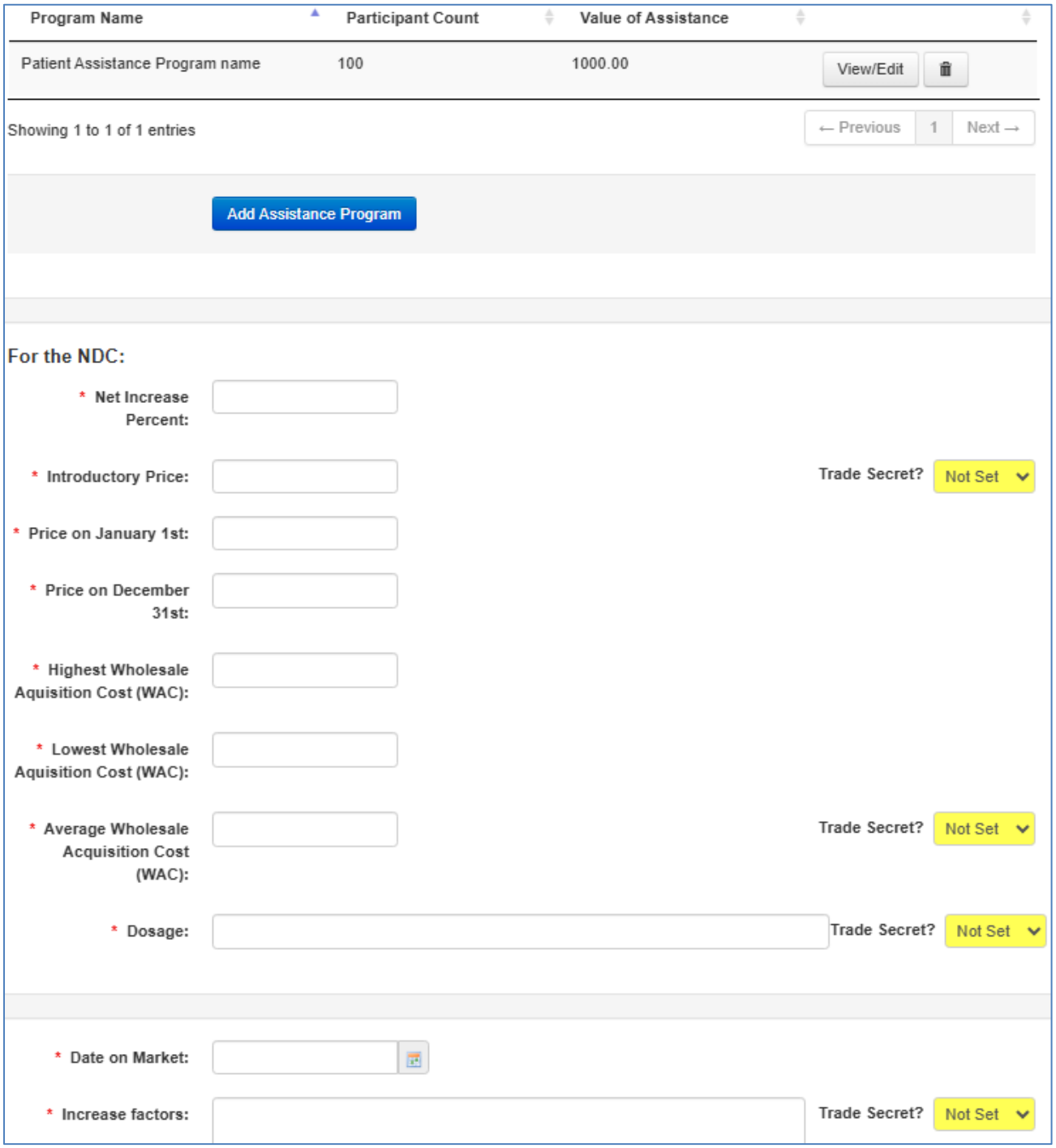
Figure 6d – Annual price increase filing details continued

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



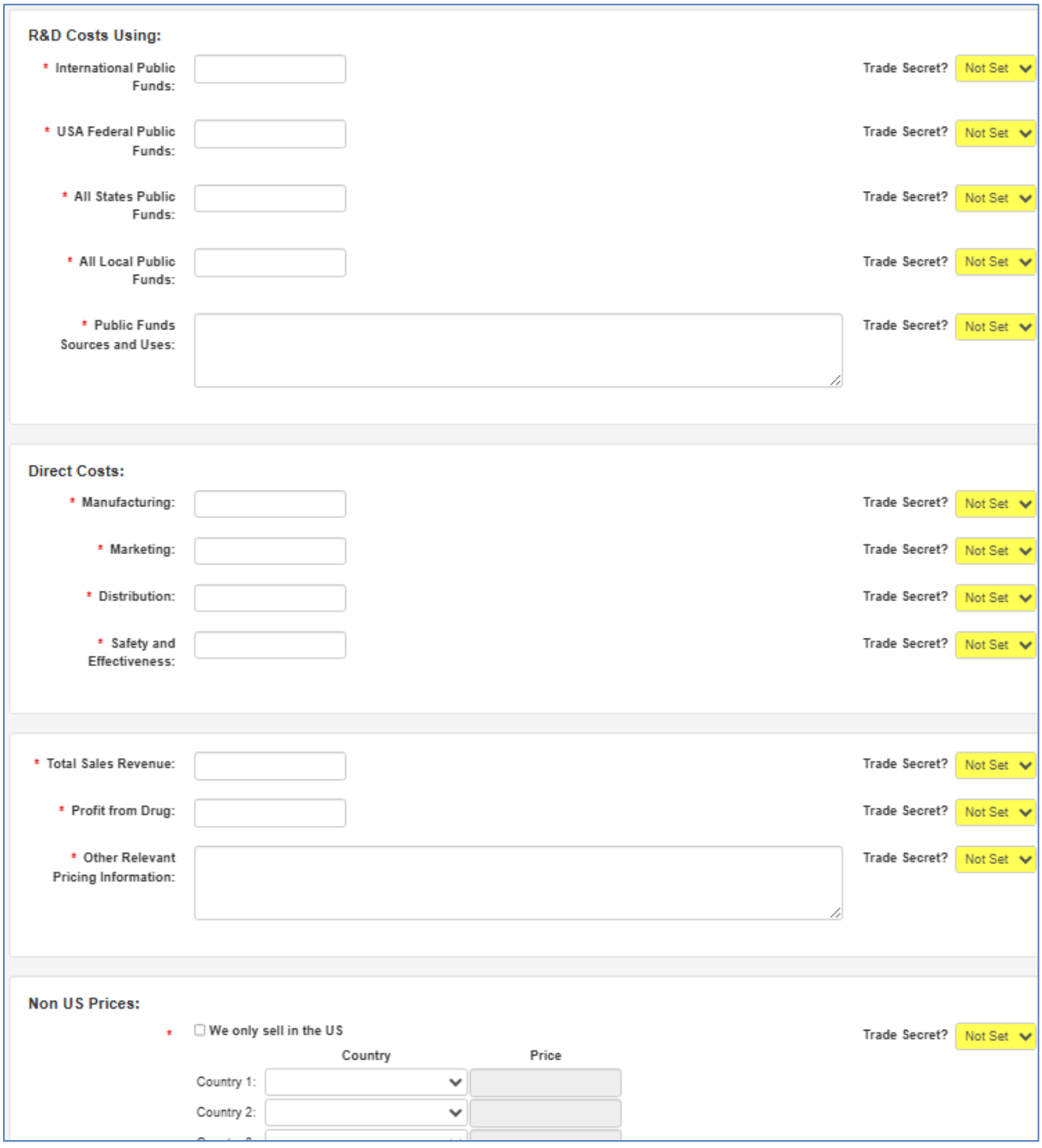
Section continued on next page.

Figure 6e – Annual price increase filing details continued



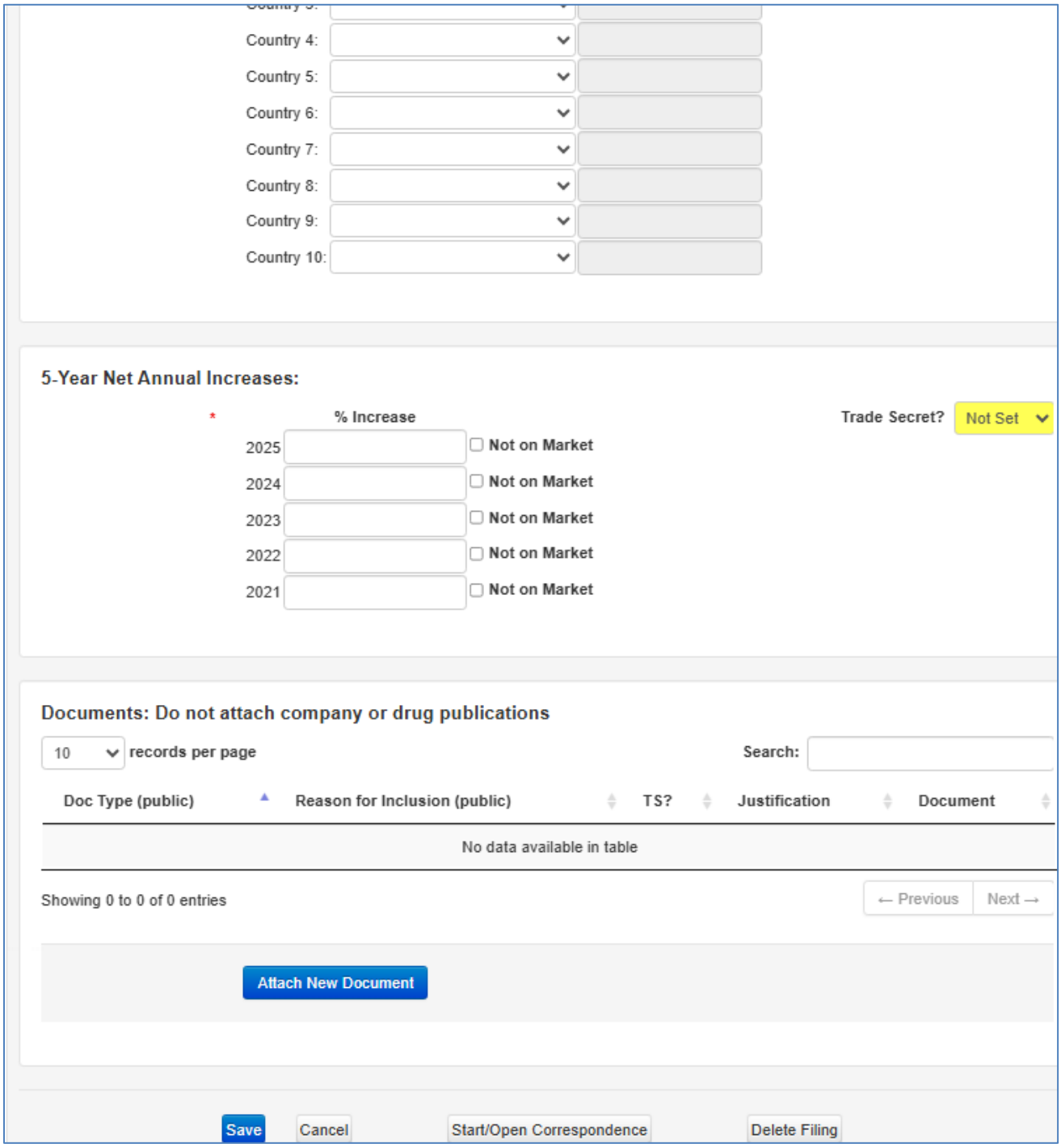
Section continued on next page.

Figure 6f – Annual price increase filing details continued



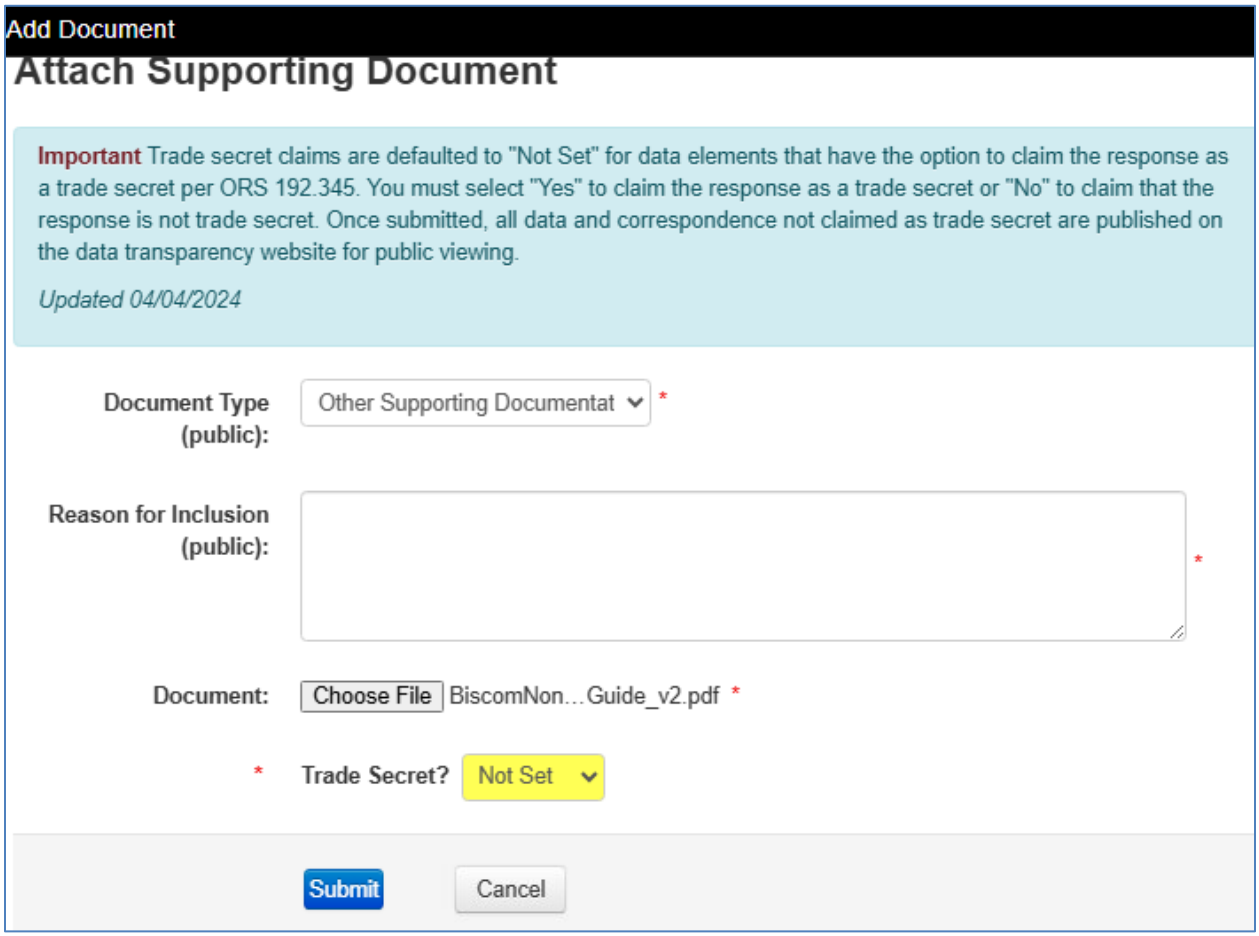
Section continued on next page.

Figure 6g – Annual price increase filing details continued



"Save Progress" will save all information that has been entered into the report but will not submit it. Select "Continue to Certification" when the report is finalized and ready for submission. Refer to Figure 7 about attaching documents and Figure 11 for the certification screen.

Figure 7a – Documents: attaching and viewing



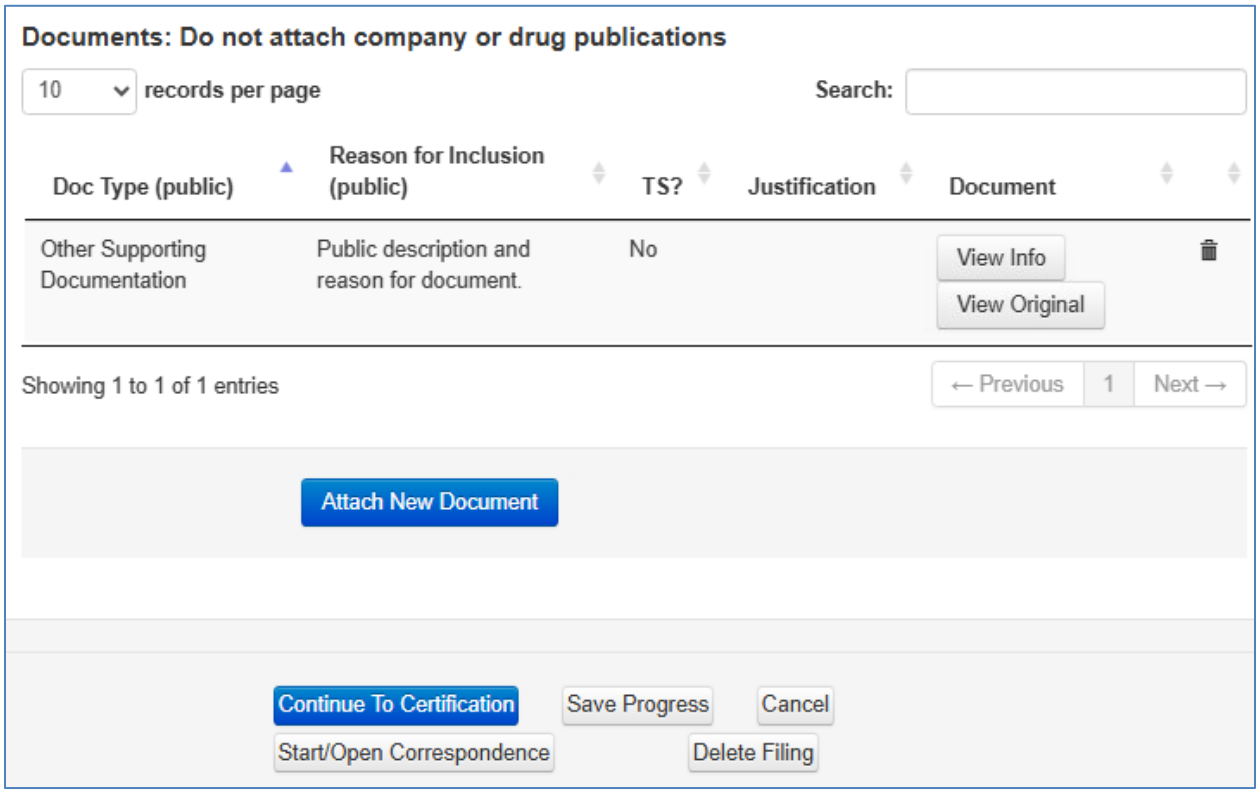
If a document is needed to explain a data element for a new drug or an annual price increase report, select the “Attach New Document” button. Identify the document type with the section of the report or choose “Other Supporting Documentation.” Describe what is being attached along with a reason.

Note: The “Reason for Inclusion” information will be published to the transparency website that is viewable by the public even if the document is claimed as a trade secret.

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.

Section continued on next page.

Figure 7b – Documents: uploaded

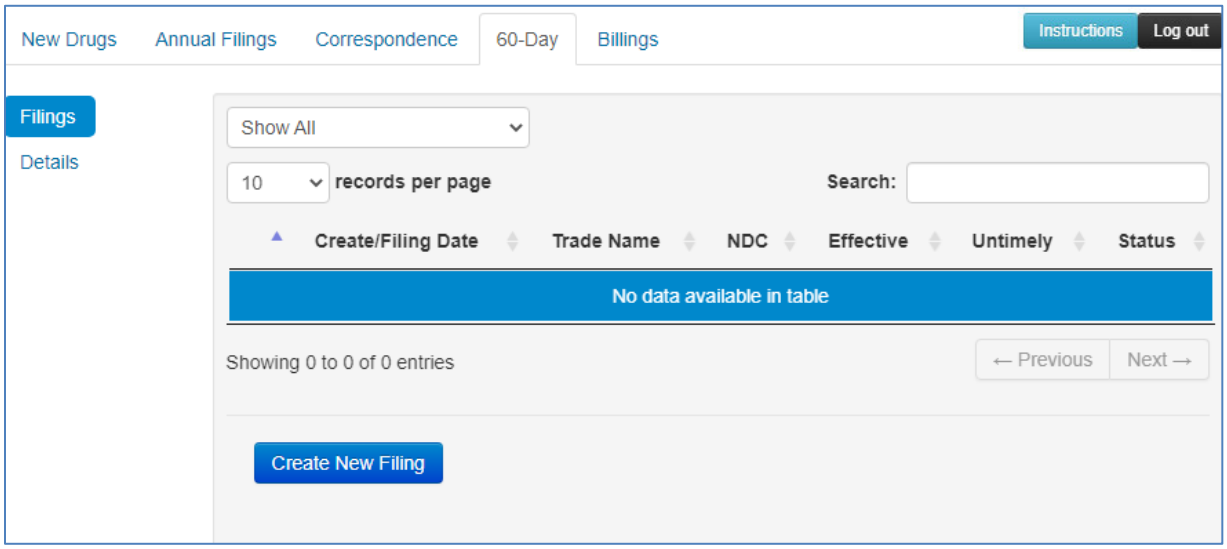


Once a document has been attached to a filing, the screen will close and the document will be displayed in the table. If multiple documents are uploaded, they can be sorted by several categories or deleted from the report using the trash can icon before the report is submitted.

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.

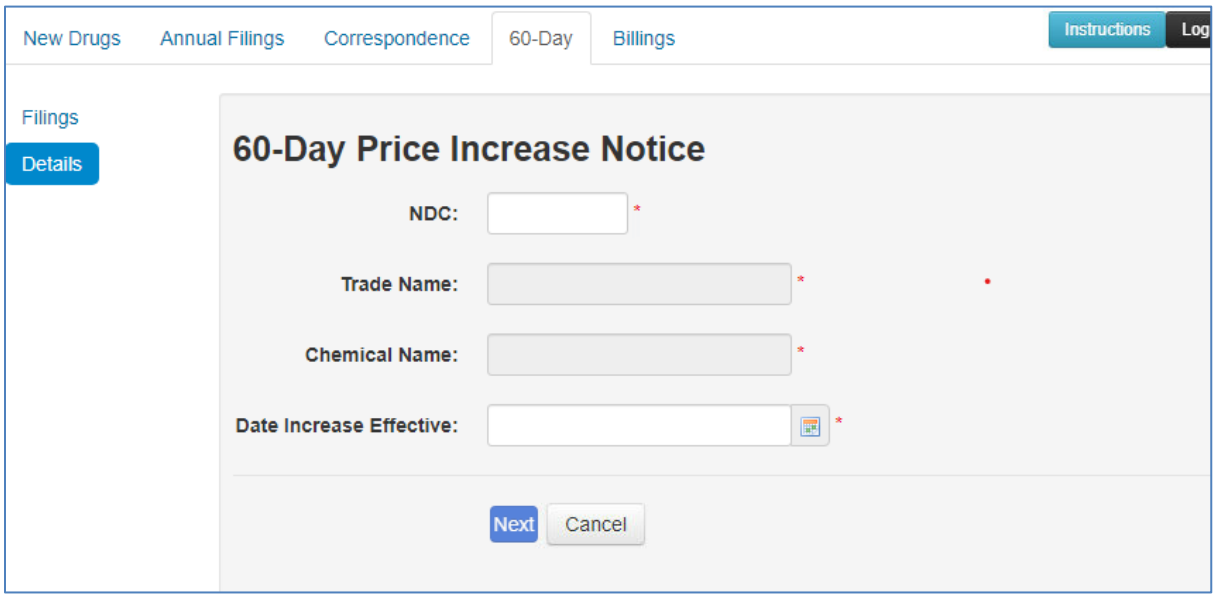
Note: Do not upload excessive or unnecessary documents.

Figure 8a – 60-day price increase notices



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

Figure 8b – 60-day price increase filing creating a report

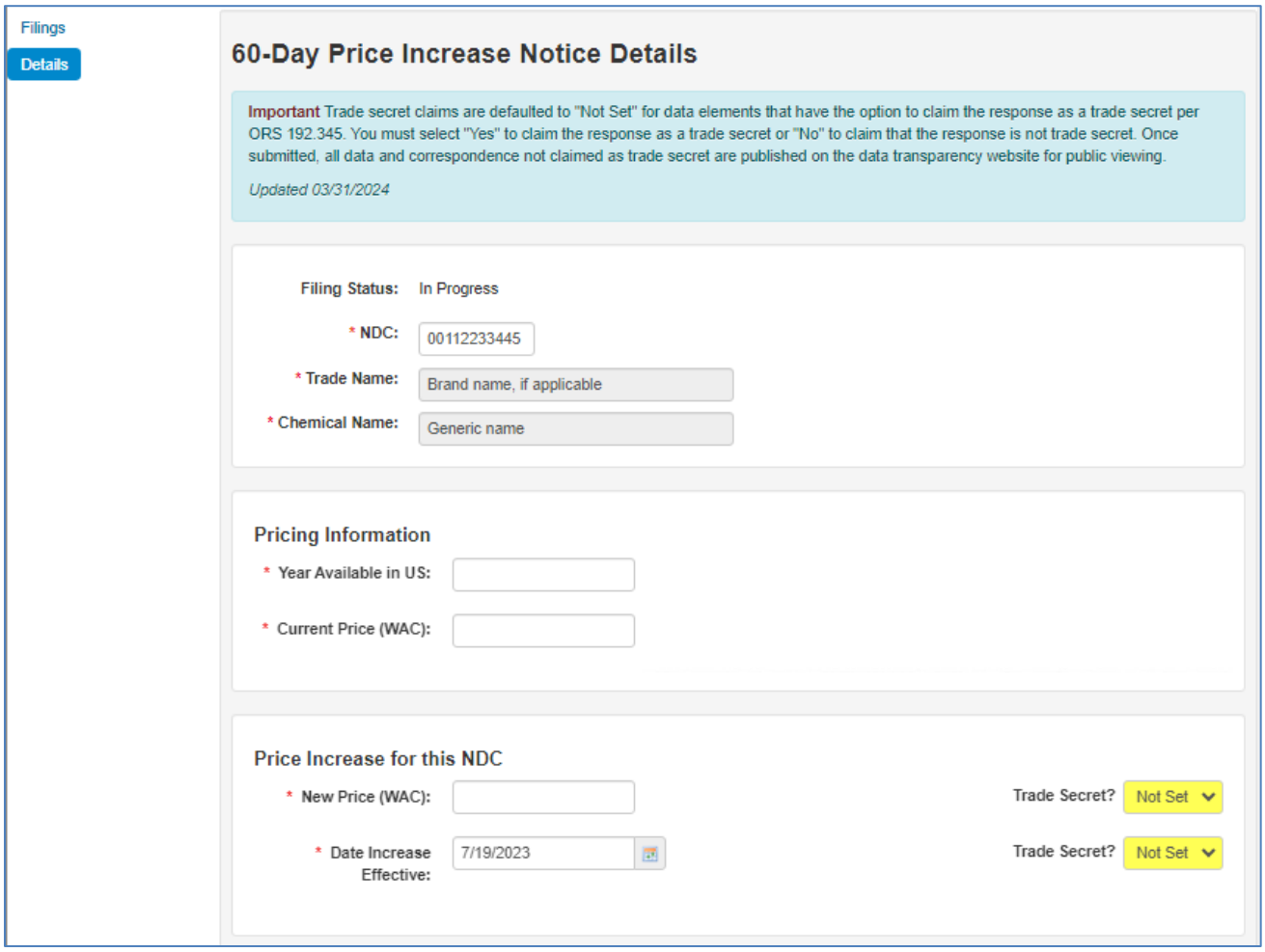


When the “Create New Filing” button has been selected, the user must enter the NDC and the effective date of the increase to initiate the filing. If not automatically populated, the trade name and chemical name must also be entered. Once this information has been reported, the filing is started and appears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

Section continued on next page.

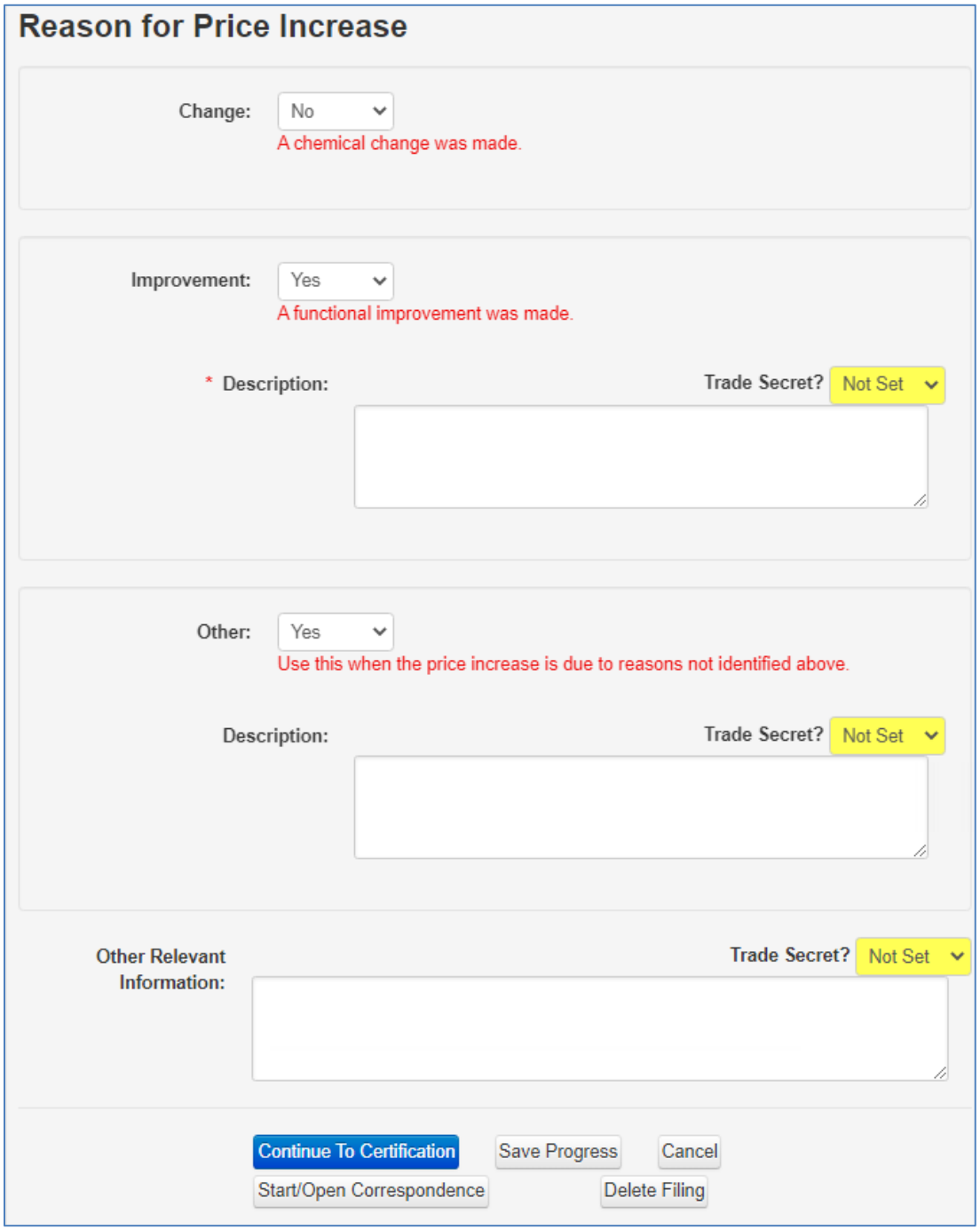
Figure 8c – 60-day price increase filing details

Figures 8c and 8d show how the filing appears in iReg. For more information and guidance about data elements, refer to Section VII (60-day price increase notice reporting) of this user guide.



Section continued on next page.

Figure 8d – 60-day price increase filing details continued



"Save Progress" will save all information that has been entered into the report but will not submit it. Select "Continue to Certification" when the report is finalized and ready for submission to the department. Refer to Figure 11 for the certification screen.

Figure 9 – Filing statuses in iReg

The screenshot 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.

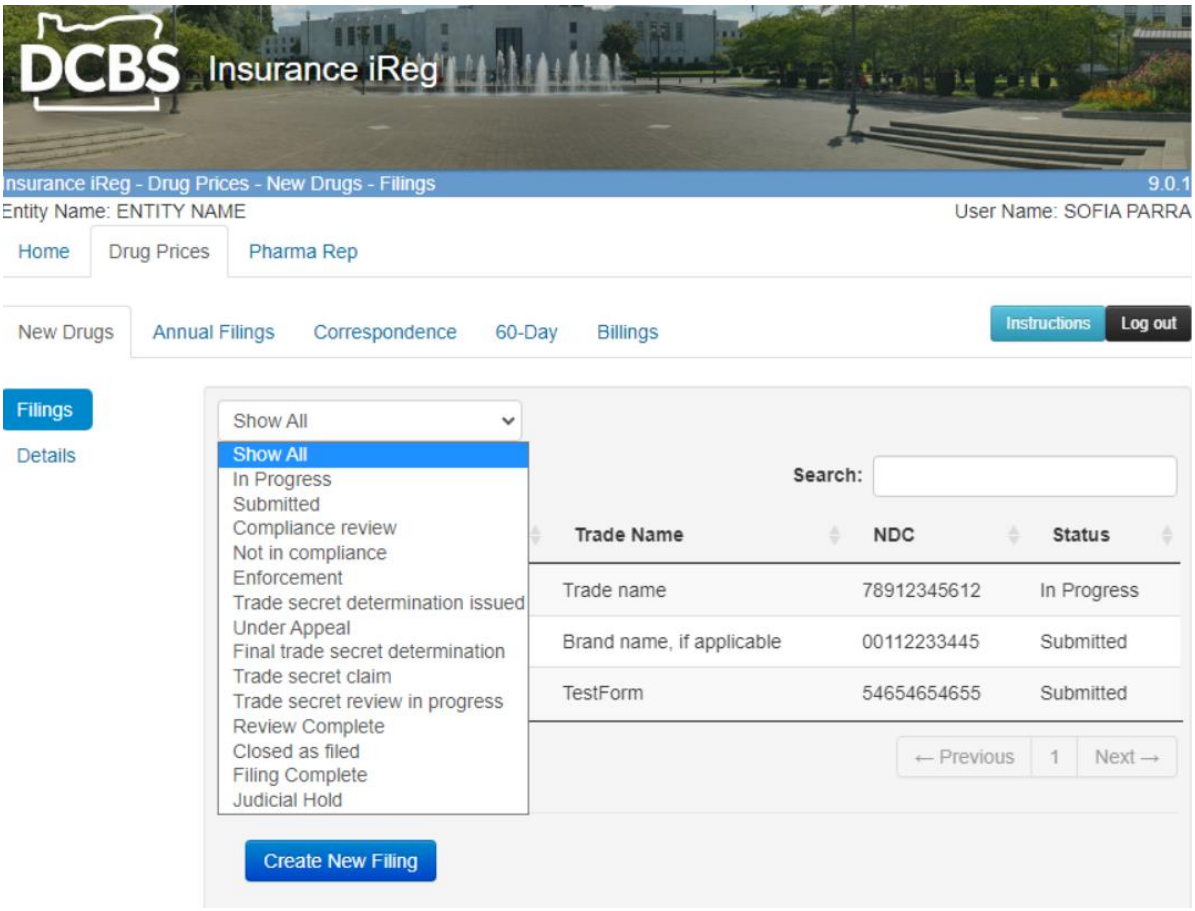


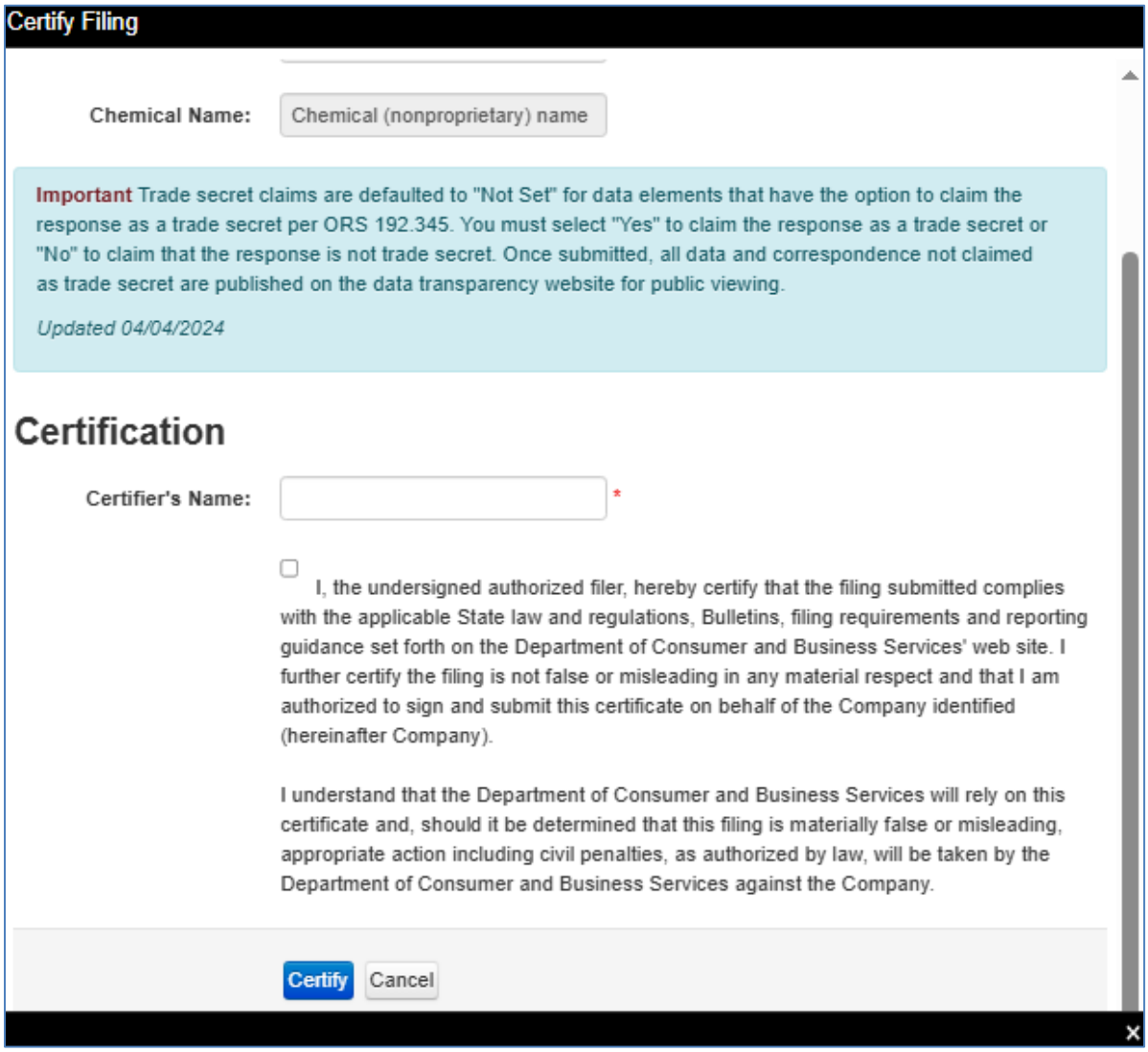
Figure 10 – Trade secret claims

Users may claim a data element as trade secret by selecting “Yes” from the trade secret drop-down menu when the option is available and identifying which specific information is claimed. Refer to the Trade Secret Supplement and OAR 836-200-0540 for more information before making any trade secret claims on the filing. 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 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.
5. The public interest does not require disclosure of the information.

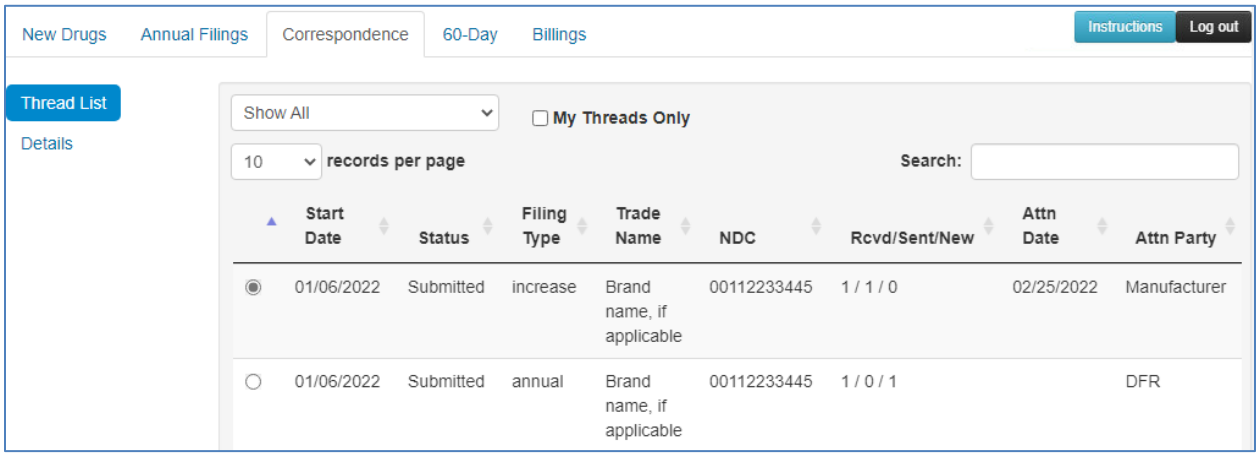
The department will review the manufacturer’s explanations and make a determination on a case-by-case basis as outlined in OAR 836-200-0540.

Figure 11 – Certification of complete filing



When a report is complete and ready to submit, select the “Certify” button. Users enter their full name and check the box to officially certify the report. Selecting 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 certifying the report.

Figure 12a – Correspondence: list of correspondence

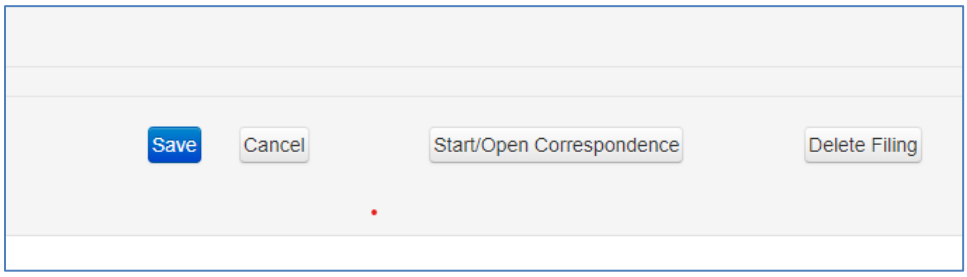


The “Correspondence” sub-tab can be used to communicate information specific to the report. Program staff members will use the correspondence function to communicate information about the report and issue a request for additional information letters. This information is available to the public once a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

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

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

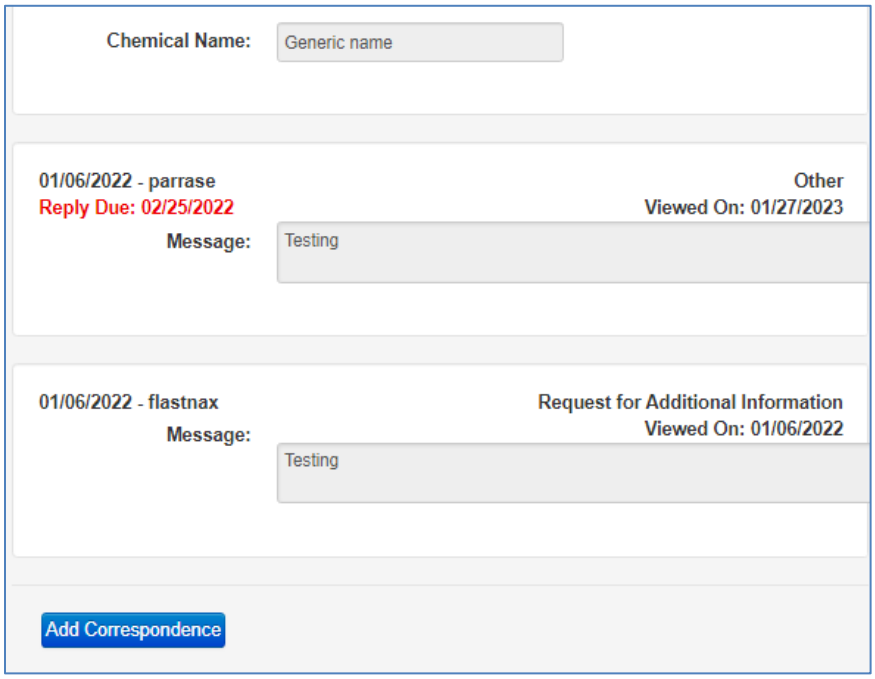
Figure 12b – Correspondence: starting correspondence and responding to request for information and noncompliance letters

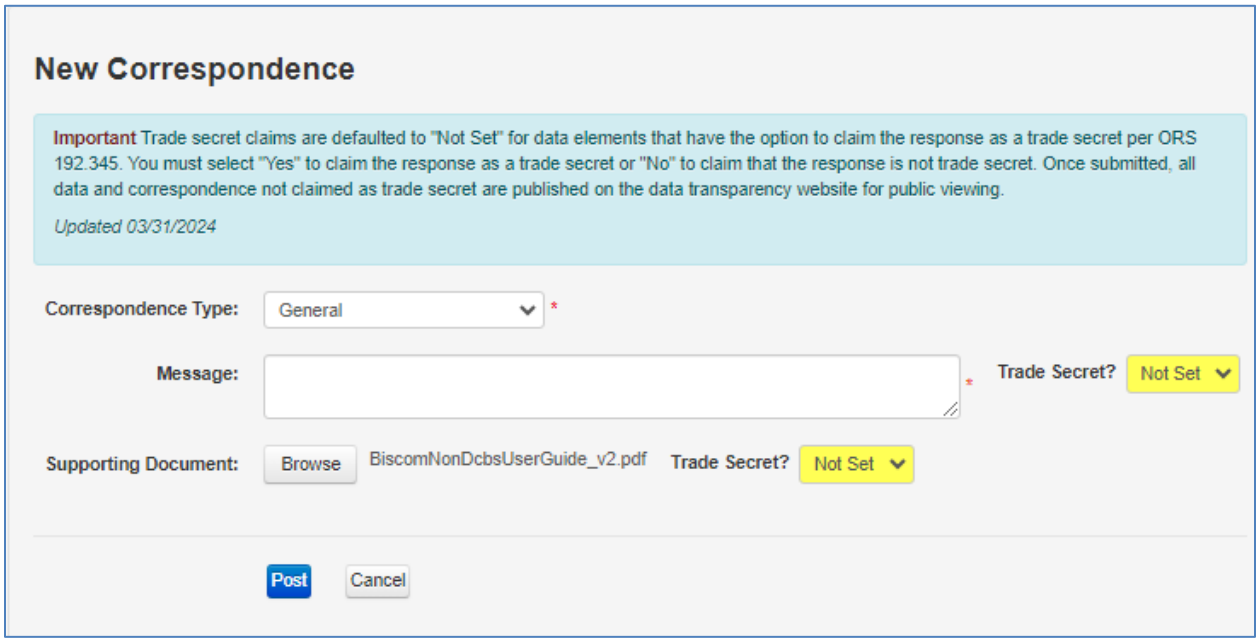


A correspondence thread must be associated with a report. It can be started from within the report by selecting the “Start/Open Correspondence” button at the bottom of a report. You can also respond to one that was already started from the list of correspondence.

Section continued on next page.

Figures 12c and 12d – Correspondence: adding correspondence

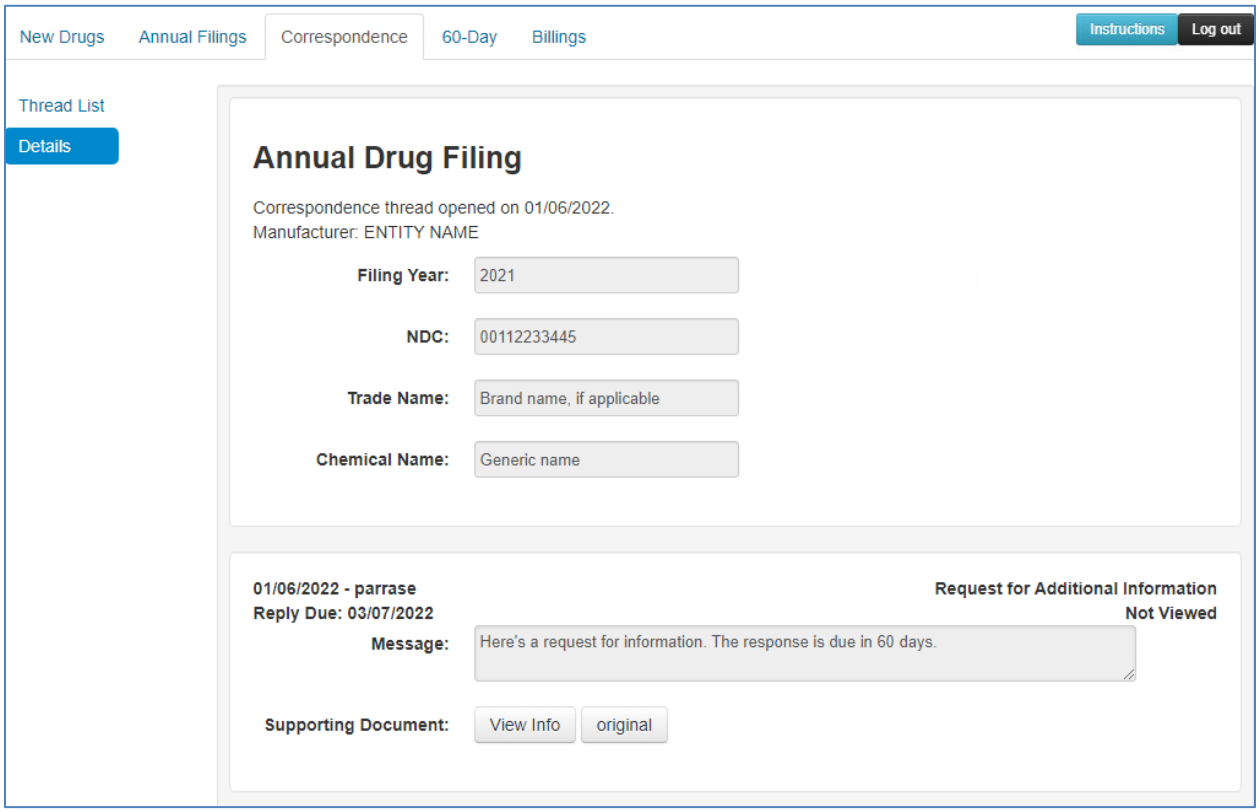




Select “Add Correspondence” to post a response or provide additional information for the report. Users may choose a correspondence type from the categories provided and enter in the main message they want to communicate and add an attachment if needed.

Either the message box or attachment (or both) can be marked as trade secret if needed. Refer to Trade Secret Supplement for more information about trade secret claims. *Section continued on next page.*

Figure 12e – Correspondence: viewing agency correspondence to manufacturer



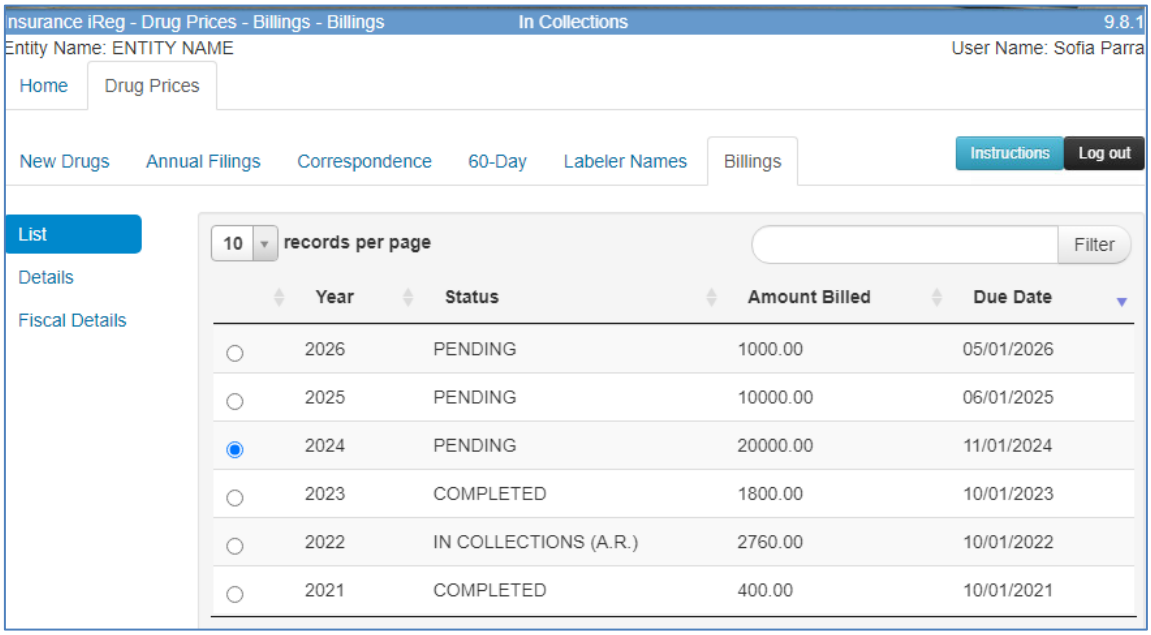
When a user receives an email that we have attached correspondence, it should be viewed as soon as possible. There are deadlines for responding to our requests that are available in the correspondence details.

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 view 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 12c about adding correspondence.

Figure 13a – Billings: list of assessments

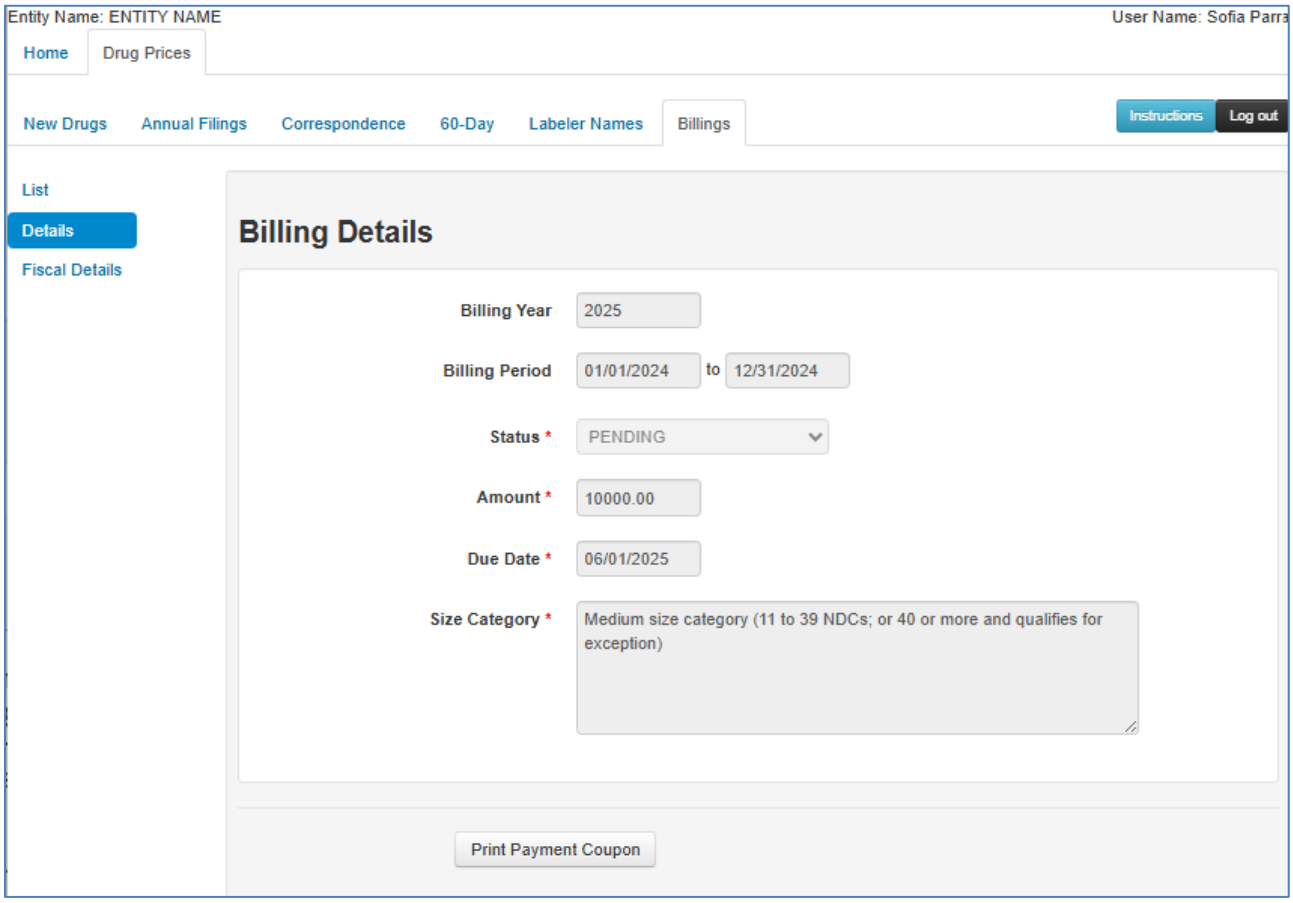
Note: Fees for billing year 2024 and later are different than fees for 2023 and earlier.



The “Billings” sub-tab shows the amounts assessed each year. To view the details and print a voucher, select the year and “Details” from 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 unit.

Section continued on next page.

Figure 13b – Billings: details and printing a voucher



To view the details of the billing and print the voucher, select “Details” from the left-hand side of the screen. You can see the annual assessment and the size category. Size category information only applies to billing year 2024 and later.

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.