Drug Price Transparency Manufacturer Reporting Training Webinar

Drug Price Transparency Program Team Division of Financial Regulation Feb. 16, 2023



Agenda



Annual price increase reporting

New drug reporting

iReg users and contacts





60-day price increase notice reporting

Correspondence and requests for information



Trade secret claims

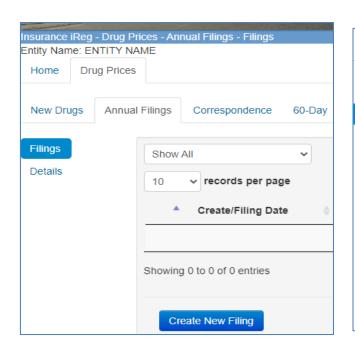
Billings and assessments

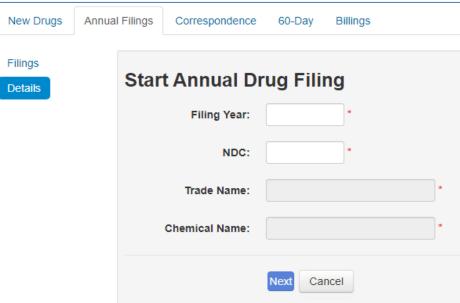
When to file?

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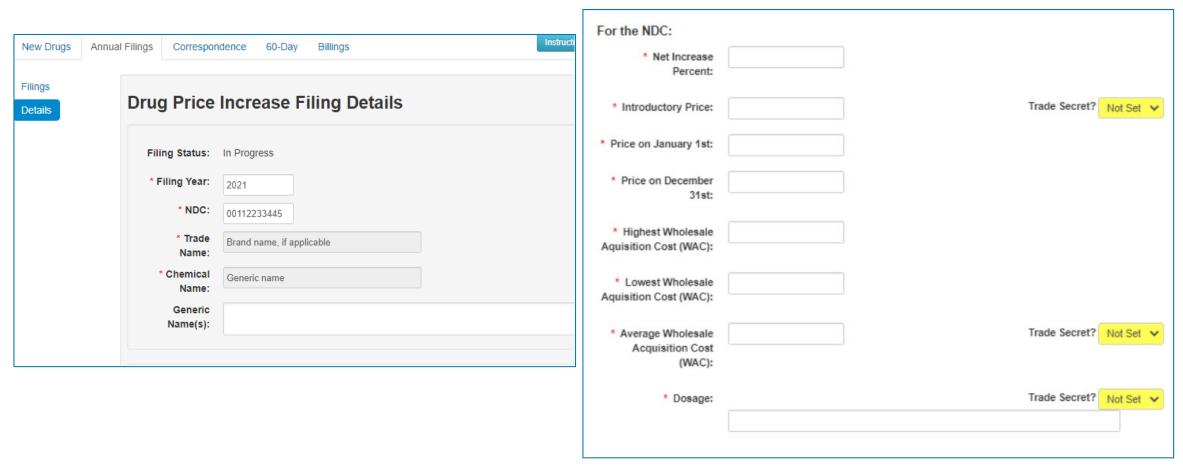
- Reporting threshold:
 - Increase in weighted average wholesale acquisition cost (WAC)
 of 10 percent or more, AND
 - WAC for drug is **\$100** or more for a 30-day supply (or course of treatment lasting less than one month).
- Due date: If required, 2022 reports are due March 15, 2023.
- Example: Drug Z costs \$500 during 2021. The price is increased to \$575 on May 1, 2022. The average price for 2022 is \$550.34 (120 days at \$500 and 245 days at \$575). The increase is 10 percent or more, so a report is required.

- Start annual price increase filing.
- Enter filing year and National Drug Code (NDC).
 - Enter trade name and chemical name if not populated.

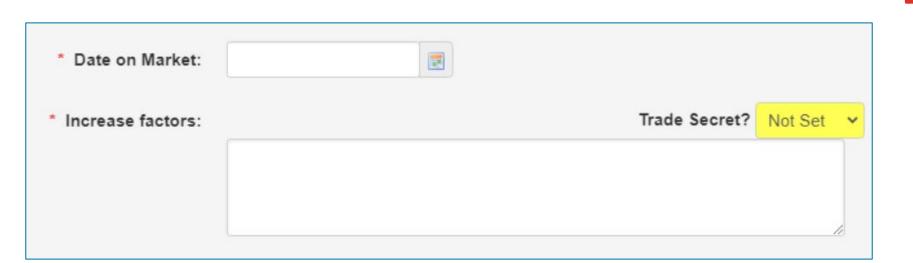






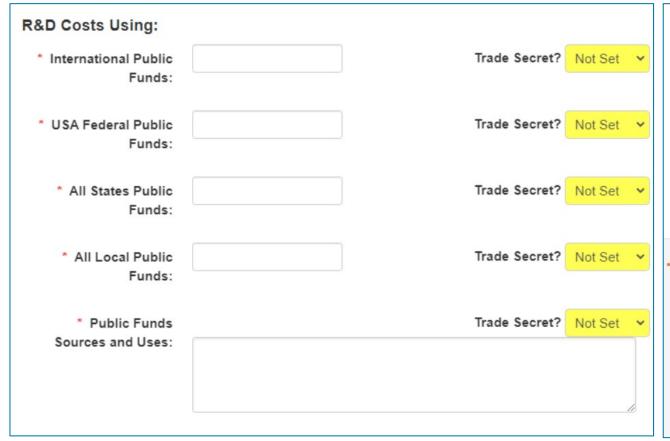


Complete the report following our user guide.



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





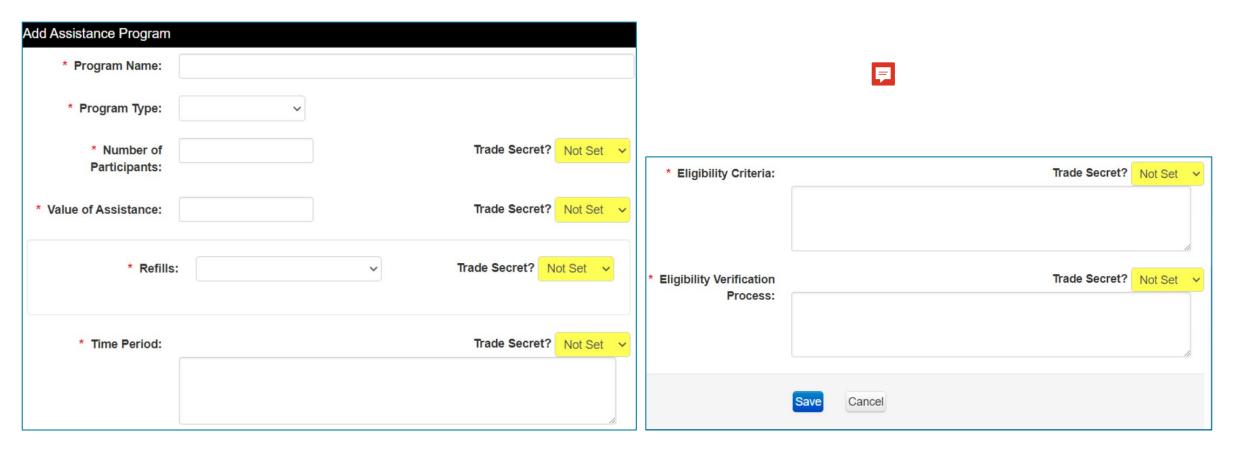
Direct Costs:	
* Manufacturing:	Trade Secret? Not Set
* Marketing:	Trade Secret? Not Set
* Distribution:	Trade Secret? Not Set V
* Safety and Effectiveness:	Trade Secret? Not Set V
* Total Sales Revenue:	Trade Secret? Not Set
* Profit from Drug:	Trade Secret? Not Set
* Other Relevant Pricing Information:	Trade Secret? Not Set



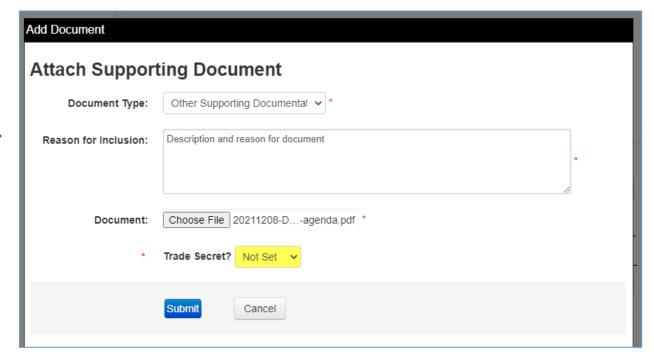




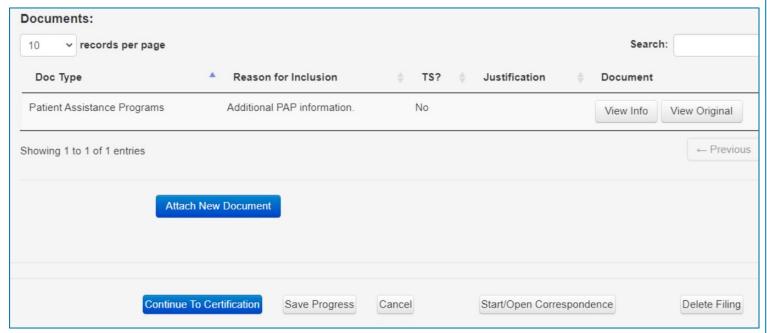
Patient Assistance Programs:						
10 v records p	per pag	ge		Search:		
Program Name	•	Participant Count	\$	Value of Assista	nce	
No data available in table						
Showing 0 to 0 of 0 en	tries				← Pre	
Add Assistance Program						



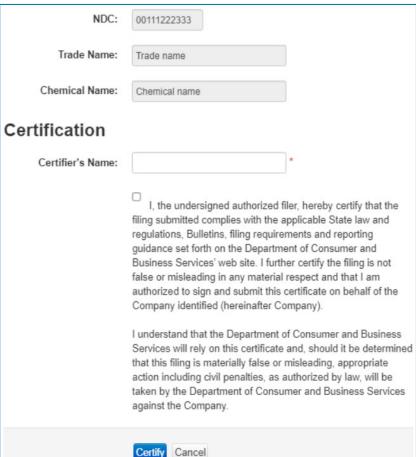
- Complete the report following our user guide.
- If a document is needed to explain a data element, click the "Attach New Document" button.
- Identify the section of the report or choose "Other Supporting Documentation."
- The reason for the inclusion information will appear on the transparency site.



Once completed, you will certify to submit the report.



When you view a submitted report, you will only have the link to its correspondence.



Tips and reminders:



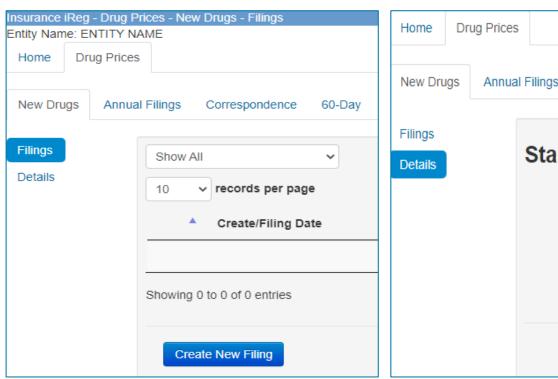
- Reports for 2022 are due March 15, 2023.
- Only file reports that are required. See formula for average price and examples in user guide.
- Report the specific information requested.
- Report accurate and complete information.
- Delete in progress reports that are not required.
- If there are missing reports due in prior years, submit as soon as possible to avoid or reduce penalties.

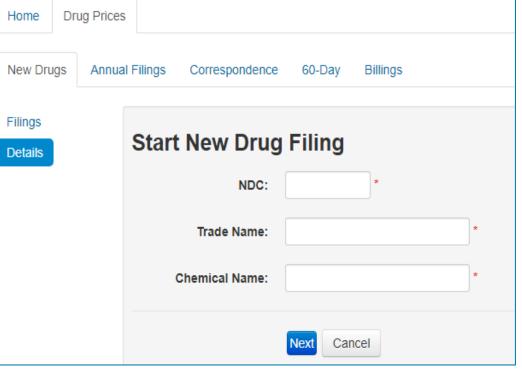
When to file?

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- Reporting threshold:
 - Price exceeds \$670 for a 30-day supply, or a course of treatment lasting less than 1 month.
- Due date: If required, due within 30 days of launch for sale in the U.S.
- If a drug meets the reporting threshold, report on each NDC being introduced to the U.S. market.

- Start new specialty drug filing.
- Enter NDC, trade name, and chemical name.

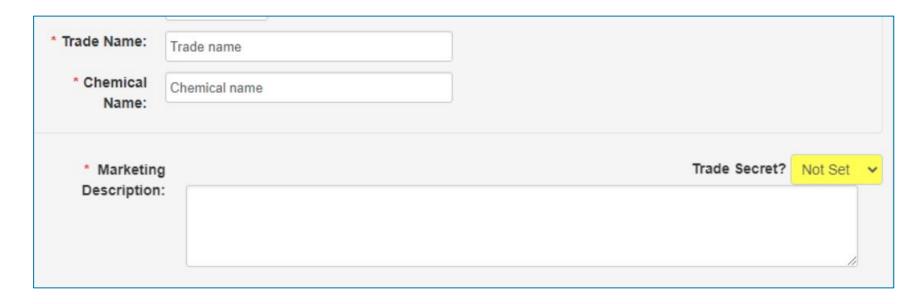






Reminder for generic drug reports:
Enter the trade name of the NDC being reported. Do not report the brand name of a competing product.

Complete the report following our user guide.





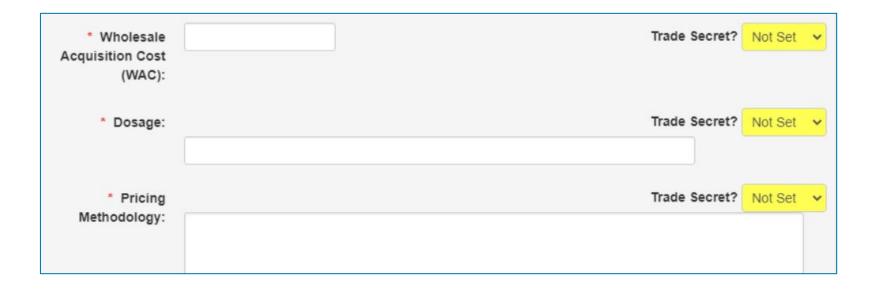
Compliance tip for marketing description:

Report marketing activities and the amounts spent and include:

- Direct-to-consumer marketing, such as paid advertising
- Marketing to promote the drug to physicians

Generic drugs: If drug is not marketed, tell us there is no marketing and no spending.

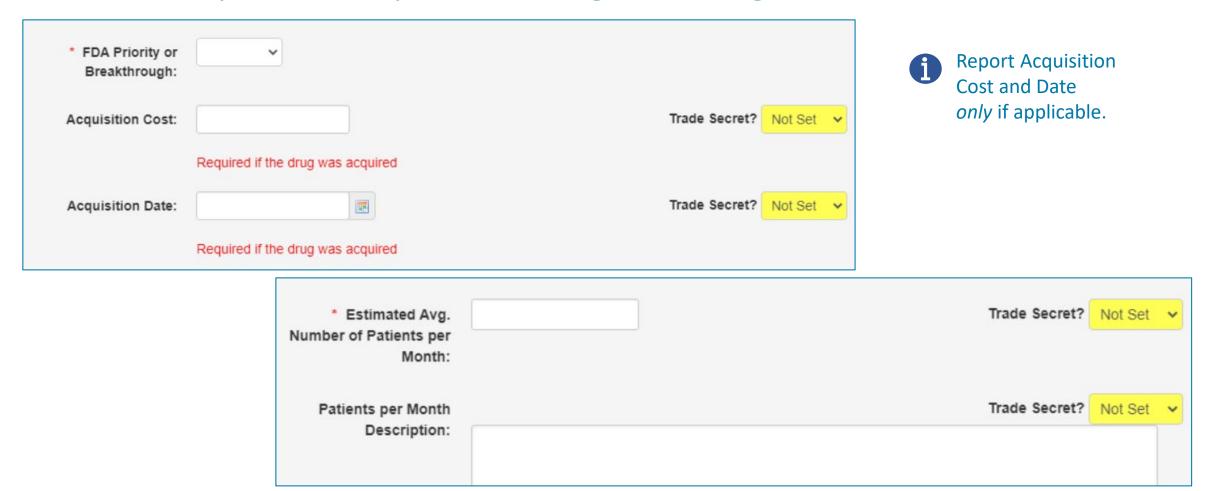
Complete the report following our user guide.



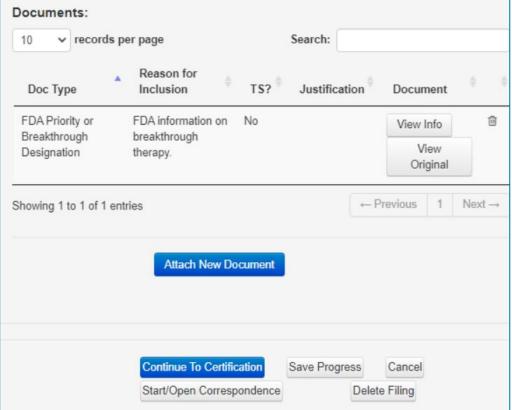


Compliance tip for pricing methodology: Report all major financial and nonfinancial factors that influenced the price.

Generic drugs: Provide comparison information *or* confirm no comparison was used and report what guided pricing.





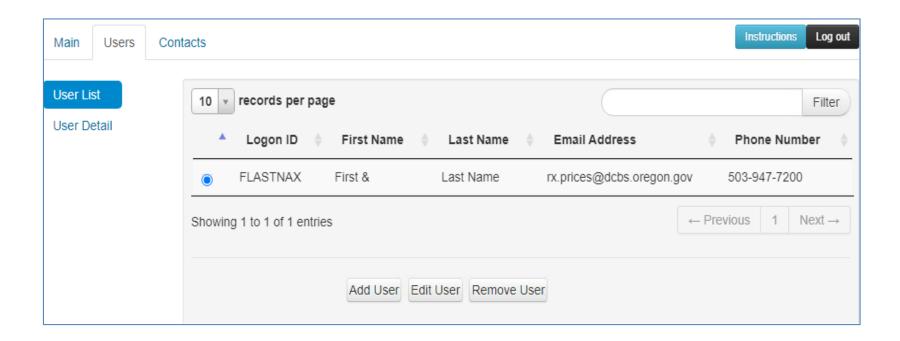


Tips and reminders:

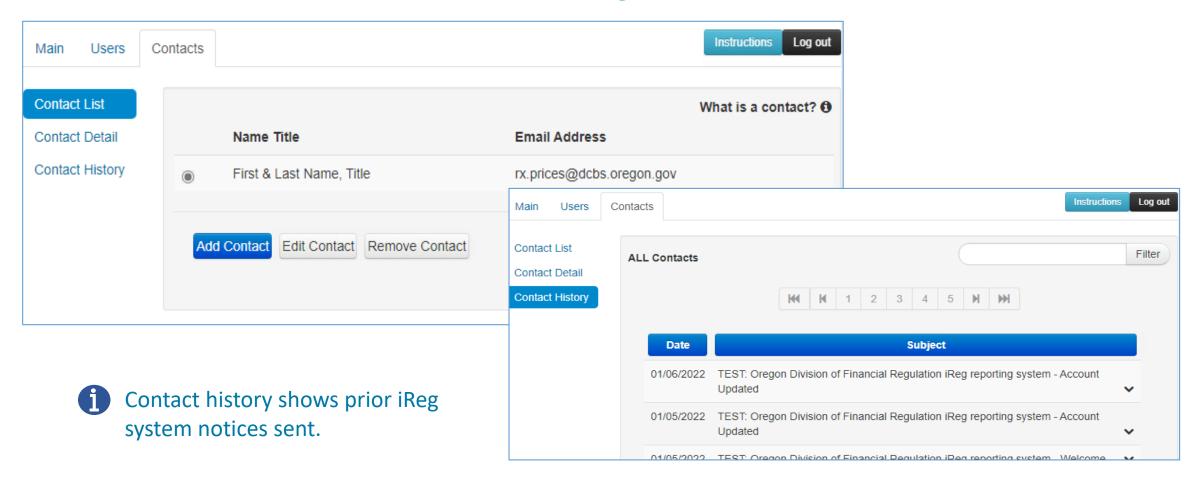
- Reports are due within 30 days of market availability.
- Report the specific information requested.
- Report accurate and complete information.
- Only file reports that are required.
- Delete in progress reports that are not required.
- If there are missing reports due in prior years, submit as soon as possible to avoid or reduce penalties.

- Manufacturers are responsible for keeping their company information up to date.
- Certain notices are only received by contacts, not users.
 - It is important to have the correct users as contacts.
- Make sure your email system is not blocking or quarantining communications from iReg (emails ending with ".gov").

 Users: Each user may also have permissions for the type of reports processed. This allows the user to view, create, edit, or submit reports for specified categories.

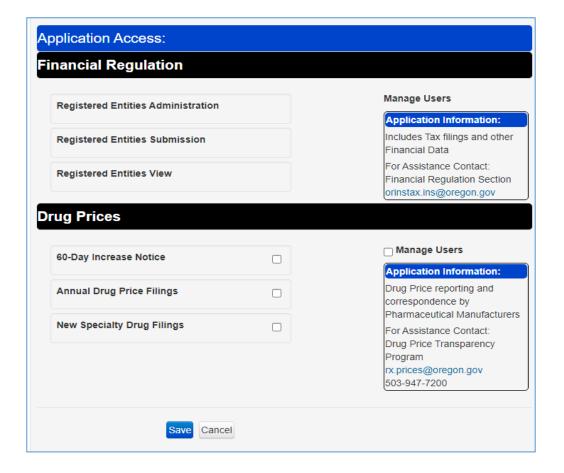


Contacts: List of contacts receiving notices for accounts



Users: access permissions

For every account in iReg, there should be at least one user with the appropriate permissions to adjust contacts and users.



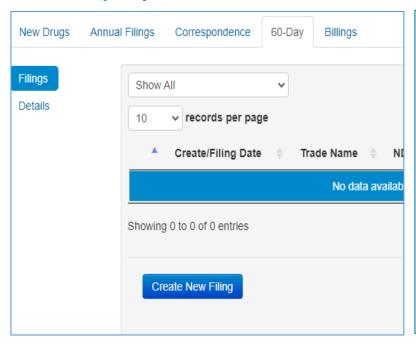
When to file?

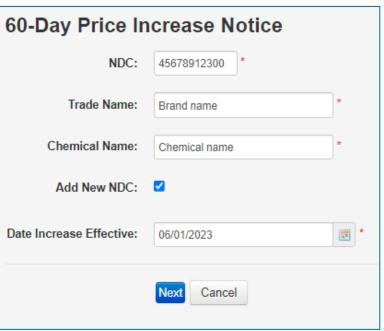
- Reporting threshold for brand-name drugs:
 - Planned increase of 10 percent or more within the 12-month period prior to the increase date
 OR
 - A planned increase of \$10,000 or more.
- Reporting threshold for generic drugs:
 - Planned increase of 25 percent or more within the 12-month period prior to the increase date
 - AND
 - The increase is \$300 or more.

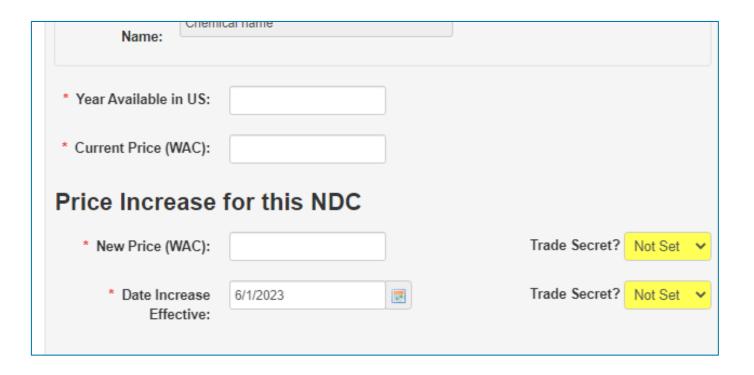
When to file?

- Due date: If required, the report must be filed at least 60 days prior to the date of the planned increase.
- Exception: This report is not required if the drug is manufactured by four or more companies and meets the criteria listed in ORS 646A.683(4).

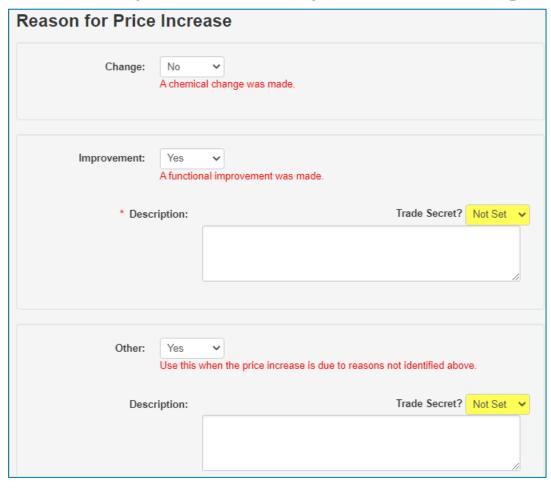
- Start 60-day price increase notice filing.
- Enter NDC and date of planned price increase.
 - Add new NDC and enter trade name and chemical name if not populated.





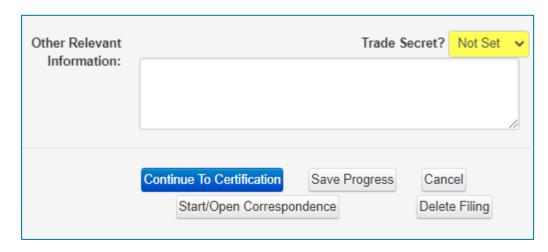


Complete the report following our user guide.





If there was no change or improvement to the drug, remember to select "yes" for other reason and provide a description.



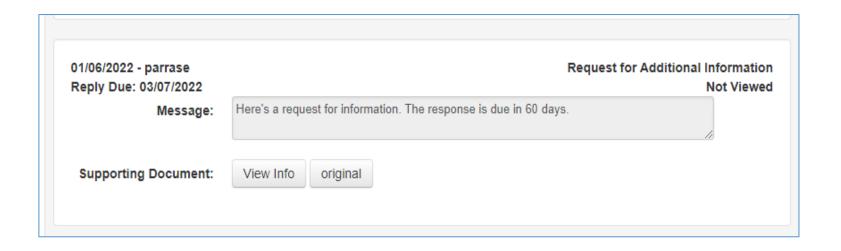
- Correspondence is a way to communicate directly with program staff members regarding a report in iReg.
- This can be used to communicate information or ask questions specific to that report.
- Respond to request for information (RFI) letters in iReg.



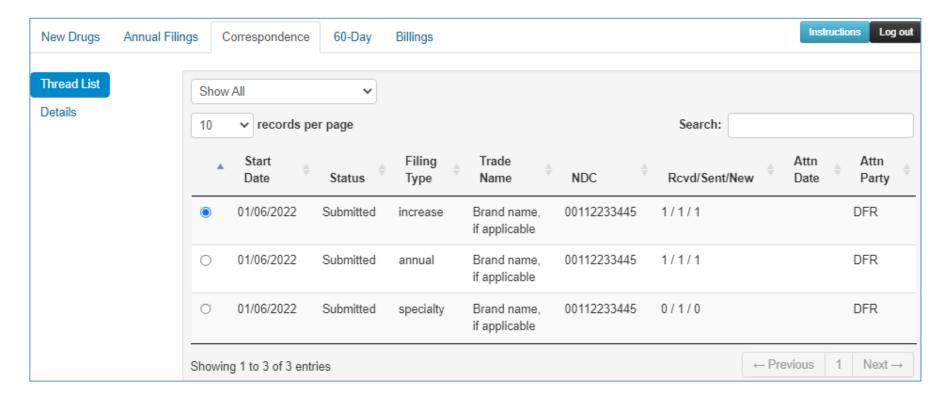
Note that iReg correspondence is published to the prescription drug price transparency website when the report status is marked "Filing Complete."

- Correspondence thread for a report can be accessed at the bottom of the report.
- View message box and attachments posted by program staff.

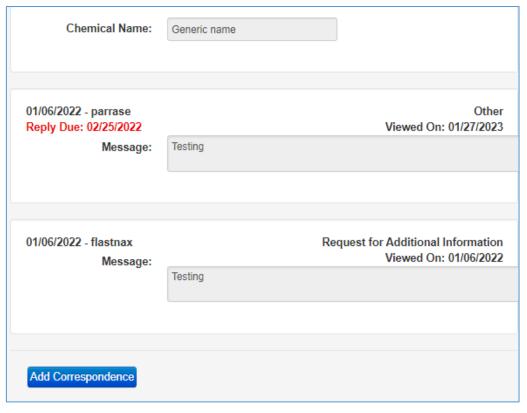


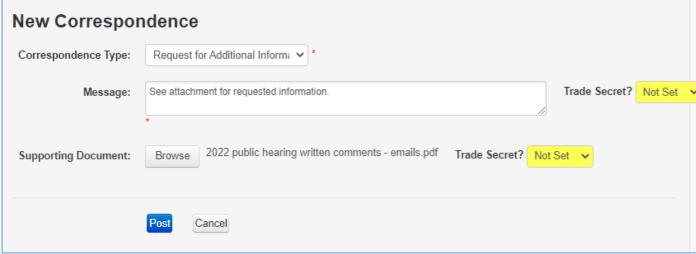


- Correspondence tab lists all correspondence.
- Each thread is associated with a report.



 When responding, select "Add Correspondence." Provide information in the message box. Attach a document, if needed.





Tips and reminders:

- Review due dates for correspondence.
- Make sure your company is not delaying or rejecting emails from iReg (email addresses ending with .gov).
- Email <u>rx.prices@dcbs.oregon.gov</u> if you have questions about how to respond.
- Correspondence is not posted to the transparency site until the report status is set to "Filing Complete."

Trade secret claims and determinations

Is it a trade secret?

- Is the information *specific*?
- Is there company protocol for protecting the information?
- Is it available anywhere else?
- Is it kept as a secret?

Trade secret claims and determinations

Examples that are not a trade secret:

- Generalized information that is not specific or detailed.
- Common industry knowledge or practice.
- Information available publicly, including anywhere on the web.
- Non-responsive entries such as "0" or "1" or "\$0" answers.
- iReg correspondence message box when only the document contains trade secrets.

Trade secret claims and determinations

Before claiming trade secret, carefully review OAR 836-200-0540 (Information Claimed to be Trade Secret).

Steps when claiming trade secret:

- 1. Clearly indicate or mark which information is asserted as trade secret.
- 2. For each piece of information, provide a written explanation that demonstrates all of the listed criteria.

Trade secret claims and determinations

Steps when claiming trade secret (continued):

- 3. The manufacturer has the burden of proof to establish that information submitted is conditionally exempt from disclosure as a trade secret.
- 4. Read the entire administrative rule and ORS 192.345.
- 5. Trade secret determinations are sent securely to contacts using Biscom. Keep contacts updated in iReg.

Trade secret claims and determinations



Common errors:

- Claiming a trade secret for information commonly shared outside the company, such as WAC or dosage.
- Listing common industry practices as trade secret.
- Listing the estimated average number of patients as a trade secret when it is from a source outside the company.
- Claiming public funds used for research and development as trade secret when funding is public information, or entering \$0 and claiming trade secret.

Trade secret claims and determinations

Tips and reminders:

- Reporting information is required even when claiming trade secret.
- Report and delineate the specific information that is a trade secret from information that is not.
- Burden of proof for trade secret claims is on the manufacturer.
- Do not send trade secret information using standard email.

Annual billing information

Annual billing owed by all reporting manufacturers.

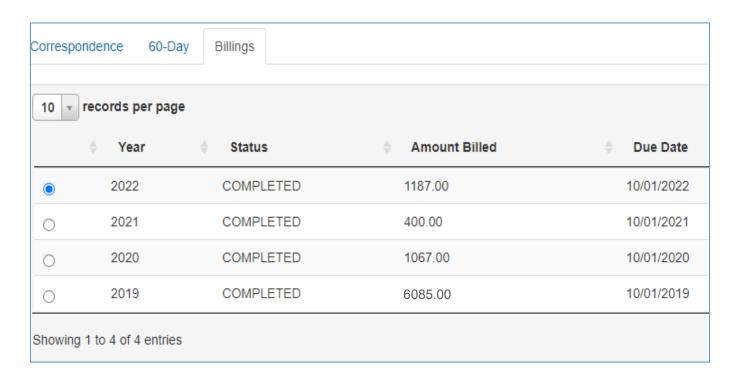


- Amount owed each year:
 - Annual assessment: Each reporting manufacturer owes this fee, currently set at \$400.
 - Reporting assessment: Manufacturers who submitted reports during the billing period owe a fee for each report. The amount varies each year.

Annual billing information

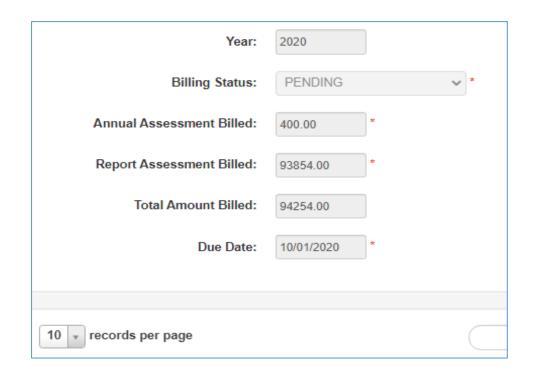
- Billing period: Aug. 1 of prior year through July 31 of current year.
 - 2023 billing period = Aug. 1, 2022, through July 31, 2023.
 Reporting assessment is based on new drug and annual increase reports filed during the period.
- Due date: Oct. 1 each year.
 - 2023 annual billing is due Oct. 1, 2023.
- Demand to pay notice: Issued 30 days before due date.
 - Demand to pay notices will be sent via iReg Sept. 1, 2023.

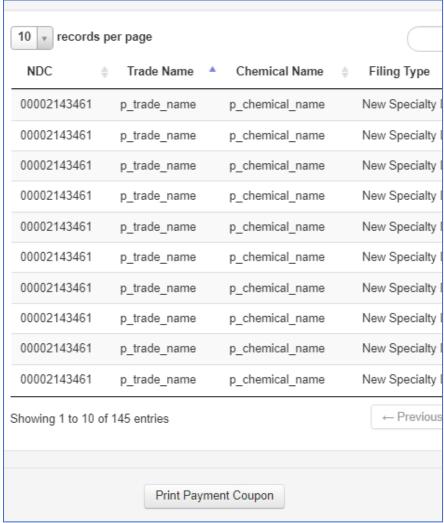
View the Billings tab to see a list of each year's assessment.



Notices about billings are usually sent through iReg and can be reviewed by viewing all contacts history in the Contacts tab.

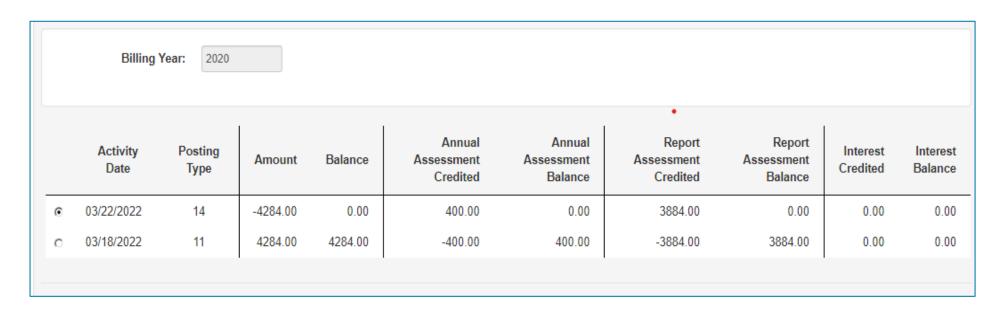
 Select "Details" to access the voucher and detailed information about the billing.



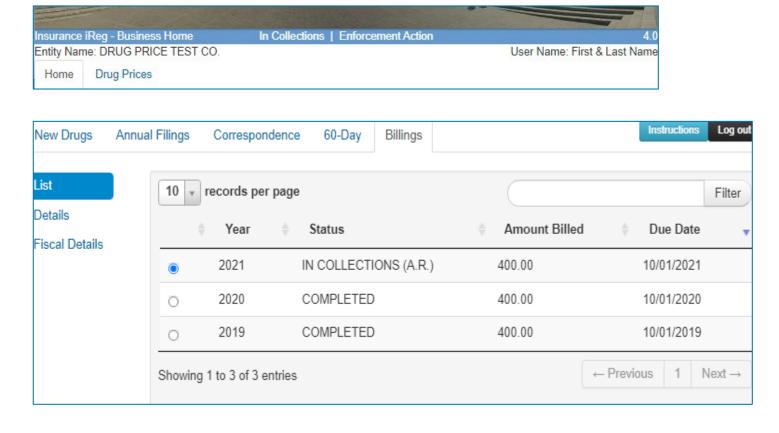




• Select "Fiscal Details" to see the financial transactions.



- Debts sent to collections will not reflect the balance available from Accounts Receivable or the Department of Revenue.
- Voucher can no longer be printed from iReg, so contact us if you need a copy for your records.



Tips and reminders:

- Make sure reports submitted are required.
- Check fiscal details for balances and payments posted.
- Include voucher when paying. Mail check payments as instructed on the voucher or call cashiering to pay by credit or debit card.
- Annual billings not paid by the due date will be sent to collections (our accounts receivable unit).
- For debts in collections, we can tell you who to contact for balance and payment options.

Links and resources

Drug Price Transparency (DPT) contacts:

- Program email: <u>rx.prices@dcbs.oregon.gov</u>; message line 503-947-7200 or 833-210-4560 (toll-free)
- Sofia Parra, program coordinator: sofia.e.parra@dcbs.oregon.gov; or call directly at 503-983-0447
- Sally Sylvester, compliance specialist: sally.b.sylvester@dcbs.oregon.gov
- Cashiering unit (credit or debit card payments): 503-947-7891; available
 8 a.m. to 4 p.m. (Monday-Friday)
- iReg reporting system: https://www4.cbs.state.or.us/exs/ins/ireg/
- DPT webpage for manufacturers with information and user guide: https://dfr.oregon.gov/drugtransparency/Pages/manufacturers.aspx

Links and resources

- DPT main webpage: https://dfr.oregon.gov/drugtransparency/
- Oregon Revised Statutes: ORS 646A.680 to 646A.692 (drug price transparency statutes). Click on link and scroll down to referenced statutes. https://www.oregonlegislature.gov/bills-laws/ors/ors646A.html
- Oregon Administrative Rules: OAR 836-200-0500 through 836-200-0560. Click on link and scroll down to referenced rules.
 https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=3795
- Bulletin 2020-12: https://dfr.oregon.gov/laws-rules/Documents/Bulletins/bulletin2020-12.pdf
- Oregon Revised Statutes: ORS 192.345 (trade secret exemption).
 https://www.oregonlegislature.gov/bills-laws/ors/ors192.html

Questions?

Contact DPT program at rx.prices@dcbs.oregon.gov or contact Sofia Parra (program coordinator) at sofia.e.parra@dcbs.oregon.gov or 503-983-0447

