Drug Price Transparency Program
Manufacturer User Guide
June 2019
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About DCBS: The Department of Consumer and Business Services is Oregon’s largest business regulatory and consumer protection agency. For more information, visit oregon.gov/dcbs.

About Oregon DFR: The Division of Financial Regulation is part of the Department of Consumer and Business Services, Oregon’s largest business regulatory and consumer protection agency. Visit oregon.gov/dcbs and dfr.oregon.gov.
I. Overview

The Prescription Drug Transparency Act, enacted during the 2018 legislative session, established Oregon’s Drug Price Transparency program. This new law requires pharmaceutical manufacturers to report specific information related to pharmaceutical pricing to the Department of Consumer and Business Services, and to pay an assessment to implement the program. The department will review the reports and disclose them to the public.

The purpose of this guide is to help pharmaceutical manufacturers comply with the transparency requirements as specified in 2018 Or Laws Chapter 7 and with OAR 836-200-0500 through OAR 836-200-0560 for Oregon’s Drug Price Transparency program.

**Important Program Dates for 2019**

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 1</td>
<td>Account creation for reporting manufacturers opens</td>
</tr>
<tr>
<td>March 15</td>
<td>Deadline to create account for manufacturers submitting reports</td>
</tr>
<tr>
<td>March 15</td>
<td>New drug reporting begins</td>
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<tr>
<td>Spring 2019</td>
<td>Annual price increase reporting begins</td>
</tr>
<tr>
<td>July 1</td>
<td>Deadline to report annual price increases</td>
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<tr>
<td>Oct. 1</td>
<td>Billing of assessments issued to reporting manufacturers</td>
</tr>
<tr>
<td>Oct. 31</td>
<td>Deadline for manufacturer to pay assessments</td>
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<tr>
<td>Fall 2019</td>
<td>Public hearing on prescription drug prices</td>
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</tbody>
</table>

The department will be using the iReg application for the filing of prescription drug price reports and for the billing of any fees assessed by the department to manufacturers.

For more information on the Prescription Drug Price Transparency Program, visit dfr.oregon.gov/drugtransparency.
II. Account Creation

Pharmaceutical manufacturers that meet the requirements of a reporting manufacturer are required to pay an annual assessment of $400 to the department. A reporting manufacturer is defined in the administrative rule (OAR 836-200-0505) as an entity:
- Required to be registered with the Oregon Board of Pharmacy as a drug manufacturer;
- That engages in the manufacture of prescription drugs as defined in 2018 OR Laws ch.7; and
- That sets or changes the wholesale acquisition cost (WAC) of the drug(s) it manufactures.

Reporting manufacturers include entities that identify as virtual manufacturers or contract to another entity the act of manufacturing. Also, any subsidiaries of a parent company falling within the definition of a reporting manufacturer are required to create their own separate account with the department.

All reporting manufacturers filing reports in 2019 are required to have an account created by March 15, 2019. In subsequent years, reporting manufacturers without an online account and required to file a report must create an account no later than Feb. 15 of that same year.

All manufacturer reporting for Oregon’s Drug Price Transparency program will occur through the iReg system. The iReg system provides the reporting mechanism, secure correspondence between the department and entities, and billing for the program assessments.

New Reporting Manufacturer Account

One account is created for the specific prescription drug manufacturer entity for the purposes of reporting and billing for the company. The program does require all subsidiaries of a parent company falling within the definition of a reporting manufacturer to create their own separate account with the department.

To create an account, manufacturers can fill out the form located on the program website. This form asks the primary contact for the company to fill out information including manufacturer name, manufacturer address, primary contact name, phone, and email address. Once the department receives this information, an account will be generated on iReg and a confirmation email will be sent to the individual identified as the primary contact for the manufacturer.
III. Assessments

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

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

All prescription drug manufacturers will be billed for the annual assessment and any applicable reporting assessment on Oct. 1 each year through the iReg system. Revenue collected from the assessments will solely be used for expenses incurred by the department for administration of the program.

Late assessments will incur an interest rate of 9 percent per year if paid later than 30 days after the date of assessment from the department.

**Annual Assessment**

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

**Reporting Assessment**

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

\[
\text{Annual Expenses} - \frac{\$400(\text{# of prescription drug manufacturers})}{\text{Total Reports}}
\]
IV. New Drug Reporting

Beginning March 15, 2019, prescription drug manufacturers are required to report within 30 days of introduction on new prescription drugs for sale in the United States at a price exceeding $670 for either a 30-day supply or a course of treatment lasting less than one month.¹

Reportable Data Elements

Reports for new drugs meeting the threshold are required to report the following data elements:

1. Full trade name of the drug

2. Full chemical or biologic product name of the drug

3. 11-digit National Drug Code (NDC) for the drug product

4. Price and dosage of the drug the manufacturer used to determine that the price exceeded the threshold

5. Description of the marketing used in the introduction of the new prescription drug, including:
   - Spending on direct-to-consumer marketing and paid advertising
   - Spending on promotion of drug to physicians or other health professionals

6. Methodology used to establish the price of the new prescription drug, including a narrative description and explanation of all major financial and nonfinancial factors that influenced the decision to set the price of the drug

7. Whether there was a breakthrough designation or priority review granted and any support documentation

8. Date and price paid for acquisition of the new prescription drug²

9. Estimate of the average number of patients who will be prescribed the new prescription drug each month

10. Research and development costs associated with the new prescription drug that were paid using public funds

¹ The threshold for new drug reporting is established by the Centers for Medicare and Medicaid Services (CMS) for specialty drugs in the Medicare Part D program; $670 is the dollar amount specified for minimum Part D specialty tier eligibility in the 2018 Final Call Letter from CMS.

² Applies only if the new prescription drug was acquired and not developed by the manufacturer.
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All data elements have specific data fields for the manufacturer to provide their information. The department offers the following guidance to help manufacturers in their reporting:

1. Full trade name of the drug
   • Refers to the exclusive name of a drug product owned by a company under trademark law. If the trade name is the same as the chemical name, please submit the chemical name in this field.

2. Full chemical or biologic name of the drug
   • Refers to the nonproprietary name of the drug product, usually the active ingredients of the product.

3. 11-digit NDCs for the drug
   • Identifies the labeler, product, and trade package size by unique code created by the Food and Drug Administration (FDA) and the manufacturer. Manufacturers are required to report all NDCs for the drug meeting the reporting thresholds. NDCs will be reported to the program in the 11-digit configuration.

4. Price and dosage of the drug the manufacturer used to determine that the price exceeded the threshold
   • Price refers to the wholesale acquisition cost for the reporting year calculated to determine the price exceeded the reporting threshold of $670 for either a 30-day supply or a course of treatment lasting less than one month.
   • Dosage refers to the total amount of a drug that would be prescribed in a single prescription to a patient taking the drug as recommended. If there is more than one such recommended dosage, the largest recommended total dosage will be considered for the purposes of determining the course of treatment.

5. Description of marketing
   • Information regarding marketing for the reported drug on:
     o Direct-to-consumer media advertisements on platforms, such as TV, magazine, radio, social media, blogs, billboards, mobile applications, or other web-based mediums.
     o Direct-to-consumer promotional incentives, such as free trial offers, rebates, coupons, and other utilization incentives if different from the patient assistance program.
     o Spending on the 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.
6. Methodology and narrative description and explanation of establishing wholesale acquisition cost price:
   • Description and explanation of any cost-based pricing, quality-adjusted pricing, value-based pricing, or other models and strategies used to establish the price.
   • Description of any fixed costs, variable costs, quality measures, utilization estimates, and other relevant information.

7. Indication of and supporting documentation for breakthrough designation or priority review given to the drug.
   • 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.

8. Date and price of acquisition of the new prescription drug paid by the manufacturer if the drug was not developed by the manufacturer.

9. Estimate average number of patients who will be prescribed the new prescription drug
   • 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.

10. Research and development costs that were paid using public funds
    • Specify all sources of public funds provided by national, state, local, or foreign government entities used in the basic or applied research for the drug, preclinical trials, and clinical trials.

Data elements not available in the public domain will have the option for the manufacturer to claim the data element as a trade secret. The department will review information claimed to be a trade secret to determine whether the information will be disclosed. See the Trade Secret Claims section and OAR 836-200-0540 for more information.

Manufacturers will be required to certify the information reported to the program is accurate and complies with state law and regulations. It is expected that manufacturers make a good-faith effort to report required information or respond to a request for more information. Failure to comply may result in civil penalties.
V. Annual Price Increase Reporting

Annual price increase reports are required for prescription drugs with a wholesale acquisition cost (WAC) of $100 or more and a net yearly increase of 10 percent or more in the WAC.

The deadline to report this information for the first year is July 1, 2019. For subsequent years, the deadline is March 15. Reporting for annual price increases will be through the iReg system. Annual price increase reports should be submitted for each National Drug Code (NDC) that meets the reporting threshold.

The reporting timeframe for the purposes of annual report filings will always be the year previous to the current calendar year. Any references to previous or preceding calendar year within data elements refers to the year before the current calendar year. For example, the previous calendar year for a report filed in 2019 is 2018.

Reportable Data Elements

Reports for annual price increase meeting the threshold are required to report the following data elements:

1. Full trade name of the drug
2. Full chemical or biologic product name of the drug
3. 11-digit NDC for the drug product
4. Price and dosage of the drug used to determine that the cost of the drug was $100 or more for a 30-day supply or a course of treatment lasting less than one month
5. WAC of the drug at the beginning of the calendar year preceding the report
6. WAC of the drug at the end of the calendar year preceding the report
7. Highest and lowest WAC of the drug at any point during the calendar year preceding the report
8. Net increase percentage in the price of the drug over the course of the previous calendar year
9. Length of time the drug has been on the market
10. Names of any generic version of the prescription drug available on the market
11. Factors that contributed to the price increase
12. Research and development costs associated with the prescription drug that were paid using public funds

13. Direct costs incurred by the manufacturer:
   • 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

14. Total sales revenue for the prescription drug during the previous calendar year

15. Profit attributable to the prescription drug during the previous calendar year

16. Introductory price of the prescription drug when it was approved for marketing by the U.S. Food and Drug Administration

17. Net yearly increase in WAC for the drug, by calendar year, during the previous five calendar years

18. Ten highest prices paid for the prescription drug during the previous calendar year in any country other than the United States

19. Any other information that the manufacturer deems relevant to the price increase and any documentation necessary to support the information reported

20. Patient assistance program addendum reporting on each patient assistance program offered by the manufacturer to consumers residing in Oregon for the reported prescription drug.

All data elements have specific data fields for the manufacturer to provide their information. The department offers the following guidance to help manufacturers in their reporting:

1. Full trade name of the drug
   • Refers to the exclusive name of a drug product owned by a company under trademark law. If the trade name is the same as the chemical name, please use submit the chemical name in this field.

2. Full chemical or biologic name of the drug
   • Refers to the nonproprietary name of the drug product, usually the active ingredients of the product.
3. 11-digit NDCs for the drug
   • Identifies the labeler, product, and trade package size by unique code
     created by the FDA and the manufacturer. NDCs will be reported to the
     program in the 11-digit configuration.

4. Price and dosage of the drug the manufacturer used to determine that the
   price exceeded the threshold
   • Price refers to the average wholesale acquisition cost for the reporting
     year calculated to determine the price exceeded the reporting
     threshold.
   • Dosage refers to the total amount of a drug that would be prescribed in
     a single prescription to a patient taking the drug as recommended. If
     there is more than one such recommended dosage, the largest
     recommended total dosage will be considered for the purposes of
     determining the course of treatment.

5. WAC of the drug at the beginning of the calendar year preceding the report
   • The beginning of the calendar year refers to the WAC of the drug on
     Jan. 1.

6. WAC of the drug at the end of the calendar year preceding the report
   • The end of the calendar year refers to the WAC of the drug on Dec. 31.

7. Highest and lowest WAC of the drug at any point during the calendar year
   preceding the report

8. Net increase percentage in the price of the drug over the course of the
   previous calendar year
   • Net yearly increase means an increase in the WAC of a drug over the
     course of a calendar year, calculated by dividing the average WAC by
     the average WAC over the course of the previous calendar year

9. Length of time the drug has been on the market
   • The amount of time from the date of market entry that the drug has
     been available to purchase.

10. Names of any generic or biosimilar version of the prescription drug available
    on the market
    • List all the names of the generic or biosimilar version of the
      prescription

11. Factors that contributed to the price increase
    • Narrative description of these factors
    • Explanation of major financial and nonfinancial factors
12. Research and development costs associated with the prescription drug that were paid using public funds
   • Specify all sources of public funds provided by national, state, local, or foreign government entities used in the basic or applied research for the drug, preclinical trials, and clinical trials.

13. Direct costs incurred by the manufacturer:
   • 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
     a. Direct costs may include any fixed or variable costs associated with the categories above

14. Total sales revenue for the prescription drug during the previous calendar year
   • The total gross sales revenue associated with the drug. Revenue is defined consistent with generally accepted accounting principles (GAAP).

15. Profit attributable to the prescription drug during the previous calendar year
   • The net profit that can be attributed to the prescription drug. Net profit is defined as consistent with GAAP.

16. Introductory price of the prescription drug when it was approved for marketing by the U.S. Food and Drug Administration
   • Introductory price means the WAC of the drug when it was approved for marketing by the FDA and entered the U.S. market

17. 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 WAC of a drug over the course of a calendar year, calculated by dividing the average WAC by the average WAC over the course of the previous calendar year
   • Previous five calendar years means the past five years from the previous calendar year. For example, a report filed in 2018 would report the net yearly increase in WAC from 2013 to 2017.
   • 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.
18. Ten highest prices paid for the prescription drug during the previous calendar year in any country other than the United States
   • For reporting prices in other countries, price should be the WAC equivalent in that country 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. Any other information that the manufacturer deems relevant to the price increase and any documentation necessary to support the information reported.

20. Patient assistance program addendum reporting on each patient assistance program offered by the manufacturer to consumers residing in Oregon for the reported prescription drug with the following data elements.
   • If a reporting manufacturer offers one or more patient assistance programs for the drug to consumers residing in Oregon to reduce consumer out-of-pocket costs, the report must include at least all of the following information for each patient assistance program relevant to the drug that is the subject of the report:
     A. The number of consumers residing in Oregon who participated in the patient assistance program over the previous calendar year
     B. The total dollar value of the coupons, discounts, co-payment assistance or other reduction in costs provided to consumers in this state who participated in the program over the previous calendar year
     C. For each drug, the number of refills that qualify for the program, if applicable
     D. If the program expires after a specified period of time, the period of time that the program is available to each consumer
     E. The eligibility criteria for the program and how eligibility is verified for accuracy

   • Any bona fide Independent Charity Patient Assistance Programs operating in full compliance with the guidance provided in the Department of Health and Human Services Office of the Inspector General’s Supplemental Special Advisory Bulletin. Independent Charity Patient Assistance Programs are exempt from reporting in this section.
   • Reporting manufacturers that provide funding for independent patient assistance programs must make a good faith effort to secure this information.

Data elements not available in the public domain have the option for the manufacturer to claim the 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. Please see the *Trade Secret Claims* section and OAR 836-200-0540 for more information.

Manufacturers are required to certify the information reported to the program is accurate and complies with state law and regulations. It is expected that manufacturers make a good-faith effort to report required information or respond to a request for more information. Failure to comply may result in civil penalties.
VI. Information Claimed to be Trade Secret

Prescription drug manufacturers may request specific information provided to the department be conditionally exempt from disclosure under ORS 192.345 as a trade secret. This is done by clicking the trade secret box next to an informational element within iReg. Each line and informational element must be clearly indicated by the manufacturer when uploading documents and claiming the information as trade secret.

For each data element or information claimed to be trade secret within the report, the manufacturer will be prompted to provide a succinct written explanation of why the information is exempt from disclosure demonstrating all of the following:

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

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

The burden of proof to establish information as conditionally exempt from disclosure as a trade secret is on the manufacturer submitting the filing. The department will review the manufacturer’s explanations and make a determination on a case-by-case basis as outlined in OAR 836-200-0540.

1. If the department determines any information claimed to be trade secret must be disclosed, the department will notify the manufacturer and provide a written explanation of the department’s determination.
2. Within 15 days of receiving the notification for disclosure, the manufacturer may submit a letter to the director of DCBS to appeal the department’s determination and request reconsideration. The letter must explain the grounds for the request.
3. The director or director’s designee will review the appeal to the determination and issue a determination within 15 days, or within a time period necessary to obtain legal review, of receiving an appeal letter.
4. If the director’s determination would result in the disclosure of information claimed to be trade secret, the department will notify the manufacturer of the director’s decision at least 21 days in advance of disclosing the information.
If the department exempts information from disclosure provided by a manufacturer, the department will post an explanation of the basis for exempting the information and a general description of the nature of the information to the department’s website.

A person may petition the Attorney General, as provided in ORS 192.411, to review a decision made by the department to exempt information from disclosure.
VII.  Review and Disclosure of Reports

All information reported to the department will be placed Under Review, once the department has acknowledged receipt of a report. The department will begin the process of reviewing submitted reports along the timeline described in OAR 836-200-0535 and outlined below.

| Within 60 calendar days of receiving a report | The director or director’s designee may submit a written request for supporting documentation or additional information to the manufacturer. Requested information is limited to information necessary to:
  - Clarify or substantiate the previously reported material or
  - Enable an analysis of factors affecting drug prices for the purpose of providing recommendations to the Oregon State Legislature

Manufacturers will receive an alert there has been correspondence posted to their account on the iReg system.

| Within 60 calendar days of receiving a request for information | Prescription drug 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 836-200-540. Any requested information that is unavailable to the manufacturer must include a written explanation as specified by 836-200-0525.

| Within 15 calendar days of receiving a request for more information | Prescription drug manufacturers may request up to an additional 30 days to prepare and submit a response to the director’s request. The request for additional time must explain the grounds for the request and the need for additional time, submitted in writing on the iReg system.

| Within 15 days of receiving a manufacturer’s request for additional time | The director or director’s designee will respond in writing through the iReg system specifying and explaining the decision to grant the request, deny the request, or grant with an amount less than requested. |
Any more information or correspondence between the manufacturer and the department regarding a drug report will occur within the iReg system to maintain records associated with the report. If the department receives information or correspondence about a specific drug report filed by the manufacturer via other communication avenues, the manufacturer will be directed to submit the correspondence in writing through the iReg system.

**Deficient Reports**

Manufacturers submitting reports to Oregon’s Drug Price Transparency program are required to submit timely reports with information as specified in Oregon Laws 2018 Chapter 7 and OAR 836-200-0500 through OAR 836-200-0560.

The department provides the following guidance **for the first year of reporting** to manufacturers regarding instances where a report is determined to be deficient. The department will provide an opportunity for manufacturers to submit an amended report.

1) Following receipt of a report, the department will review the report submitted by the manufacturer to evaluate the data submitted.

2) If a report is determined by the department to be deficient, the manufacturer will be notified by the department and requested to provide information for specified data elements.

3) The manufacturer will have 14 days to provide the department an amended report with information for specified data elements.

4) If a manufacturer elects to file an amended report in accordance with this guidance, the department will consider the report as filed on the date the amended report is received by the department. All timelines and deadlines, including the timelines and deadlines in OAR 836-200-0535, will be counted from that date.

5) This informal request does not limit the department’s authority to make an additional information request under OAR 836-200-0535.

**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 website as soon as practicable.

Prescription drug reports will be posted to the department’s website no later than 90 days after the department received the filing. Any additional information requested will be posted no later than 60 days after receiving the response. All other correspondence
or records between the department and the reporting manufacturer will be posted as soon as practicable.

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 department’s website.
VIII. 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.

<table>
<thead>
<tr>
<th>Violation</th>
<th>Missing, inaccurate, or incomplete data</th>
<th>Untimely responses for additional information</th>
<th>Failure to submit required report</th>
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</thead>
<tbody>
<tr>
<td>First Violation</td>
<td>$500 per day maximum for first 30 days.</td>
<td>$1,500 per day maximum for first 30 days</td>
<td>$2,500 per day maximum for first 30 days</td>
</tr>
<tr>
<td></td>
<td>$1,000 per day maximum after 30 days</td>
<td>$3,000 per day maximum after 30 days</td>
<td>$5,000 per day maximum after 30 days</td>
</tr>
<tr>
<td>Subsequent Violations</td>
<td>$1,000 per day maximum</td>
<td>$3,000 per day maximum</td>
<td>$5,000 per day maximum</td>
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</tbody>
</table>

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

The following are frequently asked questions regarding manufacturers and the Drug Price Transparency program:

What types of reports are required to be submitted by prescription drug manufacturers?

All reporting prescription drug manufacturers will be required to report annually on drug price increases and on new drugs when any of the following occurs:

New drug reporting
- The price of a new prescription drug for sale in the United States exceeds the threshold set by the Centers for Medicare and Medicaid Services in Medicare Part D ($670) for a 30-day supply or for a course of treatment lasting less than one month.

Annual price increase reporting
- The price at any point in 2018 was $100 or more for a one-month supply or for a course of treatment lasting less than one month; AND
- There was a net yearly increase of 10 percent or more in the price of the prescription drug.

What is a trade secret and how does it affect prescription drug reports?

The Drug Price Transparency program reviews information claimed by prescription drug manufacturers to be trade secret under ORS 192.345(2).

Under ORS 192.345(2), a trade secret is defined as including but not limited to “any formula, plan, pattern, process, tool, mechanism, compound, procedure, production data, or compilation of information which is not patented, which is known only to certain individuals within an organization, and which is used in a business it conducts, having actual or potential commercial value, and which gives its user an opportunity to obtain a business advantage over competitors who do not know or use it.

The program will review information claimed to be trade secret under ORS 192.345(2) to determine if it is a trade secret, and whether the public interest requires disclosure. Before a determination has been made, information claimed to be trade secret will not be publicly disclosed until the review process has been completed. If the department determines that information must be withheld as a trade secret, any person may appeal that determination to the Attorney General, as provided in ORS 192.411.
Are all drug manufacturers required to report to the department?

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

a) Required to be registered with the Oregon Board of Pharmacy as a drug manufacturer;

b) That engages in the manufacture of prescription drugs as defined in 2018 OR Laws ch.7; and

c) That sets or changes the wholesale acquisition cost of the drugs in manufactures.

Reporting manufacturers include entities that identify as virtual manufacturers or contract to another entity the act of manufacturing. Also, any subsidiaries of a parent company falling within the definition of a reporting manufacturer are required to create their own separate account with the department to file reports specific to their company.

Manufacturers identifying as animal or veterinary drug or durable medical equipment manufacturers are not subject to the current Oregon law.

What fees are required to be paid by prescription drug manufacturers?

There are two types of fees to be paid by prescription drug manufacturers:

1. Annual $400 assessment: This fee is required by all prescription drug manufacturers who fall within the definition of a reporting manufacturer.

2. Variable reporting assessment: Paid by prescription drug manufacturers that file reports within the reporting year. This is calculated by subtracting the revenue collected by the annual assessment from the total amount of program expenses then dividing this number by the number of reports received.

The department will bill for these fees annually in October.

When are the deadlines for prescription drug manufacturers to report to the department?

New drug reports are required to be submitted no later than 30 days after the date of market entry for the prescription drug, beginning March 15, 2019.

Annual price increase reports are required to be submitted no later than July 1, 2019, for the first year of the program. In subsequent years, annual price increase reports are required by March 15 of each year.
X. iReg Walkthrough

This section of the manufacturer user guide will walkthrough the different screens and elements within the reporting application used by manufacturers to file drug price reports with the Department. The walkthrough is displays several figures and describes the actions a user may take within the reporting system:

Figure 1 – Home
Figure 2 – Users
Figure 3a – Add User
Figure 3b – Add User: Access Permissions
Figure 4 – Contacts
Figure 5a – Contact Detail: Edit Contact
Figure 5b - Contact Detail: Edit Contact cont.
Figure 6 – Contact History
Figure 7 – Drug Prices: New Drugs
Figure 8a – Create New Filing: Start New Drug Filing
Figure 8b-d – New Drug Filing Details
Figure 9a-g – Annual Price Increase Filing details
Figure 10 – Annual Price Increase Filing - Patient Assistance Programs
Figure 11a – Attach New/Supporting Document screen
Figure 11b – Document Uploaded
Figure 12 – Trade Secret/Justification
Figure 13 – Certification of Complete Filing
Figure 14 – Correspondence
Figure 15 – New Correspondence
Figure 1 – Home

Once a user has logged on to iReg, the following home screen will display. The user can access the Main sub-tab, which has options for selecting the company for reporting. An individual user may have multiple pharmaceutical companies associated with their account. In the top right-hand corner of the screen, there are two buttons: Instructions and Log out. Instructions will take you to the general iReg help website, and Log out will exit you from the system.
Within the Users tab, a list of all users for a company/entity will be displayed. From this screen, a user can Add User, Edit User, or Remove User. Note that only users with Manage User permissions (See Figure 3) can edit or remove other users associated with the specified company. You can also select the User Detail option on the left-hand side of the screen, which will take you to same screen as Edit User.
A new user can be added by users with permissions to establish new user accounts. Required fields to establish a new user account are identified by a red star. Note that the Edit User button in Figure 2 also directs the user to this page.

The new user screen is continued below in Figure 3b.
Figure 3b – Add User: Access Permissions

Figure 3b displays the options for which permissions the new user may be delegated, including management of users or for report access. The Financial Regulation sub-section is a section used for other entities regulated by the department and is not applicable to pharmaceutical manufacturers.

New users can be delegated permissions to Manage Users underneath the Drug Prices sub-section, which allows the new user to create and edit users for the company account. The new user may also be delegated permissions to annual drug price filings and new drug filings. This allows the user to create, edit, or submit drug reports for the specified categories.
The Contacts tab displays a list of individuals 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 anything in the iReg system other than receiving emails regarding specified topics for the program.

Users have to option to Add Contact, Edit Contact, or Remove Contact. The primary user for the company should also be listed as a contact. The sub-section Edit Contact allows the user to edit or fill out the contact information. Contact History gives a list of the history of the entity’s contact additions, deletions, and edits.
Users can edit the contact information for a specific contact within the company account. Only two fields are required: Name and Title, and Email Address. All other fields are optional and can be entered at the user’s discretion.

Figure 5b below shows the types of emails that contacts can be delegated by the user.
There are several types of program topics a contact can subscribe to receive updates. A user can choose what types of emails a contact can receive. Note that at least one contact must be able to receive the required email notices from the department as noted by the red stars.

Once a user has finished assigning emails to a contact, click Save and the changes will be stored. Click Cancel to revert all edits or changes to a contact.
Figure 6 – Contact History

The Contact History screen displays the activity the specific contact has had on the account, such as establishing a new user and editing user information. Clicking on the button labeled Show History for ALL Contacts displays all history for all contacts associated with the company account.
All new drug reports created by the company display underneath the New Drugs tab. Reports can be sorted by filing date, trade name, NDC, or reporting status. A new drug filing can be created by clicking the blue Create New Filing button in the bottom left of the dark grey box. Users can also edit filings by clicking on a drug filing and then choosing the Details option on the left-hand side of the page.
When the Create New Filing button has been selected, the iReg system displays the following screen. Users are required to enter the reported drug product's NDC, trade name, and chemical name to establish the report filing. Once this information has been reported, the filing is officially established and appears in the list of filings. The Next button navigates the user to the filing details page outlining the other data elements to be reported.
All data elements are specified in Oregon Laws 2018 Chapter 7, Section 2 and in OAR 836-200-0530. Information reported will either be numeric or character specific depending on the data field. 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 trade secret under ORS 192.345. Further information on anything claimed to be trade secret is outlined below.
Figure 8c – Filing Details Continued

For more information and guidance on the data elements, see the New Drug Reporting section of this user guide.
In addition to the data fields, users may upload supporting documentation for the report. This is described further in Figure 10a.

Users can choose to Continue to Certification when the report is finalized and ready for submission to the department. Save Progress will save all information that has been entered into the report, but will not submit it.
Figure 9a – Annual Price Increase Filing

When starting an Annual Drug Price Increase report, select the Annual Filings tab to be directed to the annual filings screen. Reports can be sorted in a similarly to New Drug Reports. To create a new annual filing, click on the Create New Filing button.
Users need to fill in the year for which they are filing, and the NDC of the drug that has experienced the price increase to begin an annual price increase report.

If the NDC is not recognized by the drug database, then users have the option to add that drug and its information by filling in the Trade Name field and the Chemical Name field.
For information and guidance on the data elements, see the Annual Price Increase Reporting section of this user guide.
Figure 9d – Annual Price Increase Filing – Filing Details continued

For information and guidance on the data elements, see the Annual Price Increase Reporting section of this user guide.
Figure 9e – Annual Price Increase Filing – Filing Details continued

For information and guidance on the data elements, see the [Annual Price Increase Reporting](#) section of this user guide.
Figure 9f – Annual Price Increase Filing – Filing Details continued

For information and guidance on the data elements, see the Annual Price Increase Reporting section of this user guide.
For information and guidance on the data elements, see the Annual Price Increase Reporting section of this user guide.
When adding a Patient Assistance Program, users have the ability to type in the name of the program, select the type of program (Independent or Manufacturer), the number of participants in the program, the value of the assistance program, the amount of refills allowed (Limited, Unlimited, No Refills, Other), the time period of the program, the eligibility criteria of the program, and the eligibility verification process of the program. For information and guidance on the data elements, see the Annual Price Increase Reporting section of this user guide.
If a supporting document or attachment is required, click the Attach New Document button. The screen above will be displayed where the user can specify the document type, the reason for inclusion, and select the file to upload. Users may claim information is trade secret and provide the proper justification for the specified document.

The reporting system will accept all types of document types to upload. Users may upload multiple documents to a single report.
Once a document has been attached to a filing, the screen will close and the document will be displayed in the table as seen in Figure 9b. 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 under the Document title labeled View Info and View Original. View Info provides the same information that is displayed in the documents table, along with size of the file, date and time uploaded, and MD5 Hash. View Original lets users see the document as it was uploaded, unless it has been marked trade secret.
Figure 12 – Trade Secret/Justification

Users may claim information as trade secret by checking the trade secret box next to a data element. For each data element or information claimed to be trade secret within the report, the manufacturer will be prompted to provide a succinct written explanation of why the information is exempt from disclosure, demonstrating all of the following:

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

The department will review the manufacturer’s explanations and make a determination on a case-by-case basis as outlined in OAR 836-200-0540. For more information on the trade secret claims process, see the Information Claimed to be Trade Secret section of this guide.
Figure 13 – Certification of Complete Filing

When the report is complete and ready to submit, click the Certify button. Users must enter their full name and check the box to officially certify the report. Clicking the Certify button completes the process of filing a report.

If there are any blank or required boxes that have not been done, an error message will prompt the user to correct the issue.
Correspondence is a way to communicate directly with program staff members. This can be used to communicate any questions specific to the report. Program staff members will use the correspondence function to communicate information regarding the report.

By selecting the correspondence thread, then selecting Details in the left-hand corner of the page, users are taken to the details of the selected correspondence.
New correspondence can be started from within the report by clicking on the Start/Open Correspondence button. Users may choose a correspondence type from the categories provided and enter in the main message they want to communicate. Each correspondence allows users to claim the message information as trade secret by click the Trade Secret box. Also, users may adding any supporting documents that are requested or necessary to send to the department.