Topic(s)	Question	Program's response
30-day supply	What if the treatment is never prescribed or used for a 30-day supply?	Calculate a 30-day supply or use the course of treatment lasting less than a month. For example, if a treatment or dose is given every other month, each treatment is a course of treatment that is less than a month. Therefore, in this example the wholesale acquisition cost for a single treatment every other month (at the maximum recommended dose) is the amount used to determine if the threshold is met.
30-day supply, dosage	For weight-based dosing, can average patient weight be used?	For drug dosing based on weight, using an average adult weight would be a reasonable method for determining the cost of a 30-day supply or course of treatment lasting less than one month. The dosage field on the report is meant to have the highest recommended dosage and using the highest recommended dosage for an average weight patient is reasonable for that as well. If there is a lower strength for children, it would be a reasonable method to use an average child's weight instead.
Annual increase reporting	Define previous year. Beginning of the previous year or 12 months ago?	Previous year refers to the previous calendar year. When filing an annual price increase report, those are using the calendar year for comparison. For the reports due this year on March 15, 2023, you will be comparing the daily weighted average wholesale acquisition cost in 2022 with that amount in 2021. If filing an earlier missing report, it will be for the year that exceeds the increase threshold when compared to the calendar year just prior.
Annual increase reporting	If no price increase for the product's wholesale acquisition cost (WAC) is more than $100, it does not require reporting, correct?	That is not correct. If the WAC for a 30-day supply (or course of treatment lasting less than one month) is less than $100, a report is not required regardless of the percent of increase. If the WAC for a 30-day supply (or course of treatment lasting less than one month) is $100 or more, a report is only required if the increase of the daily weighted average is 10 percent or more. See the user guide on the webpage for manufacturers for more information.
Annual increase reporting	Since the words "and/or" are important with these laws in determining compliance, please confirm that both criteria have to be met for required reporting, not just one. This law requires manufacturers of prescription drugs sold in Oregon with a wholesale acquisition cost (WAC) of $100 or more for a one-month supply or course of treatment of less than one month's duration, and a net WAC increase of 10 percent or more during the previous calendar year, to submit a report to the Department of Consumer and Business Services.	Yes, that is correct; both criteria must be met before an annual price increase report is required. *Example 1*: If a drug's WAC for a 30-day supply increases from $30 to $90, no report is required, because the 30-day supply WAC is less than $100. *Example 2*: If a drug's WAC for a 30-day supply increases from $90 to $105 and the daily weighted average price increase was 16 percent, a report is required because the 30-day supply WAC is $100 or more and the increase from the prior year was 10 percent or more.

Topic(s)	Question	Program's response
Annual increase reporting	If there were not any wholesale acquisition cost (WAC) price increases taken for the year or previous year on any products, is the annual price increase report needed to be submitted? Wanted to be sure there was not a report needed for no WAC increases.	No. Do not file any annual price increase reports unless the threshold is met. For example, if there were no price increases during 2021 or 2022, no annual price increase report is required for 2023 because both years would have the same daily weighted average WAC. Do not file a report unless required.
Annual increase reporting	If your drug came out in mid-2022, do you average to the 6 months or use 12 months?	A new drug report is required if a new drug exceeds the threshold for new drug reporting, but a drug that was new in 2022 does not owe an annual price increase report, because there is no price in 2021.
Annual increase reporting	What if a drug is first marketed on Aug. 1, 2021, and we had a price increase on Dec. 1, 2021? How do we figure out the average price for 2021 to determine if a report is required in 2023?	When calculating the daily weighted average, you are calculating the average package price using the number of days a product was on the market at each price. A new drug that comes to market on Aug. 1, 2021, will have a price for 153 days in 2021. Let us assume a 30-day supply is $100 or more, and the package wholesale acquisition cost starts at $800 on Aug. 1 and then is increased to $850 on Dec. 1, 2021. The daily weighted average is $810.13 for 2021 (122 days at $800 and 31 days at $850). Then let us say the price remains the same until Aug. 1, 2022, when it is increased to $900. The daily weighted average is $870.96 for 2022 (212 days at $850 and 153 days at $900). In our example, a report is not required in 2023, because the increase in 2022 was less than 10 percent.
Billing and assessments	Confirming, we can use a credit card to pay the fees due in October? Is this new?	We prefer payment by check because it tends to work more smoothly with our system, but you may contact our cashiering staff to pay by credit or debit card. You will likely need to provide them with a copy of the voucher to make sure the payment is applied correctly. The contact information for our cashiering staff is near the bottom of the webpage for manufacturers.
Correspondence	Why can’t “correspondence” be sent to an email address? Going into the iReg Portal doesn't happen every day.	Correspondence goes through iReg so that it can be published once the report filing is complete. Whenever we post a message an email is sent from the iReg system. The email is sent to those listed as contacts in the system who have checked the box for that type of notice. We recommend checking all the boxes on the contact listing to make sure you do not miss any notices. Also check to make sure your company's system is not rejecting or identifying emails ending in “.gov” as junk mail.

Topic(s)	Question	Program's response
Estimated patients per month	Can you please provide some guidance on how manufacturers should report estimated monthly patients for ultra-rare diseases/conditions (less than 10 patients nationwide)?	The estimated average number of patients per month is the manufacturer's estimate of the average number of patients who will be prescribed the new prescription drug each month in the United States. The company should have an expectation of how many patients it expects or hopes will purchase the medication.
Estimated patients per month	If it is a generic, how would you determine the number of patients?	Just like a brand name drug, before going through the preparation and expense of manufacturing a generic drug, the company should have determined an expectation of how many patients it expects or hopes will purchase the medication in the United States. Data regarding potential patients with a treatable condition is often available with limited research.
Financial information	What if the financials are not broken down by National Drug Code (NDC)?	They do not need to be. We realize that companies may not break down expenses, revenue, or profits by NDC or states or regions, but we do expect them to be broken down by drug. Therefore, for consistency in reporting, use the U.S. financials for the drug.
Marketing costs	Does the marketing cost include the salaries and compensation of sales personnel?	Yes. Most companies would split costs like this based on the amount of time staff members spend selling particular products. Therefore, include that in the marketing expenses for direct-to-consumer and/or physician marketing for new specialty drug and annual price increase reports.
Missing reports	It was said during the webinar that if you haven't reported in the past, but should have, you need to ASAP to avoid civil penalties. Do you have to go all the way back and report wholesale acquisition cost at the date of the drug launch? Or only report if they have had a qualified price increase since launch? Or do you only report the current year? We have not had a qualified price increase since our drug launched in October 2018.	• Reports for new drugs that meet the reporting threshold started March 15, 2019. Therefore, only new drugs that were launched on or after that date would have to file a new specialty drug report if the threshold was met. • Annual price increase reports started in 2019 based on price increases from the year 2018. Therefore, only price increases from 2018 and forward would have a reporting requirement, if the threshold was met. • Reports for 60-day price increase notices started June 30, 2020.
New specialty drug reporting	If you have a new drug with multiple National Drug Codes (NDC), is a new drug report required for each NDC, so that you enter essentially the same exact information multiple times with the only difference being different NDCs and dosage?	Yes, a new specialty drug report is required for each NDC that meets the criteria. Unless something different was used to determine the price or market that NDC, all information should be the same on each report for the same drug, except for the package wholesale acquisition cost for that NDC. The maximum dosage should be the same for all NDCs unless it is a different strength.

Topic(s)	Question	Program's response
New specialty drug reporting	Why $670? That was moved up to $830.	The threshold for filing a new drug report is based on whether the 30-day supply (or course of treatment lasting less than one month) exceeds $670 per OAR 836-200-0505(12). We may update this in the future to match the increased minimum threshold for specialty tier eligibility set by the Centers for Medicare and Medicaid Services, but it remains at $670 at this time.
New specialty drug reporting, billing and assessments	If you have multiple National Drug Codes (NDC) for the same “new drug” due to multiple package sizes, is the manufacturer charged per NDC (multiple fees/reports) or just at the brand level (one fee/report)?	A report is required for each NDC, and the reporting fee portion of the annual billing is an amount per report. Therefore, the annual billing will be higher if there are multiple reports because of multiple product variations (NDCs).
New specialty drug reporting, definitions	Is a specialty drug different from a generic drug?	Specialty drugs are high-cost drugs with ingredient costs for a 30-day equivalent supply that are greater than the Medicare specialty tier cost threshold. Specialty drugs include brand name and generic drugs that meet the pricing criteria. The filing threshold for Oregon’s new specialty drug reporting requirement is $670, as established in 2018 and identified in OAR 836-200-0505(12). We may update this amount in the future to match the increased minimum threshold for specialty tier eligibility set by the Centers for Medicare and Medicaid Services, but it remains at $670 at this time.
Registration	Is there a deadline to register for iReg?	Yes. A reporting manufacturer is required to register before a report is required (Feb. 15 for annual increase reports or 10 days prior for new specialty drug reports). A reporting manufacturer also is required to be registered because the annual assessment is owed and our annual billing process uses the iReg system.
Submitting reports	If you have multiple National Drug Codes (NDC), is there a feature to upload a report or do you have to enter each NDC manually? If you have multiple NDCs, can you attach a list to the “additional documents,” or do you have to complete and certify a report for every individual NDC?	There is not a feature to upload multiple NDCs. A separate report is required for each NDC that meets the threshold. Do not include other NDCs in a report.

Links:
Oregon drug price transparency program webpage for manufacturers
Oregon statutes for drug price transparency program: ORS 646A.680 through 646A.692
Oregon rules for drug price transparency program: OAR 836-200-0500 through 836-200-0560