Here are common questions related to the Drug Price Transparency program and their answers. Please email us at rx.prices@dcbs.oregon.gov about additional questions not answered here.

Program area	Question and Response
General	1. What is the Prescription Drug Price Transparency Act?
	In 2018, the Oregon Legislature passed the Prescription Drug Price Transparency Act (<u>House Bill 4005</u>) to increase transparency in how prescription drugs are priced. The act established the following:
	 Oregon's Drug Price Transparency program in the Division of Financial Regulation, part of the Department of Consumer and Business Services, to provide transparency for prescription drug pricing through reporting of specific drug price information from consumers, health insurers, and prescription drug manufacturers.
	The <u>Task Force on Fair Pricing of Prescription Drugs</u> within the Oregon Legislature charged with examining and developing transparency strategies for the entire pharmaceutical supply chain.
	Reporting requirements for drug manufacturers were modified in 2019 by House Bill 2658 to require a 60-day notice of price increases meeting certain criteria.
General	2. What information is reported to the department?
	The department receives reports from consumers, health insurers, and pharmaceutical manufacturers. Different information on prescription drug pricing is reported from each stakeholder:
	Consumers – May notify the department and report on drug price increases.
	Health insurers – Report on the top 25 drugs for various categories including most frequently prescribed, most costly, and those causing the greatest increase in plan spending.
	Prescription drug manufacturers – Report on price increases and new prescription drugs above specific thresholds on wholesale acquisition cost. Reports include pricing data, reasons for increases, publicly funded research and development costs, marketing costs, sales revenue and net profit data, prices paid in other countries, and patient assistance program data.
General	3. How will information reported about prescription drug prices be used?
	Information reported by consumers, health insurers, and prescription drug manufacturers will be published on the department's website. Additionally, information will be analyzed and used to provide annual reports to the Oregon Legislature on prescription drug prices and costs and inform Oregon's Prescription Drug Affordability Board . The manufacturer reports are available to the public and can be searched on the data webpage . The public can also find the program analysis on the annual reports webpage .
General	4. What is a prescription drug? What is a brand name versus a generic prescription drug? What is a specialty drug?
	A prescription drug is a substance used to treat, cure, or prevent diseases and is required to have a doctor or health practitioner's approval for someone to purchase it. Prescription drugs can be either a brand name or generic drug. Brand name prescription drugs are protected by a patent, which provides protections to the drug developer for a set period of time when no one else can produce the same drug. A generic drug is considered to be the same as a brand name drug and competes

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	with the brand name drug once the patent has expired. Generic drugs typically cost less. A specialty drug is a high-cost drug (brand name or generic drug) that exceeds a certain price threshold.
General	5. What is WAC (wholesale acquisition cost)?
	WAC is one of the ways prescription drugs are priced and is sometimes referred to as the list price for a prescription drug. There are several other ways prescription drugs can be priced throughout the pharmaceutical supply chain. For more information on different types of pricing, refer to the Glossary of Pharmaceutical Terms. Oregon's definition for WAC uses the federal definition in 42 U.S.C. 1395w-3a(c)(6)(B).
General	6. What is the pharmaceutical supply chain? Why are other entities not required to report?
	The pharmaceutical supply chain is a complex structure that includes several types of entities working to supply consumers with drug products. Manufacturers, wholesale distributors, pharmacies, pharmacy benefit managers (PBM), health insurance companies, medical providers, and consumers make up the majority of the pharmaceutical supply chain.
	The Prescription Drug Price Transparency Act currently requires prescription drug manufacturers and health insurance companies to report on prescription drug prices. Additionally, consumers are provided the opportunity to notify the department of a prescription drug price increase.
	For more information on the transparency strategies for the pharmaceutical supply chain, refer to the Joint Interim Task Force on Fair Pricing of Prescription Drugs — Report on Transparency Strategies for the Pharmaceutical Supply Chain.
	Figure 2: Pharmaceutical supply chain for brand name drugs dispensed through retail pharmacies
	Active pharmaceutical ingredients (APIs) Annufacturer and market authorization holder (formulation, packaging, labeling) Manufacturer price (c. WAC) Distributor/Wholesaler Retail acquisition price Retail acquisition price Retail or copay price, minus coupons or other assistance Patient Retail or copay fice, minus coupons or other assistance Patient Retail or copay fice, minus coupons or other assistance Patient Patient Retail or copay fice, minus coupons or other assistance Patient Prescribing/fill decisions Prescriber Prescriber Prescriber Prescriber Prescriber Prescriber Prescriber
	NOTES: c. = circa; DIR = direct and indirect remuneration; WAC = wholesale acquisition cost. Arrows denote relationships involving the flow of product (black arrows), information or negotiation (yellow arrows), and payments (green dashed arrows).
	Source: RAND Corp. and U.S. Department of Health and Human Services; Mulcahy, Andrew W. and Kareddy, Vishnupriya. "Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships." RAND Corporation, 2021. Accessed Sept. 19, 2022.

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General	7. How are agency expenses paid for this program (funding)?	
	The main costs for the Drug Price Transparency program are funded through assessments from prescription drug manufacturers who meet the definition of reporting manufacturers.	
Consumers	8. How do I provide notice of my prescription drug price increase?	
	You can provide notice of a prescription drug price increase online using <u>our form</u> . To request a document in another format or language, or as an alternative to the online form, you can leave a message with your contact information at 503-947-7200 or 833-210-4560 (toll-free), or email <u>rx.prices@dcbs.oregon.gov</u> .	
Consumers	9. Why should I notify the department of my prescription drug price increase?	
	The department will include the information from consumer reported prescription drug price increases in the annual report to the Oregon Legislature on prescription drug prices. The report will include recommendations for legislative changes that could contain the cost of prescription drugs and reduce the effect of price increases on consumers. While we have information from manufacturers and insurers, it is important to know the effects on consumers.	
Consumers	10. What happens after I provide notice of my prescription drug price increase?	
	After you provide notice of your prescription drug price increase, members of the Drug Price Transparency team will review the report before the information is published online. This review will ensure the information reported does not contain any personally identifiable information submitted in error or any malicious content. Information asked to be reported is limited to prescription drug prices and factors that affect the price of prescription drugs, such as insurance coverage.	
Consumers	11. Will this law decrease my prescription drug price?	
	The Prescription Drug Price Transparency Act will not decrease the price of your prescription drug, but the reporting requirements created by the law help reveal some industry practices and costs. It is a first step toward understanding how prescription drugs are priced and the factors that influence prescription drug price increases. Review our consumers webpage for resources that may be helpful.	
Consumers	12. Why did my prescription drug prices increase?	
	The price you pay at the pharmacy is determined through a complex set of factors throughout the pharmaceutical supply chain. If you are uninsured, you typically are paying the list price of the drug set by the drug manufacturer as well as supply chain costs. If you have health insurance, prescription drug costs are typically regulated through placement on a tier determined by your insurance company or their pharmacy benefit manager (PBM). Placement on a higher tier typically results in a higher cost. Many health insurance companies will require a copay or coinsurance payment when you pay for the prescription drug at the pharmacy. A copay is a flat fee, such	
	as \$5 per prescription, and coinsurance is a percentage of the drug cost, such as 20 percent of the drug price, that you pay when you get a prescription drug. The negotiated reimbursement between the pharmacy and your health insurance carrier or their PBM can affect the cost.	

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	The Joint Interim Task Force examined the supply chain and the cost factors that may affect the price paid by Oregonians for pharmaceutical products. The figure below from their report displays the interactions and the cost factors involved with the different entities within the pharmaceutical supply chain.	
	Cost Factors	
	Manufacturers (Brand, Generic, Biopharmaceutical) Discounts Drug Products Fees Incentive Programs List Price List Price Uitization Demand Rebates Vertical Integration	
	Wholesaler Wholesaler Discounts Drug Products Fees Utilization Demand List Price Vertical Integration Rebates	
	Pharmacy (thitest, tedependent) Consumer Consumer	
	Pharmacy Benefit Manager Pharmacy Benefit Manager Pharmacy Benefit Manager Discounts Insurance Benefit Design Utilization Demand List Price Vertical Integration Rebates	
	Insurers (Commercial, Medicavi, Medicave) Discounts Incentive Programs Fees Insurance Benefit Design List Price Utilization Demand Rebates Vertical Integration	
	Providers (Hoogital, Medical) Discounts Incentive Programs Flees Utilization Demand List Price List Price Rebates	
	Government Entity Discounts Fees Incentive Programs List Price Rebates Utilization Demand Vertical Integration	
	Source: Legislative Policy and Research Office Data: TFPRX – Transaction and Transparency Survey, 2018 Discounts Fees Incentive Programs List Price Insurance Benefit Design Utilization Demand	
Consumers	13. Why can prescription drug prices vary between different pharmacies?	
	The price of a prescription drug can vary between pharmacies due to the negotiations between the pharmacy and several entities within the pharmaceutical supply chain. Pharmacies negotiate with wholesale distributors, pharmacy benefit managers (PBM), and health insurance companies when purchasing, dispensing, and reimbursing for prescription drugs. These negotiations can influence the cash price of the prescription drug, where your prescription drug is placed on a drug tier, and can change the price of your copay or coinsurance.	
Consumers	14. Will this department resolve an issue between me and my insurer?	
	The primary focus of the program is to receive notifications of high prices and price increases reported by manufacturers as well as information reported by insurers. If you have an issue with your health insurer, the department will help direct you to the Consumer Advocacy Team to provide you with more information on filing a complaint or resources regarding your issue. The Consumer Advocacy Team can be contacted at 888-877-4894 (toll-free) or email DFR.InsuranceHelp@oregon.gov .	
Consumers	15. I can't find my drug listed on the reports. Why?	
	Not all drugs will have a report submitted by a drug manufacturer. Drug manufacturers are required to submit reports when drug prices or price increases are more than a certain amount. Here are the reporting thresholds for the different types of reports:	
	 For new drugs, the threshold is \$670 for a 30-day supply (or course of treatment lasting less than a month). 	

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	 For annual price increase reports, the threshold is an increase of 10 percent when compared to the prior year for drugs that are \$100 or more for a 30- day supply.
	 For 60-day price increase notices, the threshold is 10 percent (or \$10,000) for brand name drugs and 25 percent plus \$300 for generic drugs (with some exceptions).
	Check the webpage for manufacturers for details.
Manufacturers	16. Are all drug manufacturers required to report to the department?
	No, only reporting manufacturers who have new drugs or price increases that exceed the reporting thresholds are required to submit reports. A "reporting manufacturer" is defined in administrative rule (OAR 836-200-0505) as an entity:
	Required to be registered with the Oregon Board of Pharmacy as a drug manufacturer;
	b. That engages in the manufacture of prescription drugs sold in this state as defined by ORS 646A.689(1)(d); and
	c. That sets or changes the wholesale acquisition cost of the drugs it manufactures.
	Reporting manufacturers include entities that identify as virtual manufacturers or contract out the act of manufacturing to another entity. Each entity that is a reporting manufacturer (even subsidiaries of a parent company that is also a reporting manufacturer) are required to create their own separate account with the department. If a parent company is setting the price, then the account creation and reporting responsibility is with the parent company.
	Manufacturers identifying as animal or veterinary drug or durable medical equipment manufacturers are not subject to the current Oregon law.
Manufacturers	17. What types of reports are required to be submitted by prescription drug manufacturers?
	All reporting manufacturers will be required to submit certain reports when the threshold for that type of report is met.
	 For new drugs, the threshold is \$670 for a 30-day supply (or course of treatment lasting less than a month).
	 For annual price increase reports, the threshold is an increase of 10 percent when compared to the prior year for drugs that are \$100 or more for a 30- day supply.
	 For 60-day price increase notices, the threshold is 10 percent (or \$10,000) for brand name drugs and 25 percent plus \$300 for generic drugs (with some exceptions).
	See the webpage for manufacturers for details.
Manufacturers	18. 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 a 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

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	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. For data elements claimed to be trade secret under ORS 192.345(2), the website will show that the data is under review. The department will review all information received including information claimed to be trade secret. If in disagreement with any trade secret claim, a determination will be issued and the manufacturer will have an opportunity to appeal the department's decision. Once the review process is completed, the data that is not considered trade secret will be publicly available on the department website. Information that is considered a trade secret will not be published unless public interest requires disclosure. If the department determines that information must be withheld as a trade secret, any person may petition the attorney general to review the determination, as provided in ORS 192.411.	
	See the user guide on the webpage for manufacturers for more information.	
Manufacturers	19. What fees are required to be paid by prescription drug manufacturers?	
	There are two types of fees paid by prescription drug manufacturers to cover costs of administering Oregon's drug price transparency program: 1. Annual assessment – This fee is currently \$400 and is required for all prescription drug manufacturers who meet the definition of a reporting manufacturer.	
	 Reporting assessment – This fee is paid by prescription drug manufacturers who file reports within the billing period (Aug. 1 of the preceding year through July 31 of the current year). This fee is calculated by subtracting the total of the annual assessment from the total amount of program expenses and then dividing the result by the number of reports received. 	
	The department will bill for these fees annually, which are due Oct. 1.	
Manufacturers	20. 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 U.S. market entry for the prescription drug. Annual price increase reports are required to be submitted no later than March 15 of each year. Reports for 60-day price increase notices are due 60 days before the planned price increase. All of the above reports have different pricing thresholds that must be met before a report is required.	
Manufacturers	21. My prescription drug company will be filing a report. Where do I find information about reporting requirements?	
	Resources for prescription drug manufacturers, including information about the reporting system and the requirements, are available on the department's webpage for manufacturers. The user guide is easy to use and contains links to Oregon's laws.	

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Manufacturers	22. When we have multiple National Drug Codes (NDCs) for the same drug to report, must we file for each NDC?
	Yes, a report is required for each NDC that meets the reporting threshold. The reporting fee portion of the annual billing is per report. Therefore, the annual billing will be higher if there are multiple reports because of multiple product variations (NDCs).
Data	23. What kind of data is being reported?
	Prescription drug manufacturers
	Information reported from pharmaceutical manufacturers includes wholesale acquisition cost pricing data, publicly funded research and development costs, marketing costs, sales revenue and net profit data, prices paid in other countries, and patient assistance program data.
	Health insurance companies
	Health insurance companies in Oregon are required each year to provide information on the top 25 drugs for various categories – most frequently prescribed, most costly, and those causing the greatest increase in plan spending. They are also required to report on the effects of prescription drug costs on premiums, including the effect of rebates or price concessions.
	<u>Consumers</u>
	Consumers are encouraged to provide the department notification of any cost increases they experience when purchasing their prescription drugs. The information from consumers, prescription drug manufacturers, and health insurers is used to inform the annual public hearing and will be included in the annual report to the Oregon Legislature.
Data	24. When is reported data available to the public? Why do some of the entries say "trade secret" and "under review"?
	Data reported to the department will be available to the public as soon as possible and can be viewed on the <u>data webpage</u> . Once data is reported from prescription drug manufacturers, it is published to the website, unless the manufacturer claims it is a trade secret.
	Data reported by prescription drug manufacturers can be claimed to be a trade secret under ORS 192.345(2).
	For data elements claimed to be trade secret under ORS 192.345(2), the website will show that the data is under review. The department will review all information received, including information claimed to be trade secret. If in disagreement with any trade secret claim, a determination will be issued and the manufacturer will have an opportunity to appeal the department's decision.
	Once the review process is completed, the data that is not considered trade secret will be publicly available on the department website. Information that is considered a trade secret will not be published unless public interest requires disclosure. If the department determines that information must be withheld as a trade secret, any person may petition the attorney general to review the determination, as provided in ORS 192.411.

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Data	25. When will the annual public hearing on prescription drug prices occur, and what will be presented?
	The annual public hearing on prescription drug prices will be held each fall, generally in late November or early December. Information reported to the department from consumers, health insurers, and manufacturers will be used to inform the hearing. Visit the public hearing webpage for videos, slides, and testimony from prior public hearings.

Links:		
Main webpage for DPT program	https://dfr.oregon.gov/drugtransparency/Pages/index.aspx	
Consumer webpage for DPT program	https://dfr.oregon.gov/drugtransparency/Pages/consumers.aspx	
Manufacturer webpage for DPT program	https://dfr.oregon.gov/drugtransparency/Pages/manufacturers.aspx	
Laws and rules – Division of Financial Regulation	https://dfr.oregon.gov/laws-rules/Pages/index.aspx	
Email DPT program staff	rx.prices@dcbs.oregon.gov	
HB 4005 (2018) Prescription DPT Act	https://olis.oregonlegislature.gov/liz/2018R1/Measures/Overview/HB4005	
HB 2658 (2019) 60-day price increase notice	https://olis.oregonlegislature.gov/liz/2019R1/Measures/Overview/HB2658	
Task Force on Fair Pricing of Prescription Drugs Report (2018)	https://www.oregonlegislature.gov/committees/jfprx	