

# Drug Price Transparency Stakeholder Webinar for Manufacturers

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# Welcome & Logistics

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- ▶ Welcome & Introductions
- ▶ Logistics
  - ▶ Webinar Instructions
  - ▶ This webinar is AUDIO RECORDED
- ▶ Agenda Review

# Agenda

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- ▶ Drug Price Transparency Program Overview
- ▶ Health Care Authority's (HCA) Rulemaking Schedule
- ▶ Listening Session – We want to hear from you!
- ▶ Contact Information – Sign up for Rulemaking Notices!

# Drug Price Transparency Program Overview

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- ▶ Chapter [43.71C RCW](#) directs the Health Care Authority to implement a drug cost transparency program through reporting from health carriers, pharmacy benefit managers, drug manufacturers and pharmacy service administrative organizations.

# Legislative Findings

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## **Washington State has a public interest in:**

- The price and cost of prescription drugs;
- Providing notice and disclosure of information relating to cost and pricing ... to provide accountability to state for prescription drug pricing;
- Rising drug cost and consumer ability to access...; and
- Containing prescription drug costs.

# Who does this apply to?

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- ▶ Covered manufactures;
- ▶ Health plans/health carriers;
- ▶ Pharmacy benefit managers; and
- ▶ Pharmacy services administrative organizations

# Covered Manufacturer

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A person, corporation, or other entity engaged in the manufacture of prescription drugs sold in or into Washington State.

“Covered Manufacturer” does not include a private label distributor or retail pharmacy that sells a drug under the retail pharmacy’s store, or a prescription drug repackager.

# Prescription Drug

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A drug regulated under chapter 69.41 or 69.50 RCW, including generic, brand name, specialty drugs, and biological products that are prescribed for outpatient use and distributed in a retail setting.



# Covered Drug

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Any prescription drug that:

1. A covered manufacturer intends to introduce to the market at a wholesale acquisition cost of \$10,000 (or more) for a course of treatment lasting less than 1 month (or a 30 day supply) ... ; or
2. Is currently marketed with a wholesale acquisition cost (WAC) more than \$100 for a 30 day supply, and the covered manufacturer increases the wholesale acquisition cost at least:
  - 20% including the proposed increase + cumulative increase over 1 calendar year prior to the date of the proposed increase; or
  - 50% including..... Over three calendar years prior to the date of the proposed increase.

# Qualifying Price Increase

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An increase in the wholesale acquisition cost (WAC) of a drug that is currently on the market with a WAC more than \$100 for a 30 day supply, and the covered manufacturer increases the wholesale acquisition cost at least:

- 20% including the proposed increase + cumulative increase over 1 calendar year prior to the date of the proposed increase; or
- 50% including..... Over three calendar years prior to the date of the proposed increase.

# Manufacturer Reporting – Data Reporting

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Requires Covered Manufacturers to submit the following data for each Covered Drug:

1. Description of factors used to set or increase wholesale acquisition cost of the drug;
2. Patent expiration date of the drug (if applicable); and
3. Multisource or single source status of the covered drug

# Manufacturer Reporting – Data Reporting

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4. Itemized cost for production and sales including annual manufacturing costs, marketing, research/development, total cost for acquisition of the drug, etc.;
5. The total financial assistance given by the manufacturer through assistance programs, rebates, and coupons.
6. For all qualifying price increases of existing drugs, must submit the year the drug was introduced to the market and the wholesale acquisition cost at time of introduction;
7. For price increases of drugs manufactured for the previous five years or more, must submit schedule of wholesale acquisition cost increases for the drug for previous five years;

# Manufacturer Reporting – Data Reporting

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8. If manufacturer acquired the drug within the previous five years, it must submit:

- Wholesale acquisition cost of the drug at the time of acquisition and in the calendar year prior to acquisition; and
- The name of the company in which the drug was acquired, the date, and purchase price.

# Manufacturer Reporting – Data Reporting

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Generally, Covered Manufacturers must submit the information:

1. At least 60 days in advance of the qualifying price increase for a covered drug; and
2. Within 30 days of release of a new covered drug.

# Manufacturer Notice of New Drug Application

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- ▶ Manufacturer must inform HCA that it has filed with the FDA:
  - ▶ A new drug application or biologics license application for a pipeline drug; or
  - ▶ A biologics license application for a biological product
- ▶ Must be filed with sixty days of the manufacturer receiving the applicable FDA approval date
- ▶ HCA may request the following:
  - ▶ Primary disease, condition, or therapeutic area studied in connection with the new drug
  - ▶ Clinical Trial comparators for the drug
  - ▶ The date at which the FDA must complete its review of the drug application

# Manufacturer Notice of New Drug Application

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## ▶ HCA may request the following:

- ▶ Primary disease, condition, or therapeutic area studied in connection with the new drug
- ▶ Clinical Trial comparators for the drug
- ▶ The date at which the FDA must complete its review of the drug application
- ▶ If the FDA has designated the drug for accelerated approval, priority review, or if the drug contains a new molecular entity



# Manufacturer Notice of Price Increase

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- ▶ A manufacturer of a covered drug must notify HCA of a qualifying price increase at least 60 days prior to planned effective date of drug increase including:
  - ▶ Date of increase, current wholesale acquisition cost, dollar amount of the future increase; and
  - ▶ A statement regarding whether a change or improvement in the drug necessitated the price increase. If so the manufacturer shall describe the change or improvement.
- ▶ If a drug is approved within 60 days of program implementation date, submission must be made as soon as possible but no later than the effective date.

# HCA Reporting Requirements

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- ▶ Must compile & analyze data.
- ▶ Prepare annual report for the public and the legislature synthesizing the data to demonstrate the overall impact that drug costs rebates, and other discounts have on health care premiums.
- ▶ Make a recommendation on how to provide advance notice of price increases to purchasers in WA.

# HCA Enforcement

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- ▶ HCA may assess a fine up to \$1000 per day for failure to comply with the requirements in law. Goes into the Medicaid Fraud Penalty Account (RCW 74.09.215);
- ▶ HCA is creating a process in compliance with Chapter 34.05 RCW; and
- ▶ HCA is developing evaluation, enforcement, and collections processes with rulemaking.

# Key Components of Implementation

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Communication

Rulemaking

Stakeholdering

Compliance

Data

- Collection/Submission
- Storage
- Governance
- Analysis

Pharmacy Cost  
Transparency Report

# HCA Rulemaking Schedule

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- ▶ Filed CR 101: published in state register #20-03
- ▶ Stakeholder Meetings: February – April, 2020
- ▶ External Review – Anticipated Release: June 8, 2020
- ▶ Tentative CR102 Filing: July 22, 2020
- ▶ Tentative Public Hearing: August 25, 2020
- ▶ Tentative Rule Effective Date: October 16, 2020

# Listening Session Prompt Questions:

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- ▶ What do you need from HCA to successfully provide the required information and data?
- ▶ Is there a State doing this well we should model?
- ▶ What are you looking for in a fair enforcement process?
- ▶ What should HCA consider while developing its fine structure?

# Sign-Up For Rulemaking Notices

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**\*\*Reminder:** You must be signed up for [GovDelivery](#) to receive future rulemaking notifications, including the scheduled public hearing, for this rulemaking or any other HCA rulemaking. To sign up, go to [HCA's Rulemaking page](#): <https://www.hca.wa.gov/about-hca/rulemaking>

Select “*Sign up for rulemaking notices*” then select the subscription topics you are interested in.

# For More Information

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- ▶ **Visit:** <https://www.hca.wa.gov/billers-providers-partners/prescription-drug-cost-transparency-update>
- ▶ **Email us:** [drugtransparency@hca.wa.gov](mailto:drugtransparency@hca.wa.gov)