Drug Price Transparency Stakeholder Zoom Meeting for Manufacturers

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Washington State Health Care Authority

Welcome & Logistics

- Welcome & Introductions
  - Team introductions
- Logistics
  - Zoom Instructions
  - This Zoom meeting is VIDEO RECORDED
- Agenda Review

Agenda

- Drug Price Transparency Program Overview
- Reports Outstanding
- Number of Registrants
- Status of Accomplishment
- Up Next in Journey
- Listening Session – We want to hear from you!
- Contact Information – Update Information!

Drug Price Transparency Program Overview

- 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.

Covered Manufacturer

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 repackage.

Prescription Drug

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

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

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

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

4. Itemized cost for production and sales including annual manufacturing costs, marking, 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

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

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

- 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

- 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

- 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

- 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.

Status of Accomplishments

- Posted Progress Report January 2021
- 465 Manufacturers registered
- Received 83 Covered Drug reports and 78 New Drug reports
- Automated the Extension request form
- Established a SFT site to submit reports
- Created a process to register and update contact information
- Solicited feedback and updated submission guide
- Provided a Tech Support inbox HCADPTTechSupport@hca.wa.gov
- Finalized Chapter 182.51 WAC

Up Next in Journey

- Update Submission Guides for October 2021 reporting
- Update registration information
- Finalize the data analytics
- Publish report for January 2022

Listening Session Prompt Questions:

- Tell us about your experience submitting reports to HCA
- What areas of the data submission process did we do well and what areas can we improve on?
- What areas of communication did we do well and what areas can we improve on?
- When should we update the data submission guide and share the new version with you so that you have enough time to review and provide comments?
- What data fields in the data submission guide did you have a difficult time understanding or interpreting?
- How can we improve our descriptions in the data submission guide, so it is clear what we are expecting?

Listening Session Prompt Questions:

- Were there any fields that you think should be nullable? If yes, why?
- Were there any fields that should allow for negative values? If yes, why?
- What sections of the data submission guide did you find confusing?
- Did you find the error log helpful? If no, how can we improve it, so it is more useful when correcting errors?

For More Information

- **Visit:** https://www.hca.wa.gov/billers-providers-partners/prescription-drug-cost-transparency-update
- **Email us:** drugtransparency@hca.wa.gov

- Tech Support inbox HCADPTTechSupport@hca.wa.gov

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