

Prescription Drug Price Transparency (DPT) program

Status report for the public

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Background

Purpose

The state of Washington has substantial public interest in the price and cost of prescription drugs, rising drug costs, and consumer ability to access prescription drugs. The Washington State legislature created a state drug price transparency program under Chapter 43.71C RCW to understand the drivers and impacts of these costs as the first step toward cost containment and greater consumer access to prescription drugs.

The Health Care Authority (HCA) has created this status report detailing the current state of the program as the agency begins to receive drug pricing and cost data from health carriers, pharmacy benefit managers (PBM), drug manufacturers and pharmacy service administrative organizations (PSAO).

Reporting entities

<u>Chapter 43.71C RCW</u> requires four types of reporting entities to submit data to HCA: drug manufacturers, health carriers, PBMs and PSAOs. These reporting entities are defined in statute as follows:

- 1. "Covered manufacturer" means 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 label, or a prescription drug repackager.
- "Health carrier" or "carrier" means a disability insurer regulated under chapter 48.20 or 48.21 RCW, a health care service contractor as defined in RCW 48.44.010, or a health maintenance organization as defined in RCW 48.46.020, and includes "issuers" as that term is used in the patient protection and affordable care act (P.L. 111-148).
- "Pharmacy benefit manager" means a person that contracts with pharmacies on behalf of an insurer, a third-party payor, or the prescription drug purchasing consortium established under RCW 70.14.060 to:
 - a. Process claims for prescription drugs or medical supplies or provide retail network management for pharmacies or pharmacists:
 - b. Pay pharmacies or pharmacists for prescription drugs or medical supplies; or
 - c. Negotiate rebates with manufacturers for drugs paid for or procured as described in this subsection.
 - d. "Pharmacy benefit manager" does not include a health care service contractor as defined in RCW 48.44.010.
- 4. Pharmacy services administrative organization" means an entity that:
 - a. Contracts with a pharmacy to act as the pharmacy's agent with respect to matters involving a pharmacy benefit manager, third-party payer, or other entities, including negotiating, executing, or administering contracts with the pharmacy benefit manager, third-party payer, or other entities; and
 - b. Provides administrative services to pharmacies.

What types of data do these reporting entities report to HCA?

The data each reporting entity submits can be categorized into different reports highlighting each required section of Chapter 43.71C RCW. Some of these reports are highlighted in Table 1.

Table 1. Summary of report types for each reporting entity, not necessarily an exclusive list

| Reporting entity | Report type | Reference |
|------------------|---|-----------------------------------|
| <u>Carriers</u> | Cost and Utilization Report | RCW 43.71C.020(1) |
| | Premium Impact Report | RCW 43.71C.020(1) |
| | Specialty Drug List | RCW 43.71C.020(1) |
| Manufacturers | New Covered Drugs and Qualifying Price Increases | RCW 43.71C.050 and RCW 43.71C.070 |
| | New Drug Application (notice from FDA that drug will be reviewed by deadline) | RCW 43.71C.060(1) |
| <u>PSAO</u> | Pharmacy Contracted Rates | RCW 43.71C.080 |
| | Pharmacy Year-Over-Year Rate Change | RCW 43.71C.080 |
| | PBM Contracted Rates | RCW 43.71C.080 |
| | PBM Year-Over-Year Rate Change | RCW 43.71C.080 |
| PBM | PBM Appeals | RCW 43.71C.030(1) |
| (effective | PBM Carriers | RCW 43.71C.030(1) |
| January 2021) | PBM Drug Benefit Plan | RCW 43.71C.030(1) |
| | PBM Drug Manufacturers | RCW 43.71C.030(1) |

| PBM Ownership | RCW 43.71C.030(1) |
|----------------|-------------------|
| PBM Pharmacies | RCW 43.71C.030(1) |

Implementation of DPT program

Background

HCA began planning the implementation of the Drug Price Transparency (DPT) program in August 2019. This included identifying internal staff from multiple divisions who would lead different areas of the project, such as rulemaking, data collection, data storage, data analytics, data governance, and communication. Since then, HCA has accomplished a number of milestones toward implementation of the program.

Timeline of events

- **2019:** Washington State Legislature passed the <u>Engrossed Second Substitute House Bill (E2SHB) 1224</u> (codified in <u>Chapter 43.71C RCW</u>).
- **2019 2021 (state biennial operating budget):** HCA received \$455,000 and 1.0 FTE (Management Analyst 4) to implement the Prescription Drug Cost Transparency program.
- **August 2, 2019:** HCA interviewed representatives from the Oregon Department of Consumer and Business Services to learn about Oregon's prescription drug price transparency efforts.
- **August 26, 2019:** HCA interviewed representatives from the California Office of Statewide Planning and Development to learn about California's prescription drug price transparency efforts.
- **November 2019:** HCA hired 1.0 FTE (Management Analyst 4) to support the work of the Drug Price Transparency initiative.
- December 2019 March 2020: HCA developed a charter and internal work plan for implementation.
- **January 1, 2020:** HCA delivered the *Prescription Drug Price Transparency and Purchasing Report* to the Washington State Legislature which details the agency's study and recommendations on joint state strategies as outlined in RCW 43.71C.800.
- January 10, 2020: HCA filed a CR-101.
- February 26, 2020: HCA hosted a stakeholder webinar (listening session) for manufacturers.
- March 2020 May 2020: Data definitions were developed for manufacturers, carriers and PSAOs and were sent out for feedback and review.
- April 1, 2020: HCA hosted a stakeholder webinar (listening session) for issuers and carriers.
- April 29, 2020: HCA hosted a stakeholder webinar (listening session) for PBMs and PSAOs.
- May 11, 2020: Internal review of the rule was sent to HCA staff.
- May 29, 2020: External review of the rule was sent to stakeholders for feedback.
- June 15, 2020: Reporting entity registration campaign kicked off for manufacturers, carriers and PSAOs.
- July 1, 2020: Submission guides for manufacturers, carriers and PSAOs were drafted and sent for stakeholder review.
- **July 21, 2020:** HCA filed a CR-102.
- August 1, 2020: Data collection system for reporting entities to report their information became operational.
- August 2020: Technical validation for data definitions were developed and tested for manufacturers, carriers and PSAOs.
- **August 25, 2020:** HCA held a public hearing for the rule.
- **September 15, 2020**: First iteration of final submission guides for manufacturers, carriers and PSAOs were published and the draft PBM definitions and submission guide were developed. HCA also field a CR-103 for the final rule (WAC 182-51).
- October 14, 2020: Draft PBM submission guide was sent out for stakeholder review and feedback.
- October 15, 2020: HCA announced plan for second phase of rulemaking under RCW 43.71C.
- October 16, 2020: The rule (WAC 182-51) became effective for manufacturers, carriers, PBMs and PSAOs.
- **November 3, 2020:** HCA filed a CR-101 for the second phase of rulemaking (WAC 182-51-0100, 182-51-0600, and 182-51-0900).
- November 13, 2020: Closing date for stakeholder feedback on draft PBM submission guide.
- **November 17, 2020:** Revised final submission guides for carriers and PSAOs posted.
- November 30, 2020: Registration campaign kicked off for PBMs.
- **December 1, 2020:** Revised final manufacturer submission guide posted.



• December 9, 2020: Internal review of the second phase of rulemaking was sent to HCA staff.

Anticipated 2021 Events

- January 1, 2021 March 1, 2021: PBMs to begin reporting information based on submission guides.
- January 18, 2021: HCA sends out second phase of rulemaking for external review to stakeholders.
- March 1, 2021: PBMs will have submitted their required data.
- March 3, 2021: HCA files CR-102 for second phase of rulemaking (WAC 182-51-0100. 182-51-0600, and 182-51-0900).
- April 6, 2021: HCA holds public hearing for second phase of rulemaking.
- **April 30, 2021:** HCA files CR-103 for second phase of rulemaking (WAC 182-51-0100. 182-51-0600, and 182-51-0900).
- **June 1, 2021:** WAC revisions become effective.

DPT program statistics

The following tables below describes registration statistics and the status of data submissions from reporting entities as of the date of this report . Registration and data submission statistics are monitored weekly and are subject to change.

Reporting entity registration statistics

Table 2: Reporting entity registration to date.

| Reporting entity type | Total requested | Total registered | Percent registered |
|---|-----------------|------------------|--------------------|
| Health Carriers | 23 | 23 | 100% |
| Pharmaceutical Manufacturers | 430 | 430 | 100% |
| Pharmacy Services Administrative Organizations* | 6 | 2 | 33% |
| Pharmacy Benefit Managers | 53 | 38 | 72% |
| Notes: | | | |
| *Missing reporting entities might be exempt | | | |

Reporting entity data submission statistics

Table 3: Total data submissions to date.

| Submission notices | Totals |
|---|--------|
| Submission attempts to date | 642 |
| Accepted submission notices | 113 |
| Rejected Submission Notices with error report | 534 |
| Extension requests | 12 |

Table 4: Accepted data submissions to date.

| Reporting entity type | Reporting entities | Number of entities attempting | *Submitted 3 accepted templates | Submitted 2 accepted templates | Submitted 1 accepted template | Percent complete |
|---|--------------------|-------------------------------|---------------------------------------|--------------------------------|-------------------------------|---------------------|
| Health Carriers (Requires 3 templates) | 23 | 17 | 9 | 6 | 1 | 39% |
| Pharmaceutical Manufacturers | 430 | 89 | N/A | 6 | 48 | 0% |
| Pharmacy Services Administrative Organizations (Requires 4 templates) | 2 | 0 | 0 | 0 | 0 | 0% |
| Pharmacy Benefit Managers (Currently under development) | 38 | 1 | N/A | N/A | N/A | 0% |

Notes:

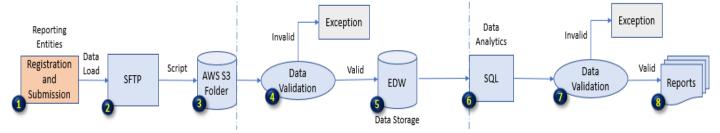
^{*}To be considered accepted, reporting entities must submit all of their required templates and each template must be accepted.

Next steps

Data collection and storage

In order to ensure consistency and compatibility with the data being submitted to HCA in accords with HCA's legislative mandate, the agency developed data submission guides and a data collection and storage process to analyze the drug pricing and cost data. First, HCA created data definitions, including rules for accurate submissions, based on the requirements in Chapter 43.71C RCW. Next, HCA developed a process that allowed for secure collection and storage. The process requires reporting entities to register and obtain a Secure File Transfer (SFT) account hosted by Washington Technology Solutions (WATECH). Data uploaded to the SFT is retrieved by state staff and validated for technical accuracy in another storage location. Reports that do not meet the specific data requirements will produce error log reports for the submitters to review and make adjustments. Reports that pass technical validation are stored in the Enterprise Data Warehouse (EDW) for data analysts to retrieve and conduct a secondary level of program validation before it is ready to be incorporated in the annual data analysis and report.

Figure 1: Process flow diagram of DPT data collection and storage.



Data analytics

HCA developed a workgroup of data analysts, pharmacists, visualization experts, and measure development experts to guide the analytical process. The workgroup is currently developing the analytic framework for each reporting entity as well as identifying which elements will be included in the report that will be released January 1, 2022. The team is also responsible for outlining the program validation checklists during data cleaning, assessing the feasibility of the analysis process, identifying access requirements for analytic tools, and interpreting the results that will be discussed in the January 1, 2022 report.

Resources

- 1. HCA's Prescription drug price transparency webpage
- 2. Contact us at: drugtransparency@hca.wa.gov
- 3. Submission guides and templates:
 - a. <u>Carriers</u>
 - b. Manufacturers
 - c. PSAO
 - d. PBM
- 4. Data submission FAQ
- 5. Reporting entity registration form