Implementing the MN Prescription Drug Price Transparency Act: Public Meeting Notes (November 30, 2021)

UPDATED JANUARY 7, 2022

Meeting Subject: Public Meeting – Rx Transparency Act Implementation Update and Presentation for Feedback of Form & Manner Draft

Date: November 30, 2021

Location: Webex

Hosts: Stefan Gildemeister, Magie Darling

Agenda

1	Welcome, Meeting Logistics	Stefan Gildemeister
2	Implementation Update	Stefan Gildemeister
3	Presentation of Update to Form & Manner Guidance	Magie Darling
4	Questions and Answers	All

Participants

In addition to staff from the Minnesota Department of Health (MDH), 57 individuals attended the public meeting. MDH promoted the meeting through GovDelivery notices and an announcement in the State Register.

Presentation and Discussion Notes

Access to the content shared during the presentation portion of the meeting is available online: November 30, 2021 Public Meeting Notes (https://www.health.state.mn.us/data/rxtransparency/docs/rxpublicmtg113021.pdf).

MDH received questions about the functionality of the reporting system and the timeline for its availability.

The **registration system** will be available early in 2022, and MDH will announce the registration system's availability by an update to the Prescription Drug Price Transparency website (https://www.health.state.mn.us/data/rxtransparency/index.html), a GovDelivery bulletin, and an email sent to Minnesota prescription drug manufacturer licensees.

When the **reporting system** is available for use, MDH will: update the Prescription Drug Price Transparency website (https://www.health.state.mn.us/data/rxtransparency/index.html), send a GovDelivery bulletin, and email all registrants of the Prescription Drug Price Transparency registration system.

MDH received input from stakeholders on desired functionalities to be available within MDH's registration and reporting system, which MDH used in its development planning for the technical build. This input included items like allowing manufacturers to have more than one individual be able to enter or review reported data, and to allow manufacturers to upload reported data as opposed to only allowing manual entry of data.

One question sought to understand the maximum per-day penalty a manufacturer may face.

The sum daily total of all penalties across one or more administrative penalty orders issued to a manufacturer for violating the Prescription Drug Price Transparency Act (the Act), may not exceed $10,000.

MDH received a question seeking to clarify reporting deadlines once a drug meets the reporting criteria after the statutory date of implementation.

The earliest date by which a report may be due to MDH is March 2, 2022.

Data must be submitted by 11:59 p.m. Central Time no later than 60 days after the report is triggered at the time of a price increase, introduction to market of a new drug, or first sale of a newly acquired drug.

Thus, if a price change that occurs on January 1, 2022 triggers reporting, the manufacturer's report is due to MDH no later than by 11:59 p.m. Central Time on March 2, 2022.

One participant asked about the reporting responsibility for ultra-orphan drugs.

Orphan and ultra-orphan drugs may trigger reporting, as they are subject to the same reporting criteria as other drugs.

To help manufacturers understand the criteria for reporting under the Prescription Drug Price Transparency Act (the Act), MDH has issued:

- Form & Manner for Prescription Drug Price Data Sets (https://www.health.state.mn.us/data/rxtransparency/docs/rxformmanner122921.pdf), which establishes the form and manner for reporting under the Act; and
- Frequently Asked Questions for Reporting Entities (https://www.health.state.mn.us/data/rxtransparency/docs/faq.pdf), which addresses commonly asked questions by manufacturers about their reporting responsibilities.

Another participant asked about the reporting responsibility for generics without a referenced brand product on the United States market at the time of introduction.

Currently, the law does not require reporting under the New Prescription Drug Reporting category for a new generic for which there is no referenced brand name drug for sale in the

United States. However, the same generic drug may still trigger Prescription Drug Price Increase Reporting at some later point.

One question sought to understand the options available to a manufacturer that may want to have reevaluated MDH's issuance of an administrative penalty order.

A manufacturer may challenge an enforcement action taken by MDH by requesting an expedited administrative hearing. Any administrative penalty order or notice of outstanding corrective action sent to a manufacturer will contain a description of the process for requesting an expedited administrative hearing.

One participant asked about MDH's work with other states on consistency in reporting.

MDH shared that it communicates with officials in other states and reviews their approach to transparency reporting as one part of MDH's broader effort to reduce manufacturer reporting burden to only necessary levels. However, the Prescription Drug Price Transparency Act in Minnesota reflects a distinct set of legislative priorities and approach to prescription drug price transparency, as does each state's transparency law.