Implementing the MN Prescription Drug Price Transparency Act: Public Meeting Notes (June 10, 2021)

UPDATED JUNE 17, 2021

Meeting Subject:	Public Meeting - Rx Transparency Act Overview, Implementation, and Presentation for Feedback of Form & Manner Draft
Date:	June 10, 2021
Location:	Webex
Hosts:	Stefan Gildemeister, Magie Darling

Agenda

1	Welcome	Stefan Gildemeister
2	Meeting Logistics	Magie Darling
3	Presentation • Approach to Implementation • Overview of the Prescription Drug Price Transparency Act	Stefan Gildemeister
4	Draft Definitions, Data Elements, and Expected Reporting Process	Jim Jones
5	Discussion & Feedback	All

Participants

In addition to staff from the Minnesota Department of Health (MDH), 56 individuals attended in the public meeting. MDH promoted the meeting through GovDelivery notices, an announcement in the State Register, and a message distributed by the Board of Pharmacy.

Presentation and Discussion Notes

Access to the content shared during the presentation portion of the meeting is available online: meeting presentation slides.

Several participants asked about the accuracy of timelines MDH referenced in its presentation and slide deck.

During the presentation MDH staff consulted with its legislative team and confirmed that the bills that shifted timelines for the start of reporting by manufacturers and the submission of legislative reports had been passed and signed into law by Governor Walz. Minnesota Laws, 2021 Regular Session, Chapter 30 – HF 2128 – Article 3, Sec. 5- 9 delayed the start of manufacturer reporting from October 2021 to January 2022. Similarly, the due date for the first legislative report was pushed back to May 15, 2022. MDH issued a revised presentation slide deck with the correct timelines and updated the draft Form & Manner document accordingly.

MDH received questions about where and when stakeholders may access meeting material, draft reporting guidelines (Form & Manner document), and the meeting notes.

All information is available on MDH's Prescription Drug Price Transparency website. MDH scheduled a GovDelivery announcement for June 18, 2021, to notify stakeholders that the material has been made available.

One question concerned the law's requirements for companies that manufacture drugs for clients who subsequently label and distribute the drugs.

By tying the reporting requirement to wholesale acquisition cost, the law places the responsibility for reporting with the entity that sets the wholesale acquisition cost (WAC). The final Form & Manner document will provide further clarification on this issue; however, MDH staff encouraged everyone to review the document and reach out with any feedback to ensure final Form & Manner document has the necessary clarity.

MDH received questions about how to report the cost of marketing and distribution, including for new drugs that meet the criteria for reporting.

MDH believes the Form & Manner document will address these questions. In addition, MDH plans to prepare a "Frequently Asked Questions" document that will address practical approaches to submitting data and will speak to particular circumstances that manufacturers may face. In that document, MDH will include responses to some of the specific questions that arose during this meeting with regard to cost associated with marking to health care providers and direct to consumers.

One participant sought to better understand how the price increase should be computed.

As noted, the statute constructs the price increase criteria for reporting as the cumulative change in price over 12- and 24-month periods. So, to assess one's reporting responsibility, a manufacturer should reference a given new price against the price for that drug 12 and 24 months prior to determine whether the change in price meets the price increase criteria for reporting.

Participants were interested in understanding how MDH approaches compliance with the statute.

MDH pointed out that the requirement to comply with reporting under the statute rests with manufacturers. In addition, MDH communicated that the agency would consult reference data to identify drugs on which it would expect a report. MDH also anticipates tracking related activities in other states that have similar reporting requirements against what is reported in Minnesota.

Additional clarity on enforcement of the statute will emerge when MDH updates the Form & Manner document to include adoption of a schedule of civil penalties. Manufacturers are encouraged to refer to the MDH administrative penalty order plan for basic information about administrative penalty procedures, forgivable and nonforgivable penalties, and determinations about the actions that constitute "serious" violations of rules and statutes. See *https://www.health.state.mn.us/communities/environment/local/docs/ehcib/apoplan2010.pdf*.

There were several questions about how information will be made available to the public and whether MDH expects to receive non-public data.

MDH clarified that in Minnesota, unlike in other states, manufacturers are obligated to submit the required information, irrespective of the applicable data classification. MDH will establish the ability for manufacturers to indicate their assessment that certain elements ought to be designated as not public or trade secret. As required by state law, the Commissioner will only publish what is permitted and required to be published under state law.

Additional clarity on the submission of protected information, MDH's process for review and determination of the classification of data elements, and the form in which information will be displayed will be included in a future update to the Form & Manner document and in a User Guide MDH anticipates publishing.