DEPARTMENT OF HEALTH

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

Health Economics Program

Meeting Agenda

- Meeting logistics
- Implementation update
- Update to Form & Manner guidance
- Questions and answers
- Next steps

Reminder: Public Comment Deadline

- Today:
  - Participants are welcome to comment verbally or in the chat during the Discussion and Feedback section.
- After today:
  - Stakeholders are welcome to email feedback on the material we will be presenting to health.Rx@state.mn.us by 4:30 p.m. CST on Dec. 8, 2021.
  - Future opportunities for providing feedback will be announced at minimum on our website and via GovDelivery bulletins.

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Approach and Progress on Implementation

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Approach to Implementing the Act

Our approach to implementing the Prescription Drug Price Transparency Act, "the Act"; (Minnesota Statues 62J.84)

- Support the statutory aims of transparency, understanding, and management of drug spending
  - Collect high-quality, complete data
  - Make easily accessible & delivered in a timely manner
- Maintain transparency in our implementation process
- Ensure opportunities for stakeholder feedback
- Limit reporting burden to necessary levels

2021-22 Timeline for Implementing the Act

Winter/Spring 2021

- Website, email, and GovDelivery launch.
- Issued draft reporting guidance on the data required for reports for public comment
- Obtained feedback in number of ways, including a public meeting

Summer 2021

- Revised reporting guidance based on feedback.
- Procured reference pricing data for use in compliance monitoring, validation, and analysis.

Fall/Winter 2021

- Issue reporting guidance on compliance enforcement, trade secrets, and technical specifications of the data.
- IT system build and obtain feedback from stakeholders.

Winter/Spring 2022

- January 1, 2022 (March 1 due date) drugs may trigger reporting.
- Begin data collection and validation, as well as compliance enforcement.
- Develop public posting system for reported data.
- Issue legislative report.

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Revised Form and Manner Pertaining to Trade Secrets, Compliance, and Enforcement

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What Final Form and Manner Document Will Contain

- Will provide guidelines to reporting entities on:
  - How to register
  - How to submit data
  - Data definitions, data elements, and due dates
  - What is considered compliance
  - Penalty schedule
- Our aim: to give clear guidance to ensure high quality reporting and minimal reporting burden
- **Today:** we are focusing on the processes pertaining to trade secrets, compliance, and enforcement.
- **Processes under development:** registration and data reporting (technology); data submission and validation; and public posting of reported data.

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Definitions

Form & Manner Definitions

Below are terms that will be referenced in the Form & Manner (F&M) Document:

Term	Definition
Not public data	Any data that is “classified by statute, federal law, or temporary classification as confidential, private, nonpublic, or protected nonpublic.
Trade secret information	**Minnesota Law:** Under the Minnesota Government Data Practices Act, a trade secret is data including a formula, pattern, compilation, program, device, method, technique, or process that meets the following criteria: 1. The data must be supplied by the affected individual or organization. 2. The data must be subject of efforts by the individual or organization that are reasonable under the circumstances to maintain its secrecy. 3. The data must derive independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use. **Federal Law:** Under the United States Defend Trade Secret Act of 2016, trade secret information is all forms and types of financial, business, scientific, technical, economic, or engineering information, including patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing if: 1. The owner thereof has taken reasonable measures to keep such information secret; and 2. The information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, another person who can obtain economic value from the disclosure or use of the information.

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Not Public Data and Trade Secrets

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Not Public Data and Trade Secrets: Overview

To increase transparency into the pricing of prescription drugs, MDH is required to publicly post the information reported by Manufacturers, except data classified by law and defined above as trade secret or not public (collectively referenced throughout this section as “not public data”).

Manufacturers are responsible for submitting not public data to MDH along with a written statement, which must identify the specific data elements that should be withheld from public disclosure and the legal basis for that position. MDH is responsible for evaluating these Manufacturer submissions and applicable law to determine whether data must be withheld.

This section provides guidance to data submitters on:

1. The process for Manufacturer identification of private data, including applicable trade secret criteria;
2. MDH decision and notice requirements; and
3. Due process measures available to challenge MDH data determinations.

Process for Designating Data as Protected from Public Disclosure

- To designate data as protected from public disclosure, a Manufacturer must identify all not public data elements in a written statement to MDH at the time of data submission.
- A Manufacturer must “clearly” and “specifically” identify any not public data in its written submission to MDH.
- A Manufacturer may not designate entire data sets, documents, or topics as protected due to the presence of not public data elements that could be redacted or withheld.
- A Manufacturer’s written statement must show that each identified data element is classified by law as not public data, citing applicable federal or state law and relevant legal authority, as necessary.
- The Manufacturer’s description should also include any documentation or evidence necessary to allow MDH to make a final determination.

Requirements for Making Trade Secret Designations, 1

For trade secret designations, the Manufacturer must demonstrate all of the following:

- That the Manufacturer supplying the claimed trade secret data is the owner of the data.
- The Manufacturer's efforts to maintain the secrecy of the data, including an explanation of why the Manufacturer believes such efforts to be reasonable under the circumstances and industry practice.
- The potential or actual economic value the Manufacturer derives from secrecy, including an explanation of why disclosure of the data would allow others to derive economic value from the data.
  - Note: The economic value must be current at the time the data designation is made—certain data may lose its actual or potential value over time.

Requirements for Making Trade Secret Designations, 2

- That the data is not readily available through proper (i.e., legal) means by those who can obtain economic value from the data.
  - For example, information may not be a trade secret if it is:
    - Publicly available, including upon request or through media, internet, or other public sources.
    - Shared with or available to regulatory, professional, consumer, or industry entities or groups (i.e., in applications, grants, disclosures, reporting, or other sources) in a manner that does not reasonably ensure secrecy from those who could obtain economic value from the data.
  - When data is not publicly available but is accessible to certain third parties, a Manufacturer should explain who has access to the data and why the Manufacturer believes the data remains protected from those who could derive economic value from the data.
- Any other information the manufacturer believes is relevant or necessary under federal or state trade secret law.

MDH Decision

MDH must take one of the following actions in response to a Manufacturer's written statement.

- **Agree** with the Manufacturer's request to withhold data from public disclosure.
  - Public Reporting: MDH must post to the MDH website a report describing the nature of the data and MDH's basis for withholding it.
- **Disagree** with the Manufacturer's request to withhold data from public disclosure.
  - 30-Day Notice: MDH must provide the Manufacturer written notice that the data will be publicly posted 30 days after the date of the notice.

MDH will base each decision on the Manufacturer's complete submission, applicable statutes and regulations, and related legal authority.

Procedures for Disputing an MDH Data Decision

- MDH's classification of data as public or not public is subject to the Minnesota Government Data Practices Act ("MGDPA"), Minnesota Statutes, chapter 13. The MGDPA provides civil and administrative remedies to challenge the determinations of a government entity in Minnesota Statutes, sections 13.08 and 13.085.
- If a Manufacturer files an MGDPA challenge to an MDH decision to publish data over a Manufacturer designation, MDH may continue to withhold data that has not been published until the challenge is resolved.
- Note: MDH may publish data the Manufacturer has designated as not public 30-days after sending a notice of intent to publish the data.

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Compliance Enforcement

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Penalties: Requirements in the Act

The Act requires MDH to impose civil penalties to manufacturers for the following issues:

- (1) failing to submit timely reports or notices as required by the Act;
- (2) failing to provide information required under the Act; or
- (3) providing inaccurate or incomplete information under the Act.

MDH is required to establish a schedule of civil penalties, not to exceed $10,000 per day of violation, based on the severity of each violation. Further, MDH is authorized to remit or mitigate civil penalties under this section upon terms and conditions MDH considers proper and consistent with public health and safety.

This section describes the MDH Administrative Penalty Order ("APO") process for imposing civil penalties and includes a penalty matrix that will be used to determine the amount of each civil penalty.

Administrative Penalty Order References

- Unless stated otherwise in this Compliance and Enforcement section, civil penalties will be issued using the Administrative Penalty Order ("APO") process described in Minnesota Statutes, section 144.99, subd. 4 and 144.991 and the MDH Administrative Penalty Order Plan ("APO Plan").
- *Plan for the Use of Administrative Penalty Order, Cease and Desist Authority, and Other Enforcement Tools*, Minnesota Department of Health, available at https://www.health.state.mn.us/communities/environment/local/docs/ehcib/apoplan2010.pdf.

Administrative Penalty Orders

An APO issued to a Manufacturer will generally include four statements:

- A concise statement of the facts of the alleged violation,
- Citation to the provision of the Act violated (or, where applicable, the terms of an order or stipulation agreement),
- A statement of the penalty amount and the factors upon which the penalty is based, and
- A statement of the Manufacturer's rights to seek review.

An APO may also include an order requiring violations to be corrected within 30 calendar days. Within 30 days of the date a Manufacturer receives an APO requiring corrective action, the Manufacturer must submit information to MDH demonstrating that the violation has been corrected or that the Manufacturer has developed a corrective plan. MDH shall determine whether the violation has been corrected (or, where applicable, whether a corrective plan is acceptable) and notify the Manufacturer of MDH's determination.

Forgivable and Non-Forgivable Penalties

Forgivable Penalties

Except in the case of repeated or serious violations, the penalty assessed in the APO must be forgiven if the Manufacturer demonstrates in writing to MDH within 30 days after receiving the APO that the Manufacturer has corrected the violation or has developed a corrective plan acceptable to MDH.

A penalty will not be forgiven if MDH determines that a Manufacturer failed to timely correct a violation or develop an acceptable corrective plan. Failure to timely correct a violation or develop an acceptable plan may also result in an additional APO.

Non-Forgivable Penalties

MDH may issue an APO with a non-forgivable penalty if a violation is deemed “serious” or “repeated.” An APO may also contain both forgivable and non-forgivable penalties, depending on the violations at issue.

- **Serious Violations**: Serious violations include conduct showing disregard of requirements or standards, or violations that present an actual or potential harm to the public health.

- **Repeated Violations:** A violation may be considered repeated if (1) the Manufacturer has previously violated one or more sections of the Act; (2) the violation is identical or similar to the previous violation; and (3) MDH notified the Manufacturer of the previous violation.

Calculation of Base Penalty Amount

Penalties must be based on the severity of each violation of the Act and may not exceed $10,000 per day of violation. MDH will assess severity and determine the penalty for each violation according to the APO Plan and the factors in sections 144.99 and 144.991.

In addition to the considerations in the APO Plan and sections 144.99 and 144.991, civil penalties will be assessed according to the following schedule.

Number of Violations (Prior or Current)	Per-Day Base Penalty Ranges
0	$500 - $2,500
1 – 2	$1,000 to $5,500
3+	$2,500 to $10,000

Adjustments to the Base Penalty

For each violation, MDH may make adjustments to the base penalty based on the factors described here. This includes adjusting a penalty below the scheduled range (for example, for less severe violations), or adjusting above the scheduled range (for example, if a violation is severe or willful, based on the following factors).

For repeat violations, MDH will consider the:

- similarity of the most recent previous violation and the violation to be penalized;
- time elapsed since the last violation;
- number of previous violations; and
- response of the person to the most recent previous violation identified.

For each violation, MDH will consider the following:

- the willfulness of the violation;
- the gravity of the violation, including any damage caused or potential for harm;
- the history of past violations (not previously considered);
- the number of violations;
- the economic benefit gained by the person by allowing or committing the violation; and
- other factors as justice may require, which MDH will specifically identify in an APO.

Penalty Due Dates

Unless a Manufacturer requests an expedited administrative hearing to review an order before the penalty is due, the penalty in an APO is due and payable:

(1) on the 31st day after the APO was received, if the Manufacturer subject to the order fails to provide information to MDH showing that the violation has been corrected or that appropriate steps have been taken toward correcting the violation; or

(2) on the 20th day after the Manufacturer receives notice of outstanding corrective action based on MDH's determination that information the Manufacturer provided is not sufficient to show the violation has been corrected or that appropriate steps have been taken toward correcting the violation.

For repeated or serious violations, MDH may issue an order with a penalty that will not be forgiven after the corrective action is taken. The penalty is due by 31 days after the order was received unless an expedited administrative hearing to review the order has been sought.

Interest at the rate established in Section 549.09 begins to accrue on penalties on the 31st day after the order with the penalty was received.

Expedited Administrative Hearing

- Within 30 days after receiving an order or within 20 days after receiving a notice of outstanding corrective action based on the department's determination that information provided to MDH is not sufficient to show the violation has been corrected or that appropriate steps have been taken toward correcting the violation, a Manufacturer may request an expedited hearing on the violation(s) as provided in Section 144.991 subdivision 5.

- The APO (or, if applicable, the notice of outstanding corrective action) will contain notice to a Manufacturer describing the process for requesting an expedited administrative hearing.

- MDH will also notify the Manufacturer of the time and place of the expedited hearing at least 15 days before the date of the hearing.

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Public Comment and Feedback

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To Comment at Today's Meeting

- To share questions or comments **now verbally**, please:
  - Click **Participants** and then the **Raise Hand** button next to your name
  - After your name has been called, please confirm you are unmuted and share your name, affiliation, and your message
- To share questions or comments **now in writing**, please:
  - Open the chat window and compose your message
  - Select whether to send your message via the chat
- To share **written** questions or comments **later**, please:
  - Email health.Rx@state.mn.us by 4:30 p.m. CST on December 8, 2021

Materials Are Available on MDH Website

- To access the materials shared today, please visit the Prescription Drug Price Transparency page of MDH's website at: health.state.mn.us/data/rxtransparency
- Announcement page contains the revised Form & Manner
- Meetings page will contain:
  - This slide deck
  - Meeting summary, including questions raised

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Next Steps and Deadlines

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Deadline for Comment for This Comment Period

- Written feedback emailed to health.Rx@state.mn.us by 4:30 p.m. CST by December 8, 2021
- MDH to review and prepare responses to feedback given at this meeting and through the comment period
- MDH to issue revised Form & Manner reporting guidance, as well as an updated FAQ document for reporting entities
- For future opportunities to provide input, please monitor our website and subscribe for our GovDelivery bulletins.

Thank you.

Please find program updates and GovDelivery subscription online at:

health.state.mn.us/data/rxtransparency

Questions or comments may be emailed to: health.Rx@state.mn.us

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