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

Updated: June 11, 2021

Stefan Gildemeister, Director Health Economics Program

Meeting Agenda

- Meeting Logistics
- Approach to Implementation
- Overview of the Prescription Drug Price Transparency Act
- Draft Definitions, Data Elements, and Expected Reporting Process
- Discussion and Feedback

Reminder: Public Comment Deadline

- Today: Participants are welcome to comment verbally or in the chat system 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. Central Time on June 24, 2021.
  - Throughout the development period, MDH will make available additional opportunities for providing public feedback. Future opportunities will be announced on our website and via GovDelivery bulletins.

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
- Meetings page will contain:
  - This slide deck
  - Meeting summary, including questions raised
  - Written draft Form & Manner document

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Approach to Implementation

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

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Overview of the Act

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The Act Has Three Core Requirements

- Manufacturer Reporting
  - Drugs with specified price increases, including newly acquired drugs
  - New drugs with specified price thresholds
- MDH Data Processing and Publishing
  - Receive, store, and review data received and expected from manufacturers
  - Post reported information that is public on MDH website
- Reporting to the Legislature
  - Aims to promote transparency and understanding of prescription drug pricing, and to support the state and other payers in managing pharmaceutical spending
  - Summarize implementation and the Act's effectiveness toward those aims

Reporting Entities and Triggering Conditions

Drug manufacturers must report specified information no later than **60 days after** any of the following reporting triggers are met:

Trigger Type	Drug Type	Price Minimum	Trigger
Price Increase (Existing and Newly Acquired Drugs)	Brand Name Drug	>=$100 WAC (Wholesale Acquisition Cost)	>=10% increase over previous 12 months OR >=16% increase over previous 24 months
Price Increase (Existing and Newly Acquired Drugs)	Generic Drug	>=$100 WAC	>=50% increase over previous 12 months
Price at Market Entry (New-to-Market Drugs)	Brand Name Drug	>$670 (Medicare Part D Specialty Threshold)	Introduction for sale in the United States
Price at Market Entry (New-to-Market Drugs)	Generic Drug	>$670 and is not at least 15% lower than equivalent brand product	Introduction for sale in the United States

Reporting Schedule

- Reporting requirements:
  - Data must be submitted by 11:59 p.m. Central Time no later than 60 days after a qualifying trigger event
  - Subject to start date on January 1, 2022*
  - Subject to the commissioner's guidance on the form and manner of submission and enforcement

* On May 25, 2021, the Governor approved HF 2128. Minnesota Laws, 2021 Regular Session, Chapter 30 – HF 2128 – Article 3, Sec. 5 – 7 amended Minnesota Statutes 2020, section 62J.84, subd. 3 – 5 to change the start date of reporting.

2021-22 Timeline for Implementing the Act

- **May** – Website goes live and GovDelivery open for subscription to updates
- **June** – Develop draft reporting guidelines and obtain feedback
- **July** – Issue final guidance
- **July to Dec** – Develop data collection technology, and obtain additional stakeholder feedback
- **Jan 2022** – Requirement for submission begins*
- **Jan to April 2022**– Develop reporting technology with testing and feedback
- **May 2022**– Draft legislative report*

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* On May 25, 2021, the Governor approved HF 2128. Minnesota Laws, 2021 Regular Session, Chapter 30 – HF 2128 – Article 3, Sec. 5 – 7, 9 amended Minnesota Statutes 2020, section 62J.84, subd. 3 – 5, 9 to change the start date of reporting and the 2022 Legislative Report.

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Draft Definitions, Data Elements, and Expected Reporting Process

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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 data definitions, data elements, and due dates.**

Form & Manner Definitions

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

Term	Definition	Source / Use
30-Day Supply	The total daily dosage units of a Prescription Drug recommended by the prescribing label approved by the federal Food and Drug Administration (FDA) for 30 days. If the FDA-approved prescribing label includes more than one recommended daily dosage, the 30-Day Supply is based on the maximum recommended daily dosage on the FDA-approved prescribing label.	Drafted for F&M – used for defining drugs that meet price increase and new drug report thresholds.
Biosimilar Drug	Prescription Drug that is produced or distributed pursuant to a biologics license application approved under United States Code, title 42, section 262(K)(3).	Incorporated from statute – used for defining drugs that meet new drug report threshold.
Brand Name Drug	Prescription Drug that is produced or distributed pursuant to: 1) an original, new drug application approved under United States Code, title 21, section 355(c), except for a generic drug as defined under Code of Federal Regulations, title 42, section 447.502; or 2) a biologics license application approved under United States Code, title 45, section 262(a)(c).	Incorporated from statute – used for defining drugs that meet price increase and new drug report thresholds, and reporting metrics specific to brand drugs.

Form & Manner Definitions (2)

Term	Definition	Source / Use
Course of Treatment	The total dosage of a single prescription for a Prescription Drug recommended by the FDA-approved prescribing label. If the FDA-approved prescribing label includes more than one recommended dosage for a single course of treatment, the course of treatment is the maximum recommended dosage on the FDA-approved prescribing label.	Drafted for F&M– used for defining drugs that meet price increase threshold.
Generic Drug	Prescription Drug that is marketed or distributed pursuant to: 1) an abbreviated new drug application approved under United States Code, title 21, section 355(j); 2) an authorized generic as defined under Code of Federal Regulations, title 42, section 447.502; or 3) a drug that entered the market the year before 1962 and was not originally marketed under a new drug application.	Incorporated from statute – used for defining drugs that meet price increase and new drug report thresholds and reporting metrics specific to generic drugs.
Manufacturer	An entity licensed to act as a drug manufacturer in the State of Minnesota under Section 151.252.	Incorporated from statute – used to define entities that must report.

Form & Manner Definitions (3)

Term	Definition	Source / Use
National Drug Code (NDC)	The three-segment code maintained by the federal Food and Drug Administration that includes a labeler code, a product code, and a package code for a drug product and that has been converted to an 11-digit format consisting of five digits in the first segment, four digits in the second segment, and two digits in the third segment. A three-segment code shall be considered converted to an 11-digit format when, as necessary, at least one “0” has been added to the front of each segment containing less than the specified number of digits such that each segment contains the specified number of digits.	Drafted for F&M - used for unique drug identification required by Subd 6.(b) – Public posting of prescription drug price information on a per-drug basis.
New Prescription Drug	Prescription Drug approved for marketing by the United States Food and Drug Administration for which no previous Wholesale Acquisition Cost has been established for comparison.	Incorporated from statute – used for defining drugs that meet new drug report threshold.
Nonproprietary Name	The generic name assigned by the United States Adopted Names (USAN) Council.	Drafted for F&M - used to specify form of data metric related to generic name

Form & Manner Definitions (4)

Term	Definition	Source / Use
Patient Assistance Program	Program that a Manufacturer offers to the public in which a consumer may reduce the consumer's out-of-pocket costs for Prescription Drugs by using coupons, discount cards, prepaid gift cards, Manufacturer debit cards, or by other means.	Incorporated from statute – referenced in price increase report metric regarding financial assistance.
Prescription Drug	Drug for human use subject to United States Code, title 21, section 353(b)(1).	Incorporated from statutory reference (Section 151.44, subd 8) – used for defining drugs that meet price increase and new drug report thresholds.
Wholesale Acquisition Cost (WAC)	Manufacturer's list price for a Prescription Drug to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price.	Incorporated from statutory reference (definition of "Price" – US Code, Title 42, section 1395w-3a(c)(6)(b)) – used for defining drugs that meet price increase and new drug report thresholds.

Proposed Price Increase Reporting Data Elements

1. Identification of the drug:
    a. NDC of the drug
    b. Description of the drug to include the following:
        i. Product name
        ii. Dosage form
        iii. Strength
        iv. Package size
2. Effective date of WAC increase
3. WAC after the price increase
4. Percent increase over previous WAC
5. Factors that contributed to the price increase
6. Name of any generic version of the drug available on the market
7. WAC price of the drug at introduction to market

Proposed Price Increase Reporting Data Elements (2)

8. Year of introduction to market
9. WAC price of the drug on the last day of each of the five calendar years preceding the price increase
10. Direct costs incurred by the manufacturer to manufacture the drug during the 12-month period preceding the price increase
11. Direct costs incurred by the manufacturer to market the drug, including advertising costs, during the 12-month period preceding the price increase
12. Direct costs incurred by the manufacturer to distribute the drug during the 12-month period preceding the price increase
13. The manufacturer's total gross revenue from sales of the drug during the 12-month period preceding the price increase
14. The manufacturer's net profit attributable to the drug during the 12-month period preceding the price increase

Proposed Price Increase Reporting Data Elements (3)

15. Total amount of financial assistance the manufacturer has provided through Patient Assistance Programs during the 12-month period preceding the price increase
16. Any agreement between the Manufacturer and any other entity contingent upon any delay in offering to market a generic version of the drug
17. Patent expiration date of the drug if it is under patent
18. Name of the company that manufactured the drug
19. Location of the company that manufactured the drug
20. If a Brand Name Drug, the ten highest prices paid for the drug during the calendar year prior to the price increase in any country other than the United States. Prices should represent the WAC equivalent in the country and be expressed in dollars according to the exchange rate on the day the report is submitted.

Proposed Price Increase Reporting Data Elements (4)

21. If the drug was acquired by the Manufacturer within the 60-day period prior to the price increase, all of the following information:
    a. WAC at acquisition
    b. WAC in the calendar year prior to acquisition
    c. Name of the company from which the drug was acquired
    d. Date of acquisition
    e. Acquisition price
22. General comments and/or additional information related to the data submitted for the drug, if applicable (optional)
23. Any documentation necessary to support the data submitted for the drug, if applicable (optional)
24. Identification of any data points for the drug that should not be publicly disclosed and the legal basis for withholding each identified data point from public disclosure

Proposed New Drug Reporting Data Elements

1. Identification of the drug:
    a. NDC of the drug
    b. Description of the drug to include the following:
        i. Product name
        ii. Dosage form
        iii. Strength
        iv. Package size
2. Date of introduction for sale in the United States
3. WAC price of the drug at introduction for sale in the United States
4. Whether the FDA granted the drug a breakthrough therapy designation or priority review
5. Direct costs incurred by the manufacturer to manufacture the drug during the 12-month period preceding introduction for sale in the United States

Proposed New Drug Reporting Data Elements (2)

6. Direct costs incurred by the manufacturer to market the drug, including advertising costs, during the 12-month period preceding introduction for sale in the United States
7. Direct costs incurred by the manufacturer to distribute the drug during the 12-month period preceding introduction for sale in the United States
8. Patent expiration date of the drug if it is under patent
9. General comments and/or additional information related to the data submitted for the drug, if applicable (optional)
10. Any documentation necessary to support the data submitted for the drug, if applicable (optional)
11. Identification of any data points for the drug that should not be publicly disclosed and the legal basis for withholding each identified data point from public disclosure

Processes Under Development

- Registration and data reporting (technology)
- Review data submission and validation
- Trade secret assertion process
- Public posting of reported data
- Compliance enforcement

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Public Comment and Feedback

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To Comment at Today's Meeting

- To share **spoken** questions or comments **now**, please:
  - Click **Participants** and then the **Raise Hand** button next to your name
  - After your name has been called, please unmute yourself and share your name, affiliation, and your message
- To share **written** questions or comments **now**, please:
  - Open the chat window and compose your message
  - Select whether to send your message to the Host or All Participants
- To share **written** questions or comments **later**, please:
  - Email health.Rx@state.mn.us by 4:30 p.m. Central Time on June 24, 2021

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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. Central Time on June 24
- MDH to review and prepare responses to feedback given at this meeting and through the comment period
- 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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