Prescription Drug Price Transparency: Frequently Asked Questions

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The Frequently Asked Questions document addresses practical approaches to submitting data and speaks to specific circumstances that manufacturers may face. The Minnesota Department of Health (MDH) is posting responses to questions received from public meetings with stakeholders, as well as from more informal inquiries. MDH will update the document as new information emerges and we receive additional questions about implementing the Minnesota Prescription Drug Transparency Act.

Revision History

Date	Version	Description
08/27/2021	1	First draft

Contents

DRAFT

Program Overview

To increase transparency into the pricing of prescription drugs, the Minnesota Legislature passed the Prescription Drug Price Transparency Act (the "Act") in 2020, which requires MDH to develop a system for collecting and reporting data from drug manufacturers on high and quickly increasing prescription drug prices (Minnesota Statutes 62J.84; amended by Minnesota Laws, 2021, Regular Session, Chapter 30 – HF 2128 – Article 3, Sec. 5 - 9).

There are three main components to implementation of the Act:

1. Prescription drug manufacturers report to MDH when drugs meet reporting criteria.
2. MDH publishes reported data that is permitted and required to be published under state law.
3. MDH analyzes the reported data and annually submits a report to the legislature that promotes transparency and supports management of prescription drug spending.

Important Dates

January 1, 2022. Changes to the price of a prescription drug, sales of new acquisitions of prescription drugs, and new listings of a prescription drug for sale in the United States on or after this date may trigger reporting, if all reporting criteria are met. A report can be triggered at any point after this date.

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.

For example, 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.

Can a drug that had a price increase prior to January 1, 2022, trigger Prescription Drug Price Increase Reporting?

No. Only price increases that occur on or after January 1, 2022, may trigger Prescription Drug Price Increase Reporting.

Can a drug introduced for sale in the United States prior to January 1, 2022, trigger New Prescription Drug Price Reporting?

No. Only drugs introduced for sale in the United States on or after January 1, 2022, may trigger New Prescription Drug Price Reporting. However, drugs introduced for sale prior to January 1, 2022, may trigger Prescription Drug Price Increase Reporting if they meet the reporting criteria on or after January 1, 2022.

Can a drug that was acquired by a manufacturer that began selling the acquired drug prior to January 1, 2022, trigger reporting of the drug acquisition data element included in the Prescription Drug Price Increase Reporting?

No. Only drugs that the acquiring manufacturer begins to sell on or after January 1, 2022, may trigger the drug acquisition data element (Item 21 in the Form and Manner section titled Prescription Drug Price Increase Reporting) included in the Prescription Drug Price Increase Reporting if they meet the reporting criteria. However, drugs acquired and first sold by the manufacturer prior to January 1, 2022, may trigger Prescription Drug Price Increase Reporting if they meet the reporting criteria on or after January 1, 2022.

Communication

How can manufacturers stay updated on implementation of the Act?

MDH will communicate updates and announcements on its website and through emailed GovDelivery bulletins. Manufacturers can monitor website updates on the Announcements page[1] and can sign up for GovDelivery bulletins.[2]

What future opportunities will there be for public feedback on implementation of the Act?

MDH is committed to implementing the Act in a transparent way. As MDH has communicated, it expects to provide opportunities in late summer and fall 2021 during which stakeholders can comment on additional sections of the draft Form and Manner that currently remain in development.[3]

Reporting Responsibility

What entities are subject to the Act?

As noted in the law, entities that are licensed to act as a drug manufacturer in the State of Minnesota under section 151.252 are subject to the Act.

What drugs meet the requirement for reporting under the Act?

Drugs intended for human use subject to United States Code, title 21, section 353(b)(1) are subject to the Act. These drugs require reporting if they meet price increase, new prescription drug, or newly acquired drug criteria. (MN Statutes 62J.84, subd. 3-5).

If multiple prescription drug manufacturers have a relationship to a prescription drug that triggers reporting, which entity has the responsibility to report?

By tying the reporting requirement to wholesale acquisition cost (WAC) price, the law places the responsibility for reporting with the entity that sets the WAC price. Other entities may report on a drug on behalf of the responsible manufacturer.

In the following scenarios, we identify which entity has the responsibility to report or have a designee report on their behalf:

[1] https://www.health.state.mn.us/data/rxtransparency/announcements.html
[2] https://public.govdelivery.com/accounts/MNMDH/subscriber/new?topic_id=MNMDH_553
[3] https://www.health.state.mn.us/data/rxtransparency/docs/rxformmanner082721.pdf

Scenario 1. Entity A manufacturers and packages a drug on behalf of Entity B. Entity B controls the price of the drug.

Entity B has the reporting responsibility for Prescription Drug Price Increase reporting (MN Statutes 62J.84, subd. 3) because it controls the price that may trigger reporting.

Scenario 2. Entity A is the parent company to Entity B, which manufactures, packages, and distributes the drug.

If Entity B controls the price of the drug, Entity B has the reporting responsibility associated with any price increases that may trigger reporting (MN Statutes 62J.84, subd. 3). If Entity A controls the price of the drug, Entity A has the reporting responsibility associated with any price increases that may trigger reporting.

Scenario 3. Entity A increased the price of a drug to a level that triggered required reporting and then sold the drug to Entity B 30-days later, at which point Entity B began selling the drug.

Entity A has the responsibility for the Prescription Drug Price Increase reporting (MN Statutes 62J.84, subd. 3) associated with the price increase that occurred prior to the sale of the drug to Entity B.

Entity B's reporting responsibility depends on whether the drug meets the criteria for reporting on the first day of sale and whether Entity B increased the price to the level that meets the reporting criteria. Possible reporting responsibilities for Entity B are:

- **No reporting responsibility.** If Entity B acquired the drug and the price of the drug does not meet the reporting criteria on the day the acquiring manufacturer begins to sell the drug, Entity B does not have a reporting responsibility related to the drug acquisition. However, future price increases may trigger required reporting for Entity B.
- **Reporting responsibility on acquisition only.** If Entity A was responsible for the full price increase that meets the reporting criteria on the day Entity B begins to sell the drug, Entity B is responsible for reporting only the elements on drug acquisition noted in the Prescription Drug Price Increase reporting (Item 21 in the Form and Manner section titled Prescription Drug Price Increase Reporting).
    - For example, assume Entity A increased the price of a drug to amount that meets reporting criteria before selling the drug to Entity B. In this situation, Entity A is responsible for reporting price increase data no later than 60 days after the price increase. Entity B is only responsible for reporting new acquisition data (Item 21), unless Entity B separately increased the price by an amount that meets price increase reporting criteria on or before the date Entity B began to sell the drug.
- **Reporting responsibility on price increase and acquisition.** If Entity B acquired and increased the price to an amount that meets the reporting criteria on or before the date the acquiring manufacturer begins to sell the drug, Entity B has the responsibility for

Prescription Drug Price Increase reporting, including data on the drug acquisition (MN Statutes 62J.84, subds. 3 and 5).

- **Note:** This responsibility applies even if Entity A was partially responsible for the price increase. To illustrate, Entity A owned a drug and increased the price by an amount that does not meet price increase reporting criteria before selling the drug to Entity B. On or before the date Entity B began to sell the drug, Entity B further increased the price to an amount that meets price increase reporting criteria. If each of Entity A's and Entity B's price increases occurred within the applicable 12- or 24-month reporting window, Entity B is responsible for reporting all price increase and newly acquired drug data. (MN Statutes 62J.84, subds. 3 and 5).

Does a manufacturer have to submit data after acquiring an existing drug?

If the acquiring manufacturer increased the price of the drug to an amount that meets the price increase criteria on or before the date the acquiring manufacturer begins to sell the drug, the acquiring manufacturer must report all data required by this section, even if the selling manufacturer was partially responsible for the price increase. However, the acquiring manufacturer is only required to report the data elements specified in Item 21 in the Form and Manner section titled Prescription Drug Price Increase Reporting if the selling manufacturer was responsible for the full price increase that meets the above criteria.

Please reference Scenario 3 of the previous question on manufacturer relationships.

Is an existing drug with a new labeler code considered a new drug if it is the same drug?

No. Please reference the Form and Manner document for the definition of a new prescription drug.

Do price increases for biosimilars trigger price increase reporting?

No. Currently, biosimilars only trigger reporting if they meet the triggers for New Prescription Drug Price reporting when they are first introduced for sale in the United States (MN Statutes 62J.84, subd. 4).

What is the minimum price threshold for reporting for new drugs?

One of the criteria for requiring reporting on new prescription drugs is based on the Centers for Medicare and Medicaid Services Specialty Drug tier threshold for Medicare Part D. This amount is $830 as of January 1, 2022; this threshold will change as the Specialty Drug tier threshold is updated in the future.

Manufacturers of a brand drug with a price greater than the Medicare Part D Specialty Drug threshold on the day the manufacturer introduces the drug for sale in the United States must report on that drug.

Manufacturers must report for a generic or biosimilar drug with a price greater than the Medicare Part D Specialty Drug threshold that is not at least 15 percent lower in price than the price of the referenced brand drug on the day the manufacturer introduces the drug for sale in the United States.

Data Definitions and Data Elements

How is the price increase calculated?

To assess reporting responsibility for a given price increase to a brand name drug, a manufacturer should reference the new price increase against the price for that drug 12 and 24 months prior to determine whether the change meets the price increase criteria (i.e., increases of 10 percent or more over 12 months, or 16 percent or more over 24 months). For example, a price increase to a brand name drug that occurs on January 1, 2022, should be compared against the price of the drug on January 1, 2021, and January 1, 2020. For price increases involving generic drugs, the manufacturer should only reference the previous 12-month period to determine whether the change meets price increase criteria (i.e., increases of 50 percent or more over that 12-month period).

If a manufacturer acquires a drug, the process for calculating a price increase remains the same: the price on the first day the manufacturer sells the drug should be compared to the price of the drug at the applicable 12- and/or 24-month prior to the price increase.

What is the "purchase price" of a newly acquired drug?

The "purchase price" is the amount the acquiring manufacturer paid to purchase the drug from another company (MN Statutes 62J.84, subd. 5(b)(2)). It is not the WAC price of the drug at the time of acquisition.

What timeframe can a manufacturer use to report direct cost and financial assistance data elements in Prescription Drug Prescription Drug Price Increase reporting?

For the data elements on direct costs to manufacture, market, and distribute the drug, as well as the data element on financial assistance provided to consumers, manufacturers have two options. A manufacturer may report the costs it incurred or the assistance it provided either:

- During the 12-month period preceding the price increase; or

- Cumulatively since the direct cost was first incurred, or the financial assistance was first provided.

Manufacturers must specify the method they choose when reporting direct cost and financial assistance information on the MDH reporting system.

What will MDH do with reported data, including direct cost and financial assistance data?

MDH is required to publicly post all reported information online, unless that information meets "trade secret" criteria or is otherwise not public under existing federal or state law. MDH is also required to synthesize the reported information in an annual report to the Minnesota Legislature. To make the information more meaningful and comparable, MDH anticipates annualizing some of the reported information. If a manufacturer reports direct costs or financial assistance information for a period other than the 12 months prior to a price increase or acquisition date, MDH anticipates using the reporting information to generate an estimate of annual spending in the reported category.

What types of financial assistance may be included in the total amount provided to patient assistance programs?

A manufacturer may report any form of financial assistance that it provided directly to consumers of the drug, provided the assistance reduced the out-of-pocket cost of the drug to consumers. Examples of financial assistance may include discounts in price or waiver of charges (based on income, need, drug availability, emergency response, or other factors), rebates, or other similar financial assistance provided directly by the manufacturer. Financial assistance does not include benefits to consumers that are not provided directly by the manufacturer, such as government assistance or other benefits that compensate the manufacturer or consumer for the purpose of reducing out-of-pocket costs to consumers.

Can manufacturers submit general comments or additional information to explain a price increase, or the price of a new or acquired drug?

In the context of price increases, manufacturers are required to describe and support the factors leading to the price increase. For all reporting, including price increase reporting, manufacturers also have the option to submit additional information and documentation that may explain or relate to the report.