DEPARTMENT OF HEALTH

Form and Manner for Prescription Drug Price Data Sets

WORKING DRAFT, UPDATED AUGUST 27, 2021

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Overview

This draft Form and Manner document sets forth a set of initial provisions for filing prescription drug price data sets from Prescription Drug Manufacturers with the Minnesota Department of Health (MDH) as required by Minnesota Statutes Section 62J.84, the Minnesota Prescription Drug Price Transparency Act (Act).

This document addresses:

- Identification of organizations required to register and report;
- Description of statutory requirements for the content and time frame for filing prescription drug price data; and
- Establishment of format and manner for the data reported.

MDH is in the process of seeking feedback on this draft document. As the agency moves forward with establishing requirements, we will update this document and make available opportunities for further feedback. Provisions not covered in this draft include:

- Private data and Trade Secrets
- Method of Submission
- Description of statutory enforcement and compliance measures.

Abbreviations

Act – The Minnesota Prescription Drug Price Transparency Act

FDA – The federal Food and Drug Administration

MDH – The Minnesota Department of Health, the public health agency in Minnesota responsible for implementing the Prescription Drug Price Transparency Act (www.health.state.mn.us)

NDC – National Drug Code

NPTS – Non-Public or Trade Secret

WAC – Wholesale Acquisition Cost

Definitions

Unless the context indicates otherwise, the following words and phrases shall have the meanings provided below:

"**30-Day Supply**" means 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.

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"**Biosimilar Drug**" means a Prescription Drug that is produced or distributed pursuant to a biologics license application approved under United States Code, title 42, section 262(K)(3).

"**Brand Name Drug**" means a 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 42, section 262(a)(c).

"**Course of Treatment**" means 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.

"**Generic Drug**" means a 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.

"**Manufacturer**" means an entity licensed to act as a drug manufacturer in the State of Minnesota under Section 151.252.

"**National Drug Code (NDC)**" means 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.

"**New Prescription Drug**" means a 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.

"**Nonproprietary Name**" means the generic name assigned by the United States Adopted Names (USAN) Council.

"**Patient Assistance Program**" means a 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.

"**Prescription Drug**" means a drug for human use subject to United States Code, title 21, section 353(b)(1).

"**Price**" is the wholesale acquisition cost (WAC) of a drug or biological, which means the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

Registration

Prior to filing a report as required under subdivisions 3, 4, and 5 of the Act, a Manufacturer must register on the MDH website using the yet to be established data submission portal.

Notwithstanding the requirements of the Act, all Manufacturers are encouraged to register with MDH to enable reception of periodic communications from the department.

To register, a Manufacturer must provide the following information:

(1) Manufacturer name

(2) Business address

(3) Business phone number

(4) The name and title of an individual authorized by the Manufacturer to receive communications from MDH regarding compliance with the Act, and the following information for the authorized individual:

  (A) Business mailing address

  (B) Business email address

  (C) Business phone number

A Manufacturer must update the Manufacturer's registration each time there is a change to any of the information specified above. Any required update must be made prior to submitting data required by the Act.

Submission Requirements

Beginning January 1, 2022, Manufacturers must submit to MDH timely, accurate, and complete prescription drug price data or data sets in accordance with the requirements of the Act. Manufacturers must certify the accuracy and completeness of any submissions to MDH, including those made by corporate entities, their subsidiaries, and contractors or other third parties engaged to submit information on the Manufacturer's behalf. Manufacturers may also submit additional documentation and information necessary to support the submissions required under the Act.

This section details separate submission requirements for:

1. Existing and Newly Acquired Prescription Drugs with certain levels of prices and increases in prices; and
2. New Prescription Drugs with certain levels of prices at introduction for sale in the United States.

Prescription Drug Price Increase Reporting[1]

A Manufacturer is required to submit data to MDH for each Prescription Drug for which:

(1) the Price was $100 or greater for a 30-Day Supply or for a Course of Treatment lasting less than 30 days; and

(2) there is a Price increase:

(A) of a Brand Name Drug of:

i. 10 percent or more over the previous 12-month period; or

ii. 16 percent or more over the previous 24-month period

(B) of a Generic Drug of 50 percent or more over the previous 12-month period

Data must be submitted by 11:59PM, Central Time no later than 60 days after the Price increase goes into effect, or 60 days after the acquiring Manufacturer begins to sell the drug if only reporting data elements under item 21 of this section. [2] The data submission must include the following information:

(1) Identification of the drug, including:

(A) The NDC of the drug

[1] Includes newly acquired prescription drug price reporting to consolidate reporting of price increase and newly acquired prescription drug reporting, when applicable.

[2] The acquiring Manufacturer is only required to report the data elements specified in item 21 of this section if the selling manufacturer was responsible for the full price increase that meets the above criteria. However, 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.

(B) Description of the drug to include the following:

i. Product name

ii. Dosage form

iii. Strength

iv. Package size

(2) Effective date of Price increase

(3) Price after the Price increase

(4) Percent increase over previous Price

(5) Factors that contributed to the Price increase

(6) Nonproprietary Name of any generic version of the drug available on the market

(7) Price of the drug at introduction to market

(8) Year of introduction to market

(9) 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:

a. During the 12-month period preceding the Price increase; or

b. Cumulatively since the direct cost was first incurred

(11) Direct costs incurred by the manufacturer to market the drug

a. During the 12-month period preceding the Price increase; or

b. Cumulatively since the direct cost was first incurred

(12) Direct costs incurred by the manufacturer to distribute the drug:

a. During the 12-month period preceding the Price increase; or

b. Cumulatively since the direct cost was first incurred

(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

(15) Total amount of financial assistance the manufacturer has provided through Patient Assistance Programs:

a. During the 12-month period preceding the Price increase; or

b. Cumulatively since the financial assistance was first provided

(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 Wholesale Acquisition Cost (WAC) equivalent in the country and be expressed in dollars according to the exchange rate on the day the report is submitted.

(21) If the Manufacturer acquired a drug and the Price meets the above reporting criteria on the day the manufacturer begins to sell the drug, the Manufacturer must report the following information:

(A) Price at acquisition

(B) Price 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 Field)

(23) Any documentation necessary to support the data submitted for the drug, if applicable (Optional Field)

(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, as described in greater detail in the Private Data and Trade Secrets section, below.

New Prescription Drug Price Reporting

A Manufacturer is required to submit data to MDH for each Prescription Drug that the Manufacturer introduces for sale in the United States where the Price at introduction is greater than the tier threshold established by the Centers for Medicare and Medicaid Services for specialty drugs in the Medicare Part D program for a 30-Day Supply for:

(1) a Brand Name Drug

(2) a Generic Drug or Biosimilar Drug where the Price at introduction is not at least 15 percent less than a referenced Brand Name Drug having the same package size as the Generic Drug or Biosimilar Drug; or, where no package size equivalent is available, the Price at introduction for the smallest dispensable amount (e.g., one pill, tablet, vial, milliliter) of the Generic Drug or Biosimilar Drug is not at least 15 percent less than the lowest cost of the smallest dispensable amount of a referenced Brand Name Drug.

Data must be submitted by 11:59PM, Central Time no later than 60 days after the drug is introduced for sale in the United States. The data submission must include the following information:

(1) Identification of the drug, including:

  (A) The 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) Price of the drug at introduction to market

(4) Whether the FDA granted the drug a breakthrough therapy designation or priority review

(5) Direct costs incurred to by the manufacturer to manufacture the drug

(6) Direct costs incurred by the manufacturer to market the drug, including advertising costs

(7) Direct costs incurred by the manufacturer to distribute the drug

(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 Field)

(10) Any documentation necessary to support the data submitted for the drug, if applicable (Optional Field)

(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, as will be described in greater detail in the Private Data and Trade Secrets section, below.

Private Data and Trade Secrets [In Development]

The Commissioner is not permitted to publicly post certain manufacturer data – including "not public data" and "trade secret information" – provided to MDH under the Act. Manufacturers are responsible for identifying this information at the time of submission, and further guidance on the topic of designating data as not public or trade secret is forthcoming.

Method of Submission [In Development]

Data required under subdivisions 3, 4, and 5 of the Act shall be submitted to MDH using the yet to be established data submission portal.

MDH is required to establish data collection processes for Manufacturer reporting and will provide data submission guidance as processes are established.

Compliance Enforcement [In Development]

MDH is required to follow the process for issuing administrative penalty orders in Minnesota Statutes, section 144.99, subdivision 4 when a manufacturer fails to comply with the requirements of the Act. In addition, the Act requires the Commissioner to adopt a schedule of civil penalties, which MDH will provide when available. 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*.

Appendix A – Prescription Drug Price Increase Data Specifications [In Development]

Appendix B – New Prescription Drug Price Data Specifications [In Development]

Appendix C – Instruction Guide on Registration, Prescription Drug Price Increase Reporting, and New Prescription Drug Price Reporting [In Development]

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