DEPARTMENT OF HEALTH

Form and Manner for Prescription Drug Price Data Sets

WORKING DRAFT, UPDATED NOVEMBER 18, 2021

Table of Contents

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, MDH will update this document with further feedback. Provisions not covered in this draft include:

- Method of Submission
- Data Specifications

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.

"**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.

"Not public data," meaning any data that is "classified by statute, federal law, or temporary classification as confidential, private, nonpublic, or protected nonpublic."

"**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.

"Trade secret information" belonging to the Manufacturer is defined under Minnesota and Federal Law.

- **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.

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

(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

[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.

(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.

Not Public Data and Trade Secrets

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.

Written Statement Content

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.

Trade Secret Data

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.
- 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: As described under the previous heading titled "MDH Evaluation and Decision," MDH may publish data the Manufacturer has designated as not public 30-days after sending a notice of intent to publish the data.

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

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 Orders

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.

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 Penalties

Except in the case of repeated or serious violations (see below section for more information on these 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.

Repeated and Serious Violations—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.

For more information about serious or repeated violations, see the MDH APO Plan (https://www.health.state.mn.us/communities/environment/local/docs/ehcib/apoplan2010.pdf).

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, which are summarized below.

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 below. 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 factors below).

- **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.

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]