DEPARTMENT OF HEALTH

Form and Manner for Prescription Drug Data Sets

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Table of Contents

Overview 3
Abbreviations 3
Definitions 3
Registration 6
Submission Requirements 7
Prescription Drug Price Growth Reporting 7
New Prescription Drug Price Reporting 9
Prescription Drugs of Substantial Public Interest Reporting 10
    Manufacturer Reporting 11
    Pharmacy Reporting 13
    Pharmacy Benefit Manager Reporting 14
    Wholesaler Reporting 15
Not Public Data and Trade Secret 16
    Process for Identifying Not Public Data or Trade Secret 16
    MDH Decision 18
    Procedures for Disputing an MDH Data Decision 18
Method of Submission 19
Compliance Enforcement 20
    Administrative Penalty Orders 20
    Forgivable Penalties 21
    Repeated and Serious Violations—Non-Forgivable Penalties 21
    Calculation of Penalty Amount 21
    Penalty Due Dates 21
    Expedited Administrative Hearing 22
Appendix A – Prescription Drug Price Growth Data Specifications 23

Appendix B – New Prescription Drug Price Data Specifications 33
Appendix C – Prescription Drugs of Substantial Public Interest Reporting (Manufacturer) 34
Appendix D – Prescription Drugs of Substantial Public Interest Reporting (Pharmacy) 44
Appendix E – Prescription Drugs of Substantial Public Interest Reporting (PBM) 46
Appendix F – Prescription Drug of Substantial Public Interest Reporting (Wholesaler) 48

Overview

This Form and Manner document sets forth provisions for filing Prescription Drug data sets from Prescription Drug Manufacturers, Pharmacies, Pharmacy Benefit Managers (PBMs), and Wholesale Drug Distributors (collectively, "Reporting Entities"), with the Minnesota Department of Health (MDH) as required by the Minnesota Prescription Drug Price Transparency Act (Act), specifically Minnesota Statutes,section 62J.84.

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 data.
- Establishment of format and manner for the data reported.

Abbreviations

The 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 – Not Public Data or Trade Secret

PBM – Pharmacy Benefit Manager

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) a 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.

"**Drug Product Family**" means a group of one or more Prescription Drugs that share a unique generic drug description or nontrade name and dosage form.

"**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" or "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"(zero) 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.

"**Pharmacy**" or "**Pharmacy Provider**" means a community/outpatient pharmacy as defined in Minnesota Rules, part 6800.0100, subpart 2, that is also licensed as a pharmacy by the Board of Pharmacy under section 151.19.

"**Pharmacy Benefit Manager**" or "**PBM**" means an entity licensed to act as a pharmacy benefit manager under section 62W.03.

"**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.

"**Pricing Unit**" means the smallest dispensable amount of a Prescription Drug product that could be dispensed.

"**Rebate"** means a discount, chargeback, or other price concession that affects the price of a Prescription Drug product, regardless of whether conferred through regular aggregate payments, on a claim-by-claim basis at the point of sale, as part of retrospective financial reconciliations, including reconciliations that also reflect other contractual arrangements, or by any other method. "Rebate" does not mean a bona fide service fee as defined in Code of Federal Regulations, title 42, section 447.502.

"**Reporting Entity**" means any manufacturer, pharmacy, pharmacy benefit manager, wholesale drug distributor, or any other entity required to submit data under this section.

"**Trade Secret**" belonging to a Reporting Entity is defined under Minnesota and Federal Law.

1. 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.

2. 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.

   (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.

"**Wholesale drug distributor**" or "**Wholesaler**" means an entity that:

(1) is licensed to act as a wholesale drug distributor under section 151.47.

(2) distributes Prescription Drugs, for which it is not the manufacturer, to persons or entities, or both, other than a consumer or patient in the state.

Registration

Beginning January 1, 2024, all Reporting Entities who have not yet registered on the MDH website are required to register to the Minnesota Rx Data Portal on the MDH website (https://rxpt.health.mn.gov).

To register, a Reporting Entity must provide the following information:

(1) Reporting Entity name

(2) Business address

(3) Business phone number

(4) The name and title of an individual authorized by the Reporting Entity 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 Reporting Entity must update its registration each time there is a change to any of the information specified above. Reporting Entities are strongly encouraged to add two or more individuals when registering to ensure continuity of access and prevent delays.

Submission Requirements

Reporting Entities must submit to MDH timely, accurate, and complete Prescription Drug data sets in accordance with the requirements of the Act. Reporting Entities 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 Reporting Entity's behalf. Reporting Entities may also submit additional documentation and information necessary to support the submissions required under the Act.

This section details separate submission requirements for:

1. Manufacturer reporting related to existing Prescription Drugs with certain levels of Prices and increases in Prices.
2. Manufacturer reporting related to New Prescription Drugs with certain levels of Prices at introduction for sale in the United States.
3. Reporting Entity reporting related to Prescription Drugs of Substantial Public Interest as determined by MDH and posted on the MDH website at Prescription Drug Price Transparency Public Interest Drug Lists (https://www.health.state.mn.us/data/rxtransparency/pilists.html) .

Prescription Drug Price Growth Reporting

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% or more over the previous 12-month period; or

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

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

Data must be submitted by 11:59 p.m., Central Time no later than 60 days after the Price increase goes into effect. 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) Price of the drug at introduction for sale in the United States.

(3) Year of introduction to market.

(4) Price of the drug on the last day of each of the five calendar years preceding the Price increase.

(5) Any agreement between a Manufacturer and any other entity contingent upon any delay in offering to market a generic or biosimilar version of the drug.

(6) Patent expiration date of the drug if it is under patent.

(7) If the Prescription Drug was acquired by the Manufacturer during the 12-month period prior to the Price Increase, 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

(8) Effective date of Price increase.

(9) Price after the Price increase.

(10) Percent increase over previous Price.

(11) Factors that contributed to the Price increase.

(12) Nonproprietary Name of any generic or biosimilar version of the drug available on the market.

(13) Direct costs incurred by the Manufacturer to manufacture the drug during the 12-month period preceding the Price increase.

(14) Direct costs incurred by the Manufacturer to market the drug during the 12-month period preceding the Price increase.

(15) Direct costs incurred by the Manufacturer to distribute the drug during the 12-month period preceding the Price increase.

(16) The Manufacturer’s total gross revenue from sales of the drug during the 12-month period preceding the Price increase.

(17) The Manufacturer's net profit attributable to the drug during the 12-month period preceding the Price increase.

(18) Total amount of financial assistance the Manufacturer has provided through Patient Assistance Programs during the 12-month period preceding the Price increase.

(19) Name of the company that manufactured the drug.

(20) Location of the company that manufactured the drug.

(21) If a Brand Name Drug, the highest price paid for the Prescription Drug during the calendar year prior to the Price Increase in the 10 countries, excluding the United States, that charged the highest single price for the Prescription Drug. 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.

(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 Not Public 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 or for a Course of Treatment lasting fewer than 30 days for:

(1) a Brand Name Drug.

(2) a Generic Drug or Biosimilar Drug where the Price at introduction is not at least 15% 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% less than the lowest cost of the smallest dispensable amount of a referenced Brand Name Drug.

Data must be submitted by 11:59 p.m., 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 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 Not Public Data and Trade Secrets section, below.

Prescription Drugs of Substantial Public Interest Reporting

No later than January 31, 2024, and quarterly thereafter, MDH will produce and post on its website at Prescription Drug Price Transparency Public Interest Drug Lists(https://www.health.state.mn.us/data/rxtransparency/pilists.html) a list of Prescription Drugs that MDH determines to represent a substantial public interest and for which Prescription Drug data sets must be submitted by Reporting Entities. MDH will base its inclusion of Prescription Drugs on any information MDH determines is relevant to providing greater consumer awareness of the factors contributing to the cost of Prescription Drugs in the state. MDH will not designate more than 500 Prescription Drugs as having a substantial public interest in any notice period.

In determining the list of Prescription Drugs of substantial public interest, MDH will consider Drug Product Families that include Prescription Drugs:

(1) that triggered Manufacturer Price Growth or New Prescription Drug reporting during the previous calendar quarter

(2) for which average claims paid amounts exceeded 125%of the Price as of the claim incurred date during the most recent calendar quarter for which claims paid amounts are available; or

(3) that are identified by members of the public during a public comment process.

Not sooner than 30 days after publicly posting the list of Prescription Drugs, MDH will notify, via email, Reporting Entities registered with MDH of the requirement to report.

For each drug identified, data must be submitted by 11:59 p.m., Central Time, no later than 60 days after the date of the notification to report. The data submission must include the information specified for each type of Reporting Entity in the sections that follow.

Manufacturer Reporting

Manufacturers must submit to MDH the information specified below for any Prescription Drug included in a notification to report issued to the Manufacturer which or for which the Manufacturer:

(1) manufactures or repackages.

(2) sets the wholesale acquisition cost.

(3) has not submitted a Price Growth report during the 120-day period prior to the date of the notification to report.

Manufacturer Prescription Drugs of Substantial Public Interest data elements:

(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) Baseline Price, which is the price of the drug product on the later of:

  (A) The day one year prior to the date of the notification to report

  (B) The introduced to market date; or

  (C) The acquisition date

(3) Price of the drug product on the date of the notification to report.

(4) Direct costs incurred by the Manufacturer for manufacturing the drug during the 12-month period prior to the date of the notification to report.

(5) Direct costs incurred by the Manufacturer for marketing the drug during the 12-month period prior to the date of the notification to report.

(6) Direct costs incurred by the Manufacturer for distributing the drug during the 12-month period prior to the date of the notification to report.

(7) Number of units of the drug sold by the Manufacturer during the 12-month period prior to the date of the notification to report.

(8) The Manufacturer's total gross revenue from sales during the 12-month period prior to the date of the notification to report.

(9) Total Rebate payable amount accrued during the 12-month period prior to the date of the notification to report.

(10) The Manufacturer's net profit attributable to the drug during the 12-month period prior to the date of the notification to report.

(11) Total amount of financial assistance the Manufacturer has provided through Patient Assistance Programs during the 12-month period prior to the date of the notification to report.

(12) Price of the drug at introduction for sale in the United States.

(13) Year of introduction to market.

(14) Price of the drug on the last day of each of the five calendar years preceding the date of the notification to report.

(15) Any agreement between a Manufacturer and any other entity contingent upon any delay in offering to market a generic or biosimilar version of the drug.

(16) Patent expiration date of the drug if it is under patent.

(17) Name of the company that manufactured the drug.

(18) Location of the company that manufactured the drug.

(19) If a Brand Name Drug, the highest price paid for the Prescription Drug during the calendar year prior to the Price Increase in the 10 countries, excluding the United States, that charged the highest single price for the Prescription Drug. 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.

(20) If the Prescription Drug was acquired by the Manufacturer during the 12-month period prior to the date of the notification to report, 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

(21) General comments and/or additional information related to the data submitted for the drug, if applicable (optional field).

(22) Any documentation necessary to support the data submitted for the drug, if applicable (optional field).

(23) 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 Not Public Data and Trade Secrets section, below.

Pharmacy Reporting

Pharmacies must submit to MDH the information specified below for any Prescription Drug included in a notification to report issued to the Pharmacy. Where a Pharmacy has not acquired or dispensed a drug included in a notification to report during the 12-month period prior to the date of the notification, the Pharmacy should provide zero (0) values for all related data fields.

MDH may grant extensions and/or exemptions to a Pharmacy's requirement to report under this section for small or independent pharmacies if data reporting would represent a hardship or undue burden to the Pharmacy. Pharmacies request extensions and/or exemptions through the data submission portal.

All exemption or extension requests should be submitted 20 calendar days in advance of the reporting deadline to provide adequate time for review.

Pharmacy Prescription Drugs of Substantial Public Interest data elements:

(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) Number of units of the drug acquired by the Pharmacy during the 12-month period prior to the date of the notification to report.

(3) The total spent before Rebates by the Pharmacy to acquire the drug during the 12-month period prior to the date of the notification to report.

(4) The total Rebate receivable amount accrued by the Pharmacy for the drug during the 12-month period prior to the date of the notification to report.

(5) The number of Pricing Units of the drug dispensed by the Pharmacy during the 12-month period prior to the date of the notification to report.

(6) The total payment receivable amount accrued by the Pharmacy for dispensing the drug—including ingredient cost, dispensing fee, and administrative fees—during the 12-month period prior to the date of the notification to report

(7) The total Rebate payable amount accrued by the Pharmacy for the drug during the 12-month period prior to the date of the notification to report.

(8) The average cash price paid by consumers to the Pharmacy per pricing unit for prescriptions dispensed where no claim was submitted to a health care service plan or health insurer during the 12-month period prior to the date of the notification to report.

(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 described in greater detail in the Not Public Data and Trade Secrets section, below.

Pharmacy Benefit Manager Reporting

PBMs must submit to MDH the information specified below for any Prescription Drug included in a notification to report issued to the PBM. Where a PBM has not administered claims for a drug included in a notification to report during the 12-month period prior to the date of the notification, the PBM should provide zero values for all related data fields.

PBM Prescription Drugs of Substantial Public Interest data elements:

(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) The number of Pricing Units of the drug product filled for which the PBM administered claims during the 12-month period prior to the notification to report.

(3) The total reimbursement amount accrued and payable to pharmacies for pricing units of the drug product filled for which the PBM administered claims during the 12-month period prior to the notification to report.

(4) The total reimbursement or administrative fee amount, or both, (the PBM must submit data for both components as applicable) accrued and receivable from payers for pricing units of the drug product filled for which the PBM administered claims during the 12-month period prior to the notification to report.

(5) The total Rebate receivable amount accrued by the PBM for the drug product during the 12-month period prior to the notification to report.

(6) The total Rebate payable amount accrued by the PBM for the drug product during the 12-month period prior to the notification to report.

(7) General comments and/or additional information related to the data submitted for the drug, if applicable (optional field).

(8) Any documentation necessary to support the data submitted for the drug, if applicable (optional field).

(9) 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 Not Public Data and Trade Secrets section, below.

Wholesaler Reporting

Wholesalers must submit to MDH the information specified below for any Prescription Drug included in a notification to report issued to the Wholesaler. Where a Wholesaler has not acquired or sold a drug included in a notification to report during the 12-month period prior to the date of the notification, the Wholesaler should provide zero (0) values for all related data fields.

Wholesaler Prescription Drugs of Substantial Public Interest data elements:

(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) Number of units of the drug acquired by the Wholesaler during the 12-month period prior to the date of the notification to report.

(3) The total spent before Rebates by the Wholesaler to acquire the drug during the 12-month period prior to the date of the notification to report.

(4) The total Rebate receivable amount accrued by the Wholesaler for the drug during the 12-month period prior to the date of the notification to report.

(5) Number of units of the drug sold by the Wholesaler during the 12-month period prior to the date of the notification to report.

(6) The Wholesaler's gross revenue from sales in the United States during the 12-month period prior to the date of the notification to report.

(7) The total Rebate payable amount accrued by the Wholesaler for the drug during the 12-month period prior to the date of the notification to report.

(8) General comments and/or additional information related to the data submitted for the drug, if applicable (optional field).

(9) Any documentation necessary to support the data submitted for the drug, if applicable (optional field).

(10) 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 Not Public Data and Trade Secrets section, below.

Not Public Data and Trade Secret

To increase transparency into the pricing of Prescription Drugs, MDH is required to publicly post the information reported by Reporting Entities, except data classified by law and defined above as Not Public Data or Trade Secret (NPTS).

Reporting Entities are responsible for submitting Not Public Data or Trade Secret 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 Reporting Entity submissions and applicable law to determine whether data must be withheld.

This section provides guidance on:

1. The process for identifying and the required content of a Reporting Entity statement identifying Not Public Data or Trade Secret.
2. MDH decision and notice requirements.
3. Due process measures available to challenge MDH data determinations.

Process for Identifying Not Public Data or Trade Secret

To designate data as protected from public disclosure, a Reporting Entity must check the box next to the data element that the Reporting Entity asserts is Not Public Data or Trade Secret.

Upon clicking the "NPTS" checkbox next to the correlating data element, the Reporting Entity will be directed to submit a written statement and will also be provided the option to upload documentation that discusses the Reporting Entity's assertion of Not Public Data or Trade Secret.

If uploading data to the data submission portal using a template, a Reporting Entity must provide indication of Not Public Data or Trade Secret by typing the value "1" in the corresponding NPTS column that immediately follows the column for each data element. After templates are processed, users must assign written statements and will also be provided the option to upload documentation that discusses the Reporting Entity's assertion of Not Public Data or Trade Secret for each data element that was identified as Not Public Data or Trade Secret.

Content of Written Statement

Not Public Data

A Reporting Entity must clearly and specifically identify any Not Public Data in its written submission to MDH. A Reporting Entity 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 Reporting Entity'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 other relevant legal authority, as necessary. The Reporting Entity's description should also include any documentation or evidence necessary to allow MDH to make a final determination.

Trade Secret

For Trade Secret designations, the Reporting Entity must demonstrate all of the following in its written statement:

1. That the Reporting Entity supplying the claimed Trade Secret data is the owner of the data.
2. The Reporting Entity's efforts to maintain the secrecy of the data, including an explanation of why the Reporting Entity believes such efforts to be reasonable under the circumstances and industry practice.
3. The potential or actual economic value the Reporting Entity 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.
4. 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 Reporting Entity should explain who has access to the data and why the Reporting Entity believes the data remains protected from those who could derive its economic value.
5. Citations to any legal authority relied upon by the Reporting Entity.
6. Any other information the Reporting Entity believes is relevant or necessary under federal or state Trade Secret law.

*****All Not Public Data or Trade Secret claims made by a Reporting Entity must be made via the "NPTS" checkbox next to the correlating data element (or in the case of a template upload, through indication in the corresponding NPTS column), which then automatically prompts the Reporting Entity to upload its written statement and supporting documentation.**

MDH Decision

MDH reviews all Not Public Data or Trade Secret assertions made by Reporting Entities based on the criteria above. MDH maintains all claimed Not Public Data or Trade Secret data as not public unless MDH disagrees with the Reporting Entity's Not Public Data or Trade Secret assertion(s) and follows the 30-day notice process below.

MDH will base each decision on the Reporting Entity's complete submission and applicable legal authority. MDH will withhold data when a Reporting Entity has demonstrated by a preponderance of the evidence (i.e., more likely than not) that the data is Not Public Data.

30-day Notice Process

If MDH disagrees with the Reporting Entity's Not Public Data or Trade Secret assertion(s), MDH must provide the Reporting Entity written notice that the data will be publicly posted 30 days after the date of the notice. The notice to the Reporting Entity will include a written explanation of MDH's decision.

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 Reporting Entity files an MGDPA challenge to an MDH decision to publish data over a Reporting Entity designation, MDH may continue to withhold data that has not been published until the challenge is resolved.

Note: MDH may publish data the Reporting Entity has designated as not public 30 days after sending a notice of intent to publish the data.

Method of Submission

Data required under the Act shall be submitted to MDH using the Prescription Drug data submission portal (https://rxpt.health.mn.gov).

Data must be submitted using one of the following methods:

(1) Uploading an MDH-provided Excel (.xlsx) template that includes all required information in the format specified in:

  (A) Appendix A (Prescription Drug Price Increase Data Specifications).

  (B) Appendix B (New Prescription Drug Price Data Specifications).

  (C) Appendix C [Prescription Drugs of Substantial Public Interest Reporting (Manufacturer)].

  (D) Appendix D [Prescription Drugs of Substantial Public Interest Reporting (Pharmacy)].

  (E) Appendix E [Prescription Drugs of Substantial Public Interest Reporting (PBM)].

  (F) Appendix F [Prescription Drugs of Substantial Public Interest Reporting (Wholesaler)].

  Templates should be downloaded from the data submission portal.

(2) Individually entering each required data field directly into the data submission portal.

Reporting Entities that indicate the existence of an agreement between a Reporting Entity and any other entity contingent upon any delay in offering to market a generic or biosimilar version of the drug will be required to upload any such agreements for each applicable NDC to the data submission portal.

As discussed in the Not Public Data and Trade Secrets section of this document, Reporting Entities that identify specific data points that should not be publicly disclosed will be required to enter a written statement supporting that position for each NDC-specific data field within the data submission portal.

Additionally, Reporting Entities have the option of uploading any documentation necessary to support data submitted for a drug within the data submission portal.

A user guide is available to assist users to navigate the data submission portal and posted on the Minnesota Prescription Drug Price Transparency website (https://www.health.state.mn.us/data/rxtransparency).

Compliance Enforcement

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

(1) failing to register on the MDH Rx Data Portal (https://rxpt.health.mn.gov).

(2) failing to submit timely reports or notices as required by the Act.

(3) failing to provide information required under the Act.

(4) 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.

The section below describes the MDH Administrative Penalty Order (APO) process.

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 (PDF) (https://www.health.state.mn.us/communities/environment/local/docs/ehcib/apoplan2010.pdf).

An APO issued to a Reporting Entity 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.
- A statement of the Reporting Entity'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 Reporting Entity receives an APO requiring corrective action, the Reporting Entity must submit information to MDH demonstrating that the violation has been corrected or that the Reporting Entity has developed a corrective plan. MDH will determine whether the violation has been corrected (or, where applicable, whether a corrective plan is acceptable) and notify the Reporting Entity of MDH's determination.

Forgivable Penalties

Except in the case of repeated or serious violations (see Repeated and Serious Violations section below for more information on these violations), the penalty assessed in the APO must be forgiven if the Reporting Entity demonstrates in writing to MDH within 30 days after receiving the APO that the Reporting Entity has corrected the violation or has developed a corrective plan acceptable to MDH.

A penalty will not be forgiven if MDH determines that a Reporting Entity 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 Reporting Entity has previously violated one or more sections of the Act; (2) the violation is identical or similar to the previous violation; (3) the previous violation was either cited in a prior APO that is final[1] or—if the prior APO is not final or if no APO was issued—supported by a preponderance of the evidence; and (4) MDH notified the Reporting Entity of the previous violation in writing.

Calculation of Penalty Amount

Penalties are 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.

For more information about serious or repeated violations, and for potential civil penalties that may be imposed, please see the MDH APO Plan (https://www.health.state.mn.us/communities/environment/local/docs/ehcib/apoplan2010.pdf).

Penalty Due Dates

Unless a Reporting Entity 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 Reporting Entity subject to the order fails to provide information to MDH showing that the violation has been

[1] A previous violation is "final" if (1) the APO was not timely appealed or (2) the violation was affirmed on appeal and any appeal rights have been exhausted.

corrected or that appropriate steps have been taken toward correcting the violation; or

(2) on the 20th day after the Reporting Entity receives notice of outstanding corrective action based on MDH's determination that information the Reporting Entity 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 MDH'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 Reporting Entity 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 Reporting Entity describing the process for requesting an expedited administrative hearing. MDH will also notify the Reporting Entity of the time and place of the expedited hearing at least 15 days before the date of the hearing.

Appendix A – Prescription Drug Price Growth Data Specifications

Data Element	Format	Size	Description	Example
NDC	Alphanumeric	11	NDC of the drug	"00000000000"
Drug Description	Alphanumeric	255	Description of the drug to including product name, dosage form, strength, package size	"Drug X Tablets 30MG 30"
WAC at Introduction	Decimal	10,2	WAC price of the drug at introduction for sale in the United States	1000.00
Year of Introduction	Integer	4	Year of introduction to market	2000
WAC Last Day 1 Year Prior	Decimal	10,2	WAC price of the drug on the last day of the year one calendar year preceding the price increase	1000.00
WAC Last Day 1 Year Prior Not Applicable Indicator	Boolean	1	Indication that WAC Last Day 1 year prior is not applicable to this item | 1 = True / 0 = False	1
WAC Last Day 2 Year Prior	Decimal	10,2	WAC price of the drug on the last day of the year two calendar years preceding the price increase	1000.00
WAC Last Day 2 Year Prior Not Applicable Indicator	Boolean	1	Indication that WAC Last Day 2 year prior is not applicable to this item | 1 = True / 0 = False	1
WAC Last Day 3 Year Prior	Decimal	10,2	WAC price of the drug on the last day of the year three calendar years preceding the price increase	1000.00
WAC Last Day 3 Year Prior Not Applicable Indicator	Boolean	1	Indication that WAC Last Day 3 year prior is not applicable to this item | 1 = True / 0 = False	1
WAC Last Day 4 Year Prior	Decimal	10,2	WAC price of the drug on the last day of the year four calendar years preceding the price increase	1000.00
WAC Last Day 4 Year Prior Not Applicable Indicator	Boolean	1	Indication that WAC Last Day 4 year prior is not applicable to this item | 1 = True / 0 = False	1

Data Element	Format	Size	Description	Example
WAC Last Day 5 Year Prior	Decimal	10,2	WAC price of the drug on the last day of the year five calendar years preceding the price increase	1000.00
WAC Last Day 5 Year Prior Not Applicable Indicator	Boolean	1	Indication that WAC Last Day 5 year prior is not applicable to this item | 1 = True / 0 = False	1
Generic Delay Agreement	Boolean	1	Indication of the existence of an agreement between a Manufacturer and any other entity contingent upon any delay in offering to market a generic or biosimilar version of the drug | 1 = True / 0 = False	1
Generic Delay Agreement NPTS Indicator	Boolean	1	Indication that Generic Delay Agreement should not be publicly disclosed | 1 = True / 0 = False	1
Patent Expiration Date	Date	10	Patent expiration date of the drug if it is under patent	12/31/2000
Patent Expiration Date Not Applicable Indicator	Boolean	1	Indication that Patent Expiration Date is not applicable to this item | 1 = True / 0 = False	1
WAC at Acquisition	Decimal	10,2	If the Manufacturer acquired the drug within the 12-month period preceding the price increase, the WAC on the date of acquisition	1000.00
WAC at Acquisition Not Applicable Indicator	Boolean	1	Indication that WAC at Acquisition is not applicable to this item | 1 = True / 0 = False	1
WAC Year Prior to Acquisition	Decimal	10,2	If the Manufacturer acquired the drug within the 12-month period preceding the price increase, the WAC on the date one calendar year prior to the acquisition	1000.00
WAC Year Prior to Acquisition Not Applicable Indicator	Boolean	1	Indication that WAC Year Prior to Acquisition is not applicable to this item | 1 = True / 0 = False	1

Data Element	Format	Size	Description	Example
Company Acquired From	Alphanumeric	255	If the Manufacturer acquired the drug within the 12-month period preceding the price increase, the name of the company from which the drug was acquired	"Company Name"
Company Acquired From Not Applicable Indicator	Boolean	1	Indication that Company Acquired From is not applicable to this item | 1 = True / 0 = False	1
Date of Acquisition	Date	10	If the Manufacturer acquired the drug within the 12-month period preceding the price increase, the date the drug was acquired	12/31/2000
Date of Acquisition Not Applicable Indicator	Boolean	1	Indication that Date of Acquisition is not applicable to this item | 1 = True / 0 = False	1
Acquisition Price	Decimal	14,2	If the Manufacturer acquired the drug within the 12-month period preceding the price increase, the acquisition price of the drug	1000.00
Acquisition Price Not Applicable Indicator	Boolean	1	Indication that Acquisition Price is not applicable to this item | 1 = True / 0 = False	1
Acquisition Price NPTS Indicator	Boolean	1	Indication that Acquisition Price should not be publicly disclosed | 1 = True / 0 = False	1
WAC Effective Date	Date	10	Effective date of WAC increase	12/31/2000
WAC After Increase	Decimal	10,2	WAC after the price increase	1000.00
Percent Increase Over Previous WAC	Decimal	10,4	Percentage increase over previous WAC	0.10
Price Increase Factors	Alphanumeric	8000	Factors that contributed to the price increase	"Supply Disruption"
Price Increase Factors NPTS Indicator	Boolean	1	Indication that Price Increase Factors should not be publicly disclosed | 1 = True / 0 = False	1
Generic Nonproprietary Name	Alphanumeric	255	Nonproprietary Name of any generic or biosimilar version of the drug available on the market, if applicable	"acetaminophen"

Data Element	Format	Size	Description	Example
Manufacturing Cost	Decimal	14,2	Direct costs incurred to manufacture the drug during the 12-month period preceding the price increase	1000.00
Manufacturing Cost NPTS Indicator	Boolean	1	Indication that Manufacturing Cost should not be publicly disclosed | 1 = True / 0 = False	1
Marketing Cost	Decimal	14,2	Direct costs incurred to market the drug, including advertising costs, during the 12-month period preceding the price increase	1000.00
Marketing Cost NPTS Indicator	Boolean	1	Indication that Marketing Cost should not be publicly disclosed | 1 = True / 0 = False	1
Distributing Cost	Decimal	14,2	Direct costs incurred to distribute the drug during the 12-month period preceding the price increase	1000.00
Distributing Cost NPTS Indicator	Boolean	1	Indication that Distributing Cost should not be publicly disclosed | 1 = True / 0 = False	1
Gross Revenue From Sales	Decimal	14,2	Total gross revenue from sales of the drug during the 12-month period preceding the price increase	1000.00
Gross Revenue From Sales NPTS Indicator	Boolean	1	Indication that Gross Revenue From Sales should not be publicly disclosed | 1 = True / 0 = False	1
Net Profit	Decimal	14,2	Net profit attributable to the drug during the 12-month period preceding the price increase	1000.00
Net Profit NPTS Indicator	Boolean	1	Indication that Net Profit should not be publicly disclosed | 1 = True / 0 = False	1
Financial Assistance Provided	Decimal	14,2	Total amount of financial assistance provided through Patient Assistance Programs during the 12-month period preceding the price increase	1000.00
Financial Assistance Provided NPTS Indicator	Boolean	1	Indication that Financial Assistance Provided should not be publicly disclosed | 1 = True / 0 = False	1
Manufacturing Company	Alphanumeric	255	Name of the company that manufactured the drug	"Company Name"

Data Element	Format	Size	Description	Example
Manufacturing Company NPTS Indicator	Boolean	1	Indication that Manufacturing Company should not be publicly disclosed | 1 = True / 0 = False	1
Manufacturing Company Address	Alphanumeric	255	Address of the company that manufactured the drug	"123 Main St., Anytown, MN 00000"
Manufacturing Company Address NPTS Indicator	Boolean	1	Indication that Manufacturing Company Address should not be publicly disclosed | 1 = True / 0 = False	1
Brand Foreign Country 1	Alphanumeric	255	If a Brand Name Drug, the name of the country with the highest price paid for the drug during the calendar year prior to the price increase other than the United States	"Country Name"
Brand Foreign Price 1	Decimal	10,2	If a Brand Name Drug, the highest price paid for the drug during the calendar year prior to the price increase in a country other than the United States. Price should represent the WAC equivalent in the country and be expressed in dollars according to the current exchange rate	1000.00
Brand Foreign Country 1 Not Applicable Indicator	Boolean	1	Indication that Brand Foreign Country 1 is not applicable to this item | 1 = True / 0 = False	1
Brand Foreign Country 1 NPTS Indicator	Boolean	1	Indication that Brand Foreign Country 1 should not be publicly disclosed | 1 = True / 0 = False	1
Brand Foreign Country 2	Alphanumeric	255	If a Brand Name Drug, the name of the country with the second highest price paid for the drug during the calendar year prior to the price increase other than the United States	"Country Name"
Brand Foreign Price 2	Decimal	10,2	If a Brand Name Drug, the second highest price paid for the drug during the calendar year prior to the price increase in a country other than the United States. Price should represent the WAC equivalent in	1000.00

Data Element	Format	Size	Description	Example
			the country and be expressed in dollars according to the current exchange rate	
Brand Foreign Country 2 Not Applicable Indicator	Boolean	1	Indication that Brand Foreign Country 2 is not applicable to this item | 1 = True / 0 = False	1
Brand Foreign Country 2 NPTS Indicator	Boolean	1	Indication that Brand Foreign Country 2 should not be publicly disclosed | 1 = True / 0 = False	1
Brand Foreign Country 3	Alphanumeric	255	If a Brand Name Drug, the name of the country with the third highest price paid for the drug during the calendar year prior to the price increase other than the United States	"Country Name"
Brand Foreign Price 3	Decimal	10,2	If a Brand Name Drug, the third highest price paid for the drug during the calendar year prior to the price increase in a country other than the United States. Price should represent the WAC equivalent in the country and be expressed in dollars according to the current exchange rate	1000.00
Brand Foreign Country 3 Not Applicable Indicator	Boolean	1	Indication that Brand Foreign Country 3 is not applicable to this item | 1 = True / 0 = False	1
Brand Foreign Country 3 NPTS Indicator	Boolean	1	Indication that Brand Foreign Country 3 should not be publicly disclosed | 1 = True / 0 = False	1
Brand Foreign Country 4	Alphanumeric	255	If a Brand Name Drug, the name of the country with the fourth highest price paid for the drug during the calendar year prior to the price increase other than the United States	"Country Name"
Brand Foreign Price 4	Decimal	10,2	If a Brand Name Drug, the fourth highest price paid for the drug during the calendar year prior to the price increase in a country other than the United States. Price should represent the WAC equivalent in	1000.00

Data Element	Format	Size	Description	Example
			the country and be expressed in dollars according to the current exchange rate	
Brand Foreign Country 4 Not Applicable Indicator	Boolean	1	Indication that Brand Foreign Country 4 is not applicable to this item | 1 = True / 0 = False	1
Brand Foreign Country 4 NPTS Indicator	Boolean	1	Indication that Brand Foreign Country 4 should not be publicly disclosed | 1 = True / 0 = False	1
Brand Foreign Country 5	Alphanumeric	255	If a Brand Name Drug, the name of the country with the fifth highest price paid for the drug during the calendar year prior to the price increase other than the United States	"Country Name"
Brand Foreign Price 5	Decimal	10,2	If a Brand Name Drug, the fifth highest price paid for the drug during the calendar year prior to the price increase in a country other than the United States. Price should represent the WAC equivalent in the country and be expressed in dollars according to the current exchange rate	1000.00
Brand Foreign Country 5 Not Applicable Indicator	Boolean	1	Indication that Brand Foreign Country 5 is not applicable to this item | 1 = True / 0 = False	1
Brand Foreign Country 5 NPTS Indicator	Boolean	1	Indication that Brand Foreign Country 5 should not be publicly disclosed | 1 = True / 0 = False	1
Brand Foreign Country 6	Alphanumeric	255	If a Brand Name Drug, the name of the country with the sixth highest price paid for the drug during the calendar year prior to the price increase other than the United States	"Country Name"
Brand Foreign Price 6	Decimal	10,2	If a Brand Name Drug, the sixth highest price paid for the drug during the calendar year prior to the price increase in a country other than the United States. Price should represent the WAC equivalent in	1000.00

Data Element	Format	Size	Description	Example
			the country and be expressed in dollars according to the current exchange rate	
Brand Foreign Country 6 Not Applicable Indicator	Boolean	1	Indication that Brand Foreign Country 6 is not applicable to this item | 1 = True / 0 = False	1
Brand Foreign Country 6 NPTS Indicator	Boolean	1	Indication that Brand Foreign Country 6 should not be publicly disclosed | 1 = True / 0 = False	1
Brand Foreign Country 7	Alphanumeric	255	If a Brand Name Drug, the name of the country with the seventh highest price paid for the drug during the calendar year prior to the price increase other than the United States	"Country Name"
Brand Foreign Price 7	Decimal	10,2	If a Brand Name Drug, the seventh highest price paid for the drug during the calendar year prior to the price increase in a country other than the United States. Price should represent the WAC equivalent in the country and be expressed in dollars according to the current exchange rate	1000.00
Brand Foreign Country 7 Not Applicable Indicator	Boolean	1	Indication that Brand Foreign Country 7 is not applicable to this item | 1 = True / 0 = False	1
Brand Foreign Country 7 NPTS Indicator	Boolean	1	Indication that Brand Foreign Country 7 should not be publicly disclosed | 1 = True / 0 = False	1
Brand Foreign Country 8	Alphanumeric	255	If a Brand Name Drug, the name of the country with the eighth highest price paid for the drug during the calendar year prior to the price increase other than the United States	"Country Name"
Brand Foreign Price 8	Decimal	10,2	If a Brand Name Drug, the eighth highest price paid for the drug during the calendar year prior to the price increase in a country other than the United States. Price should represent the WAC equivalent in	1000.00

Data Element	Format	Size	Description	Example
			the country and be expressed in dollars according to the current exchange rate	
Brand Foreign Country 8 Not Applicable Indicator	Boolean	1	Indication that Brand Foreign Country 8 is not applicable to this item | 1 = True / 0 = False	1
Brand Foreign Country 8 NPTS Indicator	Boolean	1	Indication that Brand Foreign Country 8 should not be publicly disclosed | 1 = True / 0 = False	1
Brand Foreign Country 9	Alphanumeric	255	If a Brand Name Drug, the name of the country with the nineth highest price paid for the drug during the calendar year prior to the price increase other than the United States	"Country Name"
Brand Foreign Price 9	Decimal	10,2	If a Brand Name Drug, the nineth highest price paid for the drug during the calendar year prior to the price increase in a country other than the United States. Price should represent the WAC equivalent in the country and be expressed in dollars according to the current exchange rate	1000.00
Brand Foreign Country 9 Not Applicable Indicator	Boolean	1	Indication that Brand Foreign Country 9 is not applicable to this item | 1 = True / 0 = False	1
Brand Foreign Country 9 NPTS Indicator	Boolean	1	Indication that Brand Foreign Country 9 should not be publicly disclosed | 1 = True / 0 = False	1
Brand Foreign Country 10	Alphanumeric	255	If a Brand Name Drug, the name of the country with the tenth highest price paid for the drug during the calendar year prior to the price increase other than the United States	"Country Name"
Brand Foreign Price 10	Decimal	10,2	If a Brand Name Drug, the tenth highest price paid for the drug during the calendar year prior to the price increase in a country other than the United States. Price should represent the WAC equivalent in	1000.00

Data Element	Format	Size	Description	Example
			the country and be expressed in dollars according to the current exchange rate	
Brand Foreign Country 10 Not Applicable Indicator	Boolean	1	Indication that Brand Foreign Country 10 is not applicable to this item | 1 = True / 0 = False	1
Brand Foreign Country 10 NPTS Indicator	Boolean	1	Indication that Brand Foreign Country 10 should not be publicly disclosed | 1 = True / 0 = False	1
General Comments	Alphanumeric	8000	General comments and/or additional information related to the data submitted for the drug, if applicable	"General Comments"
General Comments NPTS Indicator	Boolean	1	Indication that General Comments should not be publicly disclosed | 1 = True / 0 = False	1

Appendix B – New Prescription Drug Price Data Specifications

Data Element	Format	Size	Description	Example
NDC	Alphanumeric	11	NDC of the drug	"00000000000"
Drug Description	Alphanumeric	255	Description of the drug to including product name, dosage form, strength, package size	"Drug X Tablets 30MG 30"
Date of Introduction	Date	10	Date of introduction for sale in the United States	12/31/2000
WAC at Introduction	Decimal	10,2	WAC price of the drug at introduction to market	1000.00
Breakthrough Therapy Designation	Boolean	1	Indication of whether the drug was granted breakthrough therapy designation by the federal Food and Drug Administration | 1 = True / 0 = False	1
Priority Review	Boolean	1	Indication of whether the drug was granted priority review by the federal Food and Drug Administration | 1 = True / 0 = False	1
Manufacturing Cost	Decimal	14,2	Direct costs incurred to manufacture the drug	1000.00
Manufacturing Cost NPTS Indicator	Boolean	1	Indication that Manufacturing Cost should not be publicly disclosed | 1 = True / 0 = False	1
Marketing Cost	Decimal	14,2	Direct costs incurred to market the drug, including advertising costs	1000.00
Marketing Cost NPTS Indicator	Boolean	1	Indication that Marketing Cost should not be publicly disclosed | 1 = True / 0 = False	1
Distributing Cost	Decimal	14,2	Direct costs incurred to distribute the drug	1000.00
Distributing Cost NPTS Indicator	Boolean	1	Indication that Distributing Cost should not be publicly disclosed | 1 = True / 0 = False	1
Patent Expiration Date	Date	10	Patent expiration date of the drug if it is under patent	12/31/2000
Patent Expiration Date Not Applicable Indicator	Boolean	1	Indication that Patent Expiration Date is not applicable to this item | 1 = True / 0 = False	1
General Comments	Alphanumeric	8000	General comments and/or additional information related to the data submitted for the drug, if applicable	"General Comments"
General Comments NPTS Indicator	Boolean	1	Indication that General Comments should not be publicly disclosed | 1 = True / 0 = False	1

Appendix C – Prescription Drugs of Substantial Public Interest Reporting (Manufacturer)

Data Element	Format	Size	Description	Example
NDC	Alphanumeric	11	NDC of the drug	"00000000000"
Drug Description	Alphanumeric	255	Description of the drug to including product name, dosage form, strength, package size	"Drug X Tablets 30MG 30"
Baseline WAC	Decimal	10,2	WAC price of the drug on the later of: • The day one year prior to the date of the notification to report; • The introduced to market date; or • The acquisition date	1000.00
WAC at Notification	Decimal	10,2	WAC price of the drug product on the date of the notification to report	1000.00
WAC at Introduction	Decimal	10,2	WAC price of the drug at introduction for sale in the United States	1000.00
Year of Introduction	Integer	4	Year of introduction to market	2000
WAC Last Day 1 Year Prior	Decimal	10,2	WAC price of the drug on the last day of the year one calendar year preceding the date of the notification to report	1000.00
WAC Last Day 1 Year Prior Not Applicable Indicator	Boolean	1	Indication that WAC Last Day 1 year prior is not applicable to this item | 1 = True / 0 = False	1
WAC Last Day 2 Year Prior	Decimal	10,2	WAC price of the drug on the last day of the year two calendar years preceding the date of the notification to report	1000.00
WAC Last Day 2 Year Prior Not Applicable Indicator	Boolean	1	Indication that WAC Last Day 2 year prior is not applicable to this item | 1 = True / 0 = False	1
WAC Last Day 3 Year Prior	Decimal	10,2	WAC price of the drug on the last day of the year three calendar years preceding the date of the notification to report	1000.00

Data Element	Format	Size	Description	Example
WAC Last Day 3 Year Prior Not Applicable Indicator	Boolean	1	Indication that WAC Last Day 3 year prior is not applicable to this item | 1 = True / 0 = False	1
WAC Last Day 4 Year Prior	Decimal	10,2	WAC price of the drug on the last day of the year four calendar years preceding the date of the notification to report	1000.00
WAC Last Day 4 Year Prior Not Applicable Indicator	Boolean	1	Indication that WAC Last Day 4 year prior is not applicable to this item | 1 = True / 0 = False	1
WAC Last Day 5 Year Prior	Decimal	10,2	WAC price of the drug on the last day of the year five calendar years preceding the date of the notification to report	1000.00
WAC Last Day 5 Year Prior Not Applicable Indicator	Boolean	1	Indication that WAC Last Day 5 year prior is not applicable to this item | 1 = True / 0 = False	1
Generic Delay Agreement	Boolean	1	Indication of the existence of an agreement between a Manufacturer and any other entity contingent upon any delay in offering to market a generic or biosimilar version of the drug | 1 = True / 0 = False	1
Generic Delay Agreement NPTS Indicator	Boolean	1	Indication that Generic Delay Agreement should not be publicly disclosed | 1 = True / 0 = False	1
Patent Expiration Date	Date	10	Patent expiration date of the drug if it is under patent	12/31/2000
Patent Expiration Date Not Applicable Indicator	Boolean	1	Indication that Patent Expiration Date is not applicable to this item | 1 = True / 0 = False	1
Acquisition Not Applicable Indicator	Boolean	1	Indication that Drug Product was not acquired by the Manufacturer during the previous 12-month	

Data Element	Format	Size	Description	Example
			period preceding the date of the notification to report | 1 = True / 0 = False	
WAC at Acquisition	Decimal	10,2	If the Manufacturer acquired the drug within the 12-month period preceding the date of the notification to report, the WAC on the date of acquisition	1000.00
WAC Year Prior to Acquisition	Decimal	10,2	If the Manufacturer acquired the drug within the 12-month period preceding the date of the notification to report, the WAC on the date one calendar year prior to the acquisition	1000.00
Company Acquired From	Alphanumeric	255	If the Manufacturer acquired the drug within the 12-month period preceding the date of the notification to report, the name of the company from which the drug was acquired	"Company Name"
Date of Acquisition	Date	10	If the Manufacturer acquired the drug within the 12-month period preceding the date of the notification to report, the date the drug was acquired	12/31/2000
Acquisition Price	Decimal	14,2	If the Manufacturer acquired the drug within the 12-month period preceding the date of the notification to report, the acquisition price of the drug	1000.00
Acquisition Price NPTS Indicator	Boolean	1	Indication that Acquisition Price should not be publicly disclosed | 1 = True / 0 = False	1
Manufacturing Cost	Decimal	14,2	Direct costs incurred to manufacture the drug during the 12-month period preceding the date of the notification to report	1000.00
Manufacturing Cost NPTS Indicator	Boolean	1	Indication that Manufacturing Cost should not be publicly disclosed | 1 = True / 0 = False	1
Marketing Cost	Decimal	14,2	Direct costs incurred to market the drug, including advertising costs, during the 12-month period preceding the date of the notification to report	1000.00

Data Element	Format	Size	Description	Example
Marketing Cost NPTS Indicator	Boolean	1	Indication that Marketing Cost should not be publicly disclosed | 1 = True / 0 = False	1
Distributing Cost	Decimal	14,2	Direct costs incurred to distribute the drug during the 12-month period preceding the date of the notification to report	1000.00
Distributing Cost NPTS Indicator	Boolean	1	Indication that Distributing Cost should not be publicly disclosed | 1 = True / 0 = False	1
Units Sold	Integer	19	Number of units of the drug sold during the 12-month period prior to the date of the notification to report	1000000
Units Sold NPTS Indicator	Boolean	1	Indication that Units Sold should not be publicly disclosed | 1 = True / 0 = False	1
Gross Revenue From Sales	Decimal	14,2	Total gross revenue from sales of the drug during the 12-month period preceding the price increase	1000.00
Gross Revenue From Sales NPTS Indicator	Boolean	1	Indication that Gross Revenue From Sales should not be publicly disclosed | 1 = True / 0 = False	1
Net Profit	Decimal	14,2	Net profit attributable to the drug during the 12-month period preceding the price increase	1000.00
Net Profit NPTS Indicator	Boolean	1	Indication that Net Profit should not be publicly disclosed | 1 = True / 0 = False	1
Total Rebate Payable	Decimal	14,2	Total Rebate payable amount accrued for the drug during the 12-month period prior to the date of the notification to report	1000.00
Total Rebate Payable NPTS Indicator	Boolean	1	Indication that Total Rebate Payable should not be publicly disclosed | 1 = True / 0 = False	1
Financial Assistance Provided	Decimal	14,2	Total amount of financial assistance provided through Patient Assistance Programs during the 12-month period preceding the price increase	1000.00
Financial Assistance Provided NPTS Indicator	Boolean	1	Indication that Financial Assistance Provided should not be publicly disclosed | 1 = True / 0 = False	1

Data Element	Format	Size	Description	Example
Manufacturing Company	Alphanumeric	255	Name of the company that manufactured the drug	"Company Name"
Manufacturing Company NPTS Indicator	Boolean	1	Indication that Manufacturing Company should not be publicly disclosed | 1 = True / 0 = False	1
Manufacturing Company Address	Alphanumeric	255	Address of the company that manufactured the drug	"123 Main St., Anytown, MN 00000"
Manufacturing Company Address NPTS Indicator	Boolean	1	Indication that Manufacturing Company Address should not be publicly disclosed | 1 = True / 0 = False	1
Brand Foreign Country 1	Alphanumeric	255	If a Brand Name Drug, the name of the country with the highest price paid for the drug during the calendar year prior to the date of notification to report other than the United States	"Country Name"
Brand Foreign Price 1	Decimal	10,2	If a Brand Name Drug, the highest price paid for the drug during the calendar year prior to the date of the notification to report in a country other than the United States. Price should represent the WAC equivalent in the country and be expressed in dollars according to the current exchange rate	1000.00
Brand Foreign Country 1 Not Applicable Indicator	Boolean	1	Indication that Brand Foreign Country 1 is not applicable to this item | 1 = True / 0 = False	1
Brand Foreign Country 1 NPTS Indicator	Boolean	1	Indication that Brand Foreign Country 1 should not be publicly disclosed | 1 = True / 0 = False	1
Brand Foreign Country 2	Alphanumeric	255	If a Brand Name Drug, the name of the country with the second highest price paid for the drug during the calendar year prior to the price increase other than the United States	"Country Name"
Brand Foreign Price 2	Decimal	10,2	If a Brand Name Drug, the second highest price paid for the drug during the calendar year prior to the price increase in a country other than the United States. Price should represent the WAC equivalent in	1000.00

Data Element	Format	Size	Description	Example
			the country and be expressed in dollars according to the current exchange rate	
Brand Foreign Country 2 Not Applicable Indicator	Boolean	1	Indication that Brand Foreign Country 2 is not applicable to this item | 1 = True / 0 = False	1
Brand Foreign Country 2 NPTS Indicator	Boolean	1	Indication that Brand Foreign Country 2 should not be publicly disclosed | 1 = True / 0 = False	1
Brand Foreign Country 3	Alphanumeric	255	If a Brand Name Drug, the name of the country with the third highest price paid for the drug during the calendar year prior to the date of the notification to report other than the United States	"Country Name"
Brand Foreign Price 3	Decimal	10,2	If a Brand Name Drug, the third highest price paid for the drug during the calendar year prior to the date of the notification to report in a country other than the United States. Price should represent the WAC equivalent in the country and be expressed in dollars according to the current exchange rate	1000.00
Brand Foreign Country 3 Not Applicable Indicator	Boolean	1	Indication that Brand Foreign Country 3 is not applicable to this item | 1 = True / 0 = False	1
Brand Foreign Country 3 NPTS Indicator	Boolean	1	Indication that Brand Foreign Country 3 should not be publicly disclosed | 1 = True / 0 = False	1
Brand Foreign Country 4	Alphanumeric	255	If a Brand Name Drug, the name of the country with the fourth highest price paid for the drug during the calendar year prior to the date of the notification to report other than the United States	"Country Name"
Brand Foreign Price 4	Decimal	10,2	If a Brand Name Drug, the fourth highest price paid for the drug during the calendar year prior to the date of the notification to report in a country other than the United States. Price should represent the	1000.00

Data Element	Format	Size	Description	Example
			WAC equivalent in the country and be expressed in dollars according to the current exchange rate	
Brand Foreign Country 4 Not Applicable Indicator	Boolean	1	Indication that Brand Foreign Country 4 is not applicable to this item | 1 = True / 0 = False	1
Brand Foreign Country 4 NPTS Indicator	Boolean	1	Indication that Brand Foreign Country 4 should not be publicly disclosed | 1 = True / 0 = False	1
Brand Foreign Country 5	Alphanumeric	255	If a Brand Name Drug, the name of the country with the fifth highest price paid for the drug during the calendar year prior to the date of the notification to report other than the United States	"Country Name"
Brand Foreign Price 5	Decimal	10,2	If a Brand Name Drug, the fifth highest price paid for the drug during the calendar year prior to the date of the notification to report in a country other than the United States. Price should represent the WAC equivalent in the country and be expressed in dollars according to the current exchange rate	1000.00
Brand Foreign Country 5 Not Applicable Indicator	Boolean	1	Indication that Brand Foreign Country 5 is not applicable to this item | 1 = True / 0 = False	1
Brand Foreign Country 5 NPTS Indicator	Boolean	1	Indication that Brand Foreign Country 5 should not be publicly disclosed | 1 = True / 0 = False	1
Brand Foreign Country 6	Alphanumeric	255	If a Brand Name Drug, the name of the country with the sixth highest price paid for the drug during the calendar year prior to the date of the notification to report other than the United States	"Country Name"
Brand Foreign Price 6	Decimal	10,2	If a Brand Name Drug, the sixth highest price paid for the drug during the calendar year prior to the date of the notification to report in a country other than the United States. Price should represent the	1000.00

Data Element	Format	Size	Description	Example
			WAC equivalent in the country and be expressed in dollars according to the current exchange rate	
Brand Foreign Country 6 Not Applicable Indicator	Boolean	1	Indication that Brand Foreign Country 6 is not applicable to this item | 1 = True / 0 = False	1
Brand Foreign Country 6 NPTS Indicator	Boolean	1	Indication that Brand Foreign Country 6 should not be publicly disclosed | 1 = True / 0 = False	1
Brand Foreign Country 7	Alphanumeric	255	If a Brand Name Drug, the name of the country with the seventh highest price paid for the drug during the calendar year prior to the date of the notification to report other than the United States	"Country Name"
Brand Foreign Price 7	Decimal	10,2	If a Brand Name Drug, the seventh highest price paid for the drug during the calendar year prior to the date of the notification to report in a country other than the United States. Price should represent the WAC equivalent in the country and be expressed in dollars according to the current exchange rate	1000.00
Brand Foreign Country 7 Not Applicable Indicator	Boolean	1	Indication that Brand Foreign Country 7 is not applicable to this item | 1 = True / 0 = False	1
Brand Foreign Country 7 NPTS Indicator	Boolean	1	Indication that Brand Foreign Country 7 should not be publicly disclosed | 1 = True / 0 = False	1
Brand Foreign Country 8	Alphanumeric	255	If a Brand Name Drug, the name of the country with the eighth highest price paid for the drug during the calendar year prior to the date of the notification to report other than the United States	"Country Name"
Brand Foreign Price 8	Decimal	10,2	If a Brand Name Drug, the eighth highest price paid for the drug during the calendar year prior to the date of the notification to report in a country other than the United States. Price should represent the	1000.00

Data Element	Format	Size	Description	Example
			WAC equivalent in the country and be expressed in dollars according to the current exchange rate	
Brand Foreign Country 8 Not Applicable Indicator	Boolean	1	Indication that Brand Foreign Country 8 is not applicable to this item | 1 = True / 0 = False	1
Brand Foreign Country 8 NPTS Indicator	Boolean	1	Indication that Brand Foreign Country 8 should not be publicly disclosed | 1 = True / 0 = False	1
Brand Foreign Country 9	Alphanumeric	255	If a Brand Name Drug, the name of the country with the nineth highest price paid for the drug during the calendar year prior to the date of the notification to report other than the United States	"Country Name"
Brand Foreign Price 9	Decimal	10,2	If a Brand Name Drug, the nineth highest price paid for the drug during the calendar year prior to the date of the notification to report in a country other than the United States. Price should represent the WAC equivalent in the country and be expressed in dollars according to the current exchange rate	1000.00
Brand Foreign Country 9 Not Applicable Indicator	Boolean	1	Indication that Brand Foreign Country 9 is not applicable to this item | 1 = True / 0 = False	1
Brand Foreign Country 9 NPTS Indicator	Boolean	1	Indication that Brand Foreign Country 9 should not be publicly disclosed | 1 = True / 0 = False	1
Brand Foreign Country 10	Alphanumeric	255	If a Brand Name Drug, the name of the country with the tenth highest price paid for the drug during the calendar year prior to the date of the notification to report other than the United States	"Country Name"
Brand Foreign Price 10	Decimal	10,2	If a Brand Name Drug, the tenth highest price paid for the drug during the calendar year prior to the date of the notification to report in a country other than the United States. Price should represent the	1000.00

Data Element	Format	Size	Description	Example
			WAC equivalent in the country and be expressed in dollars according to the current exchange rate	
Brand Foreign Country 10 Not Applicable Indicator	Boolean	1	Indication that Brand Foreign Country 10 is not applicable to this item | 1 = True / 0 = False	1
Brand Foreign Country 10 NPTS Indicator	Boolean	1	Indication that Brand Foreign Country 10 should not be publicly disclosed | 1 = True / 0 = False	1
General Comments	Alphanumeric	8000	General comments and/or additional information related to the data submitted for the drug, if applicable	"General Comments"
General Comments NPTS Indicator	Boolean	1	Indication that General Comments should not be publicly disclosed | 1 = True / 0 = False	1

Appendix D – Prescription Drugs of Substantial Public Interest Reporting (Pharmacy)

Data Element	Format	Size	Description	Example
NDC	Alphanumeric	11	NDC of the drug	"00000000000"
Item Description	Alphanumeric	255	Description of the drug to including product name, dosage form, strength, package size	"Drug X Tablets 30MG 30"
NDC Units Acquired	Integer	19	Number of units of the drug acquired during the 12-month period prior to the date of the notification to report	1000
NDC Units Acquired NPTS Indicator	Boolean	1	Indication that NDC Units Acquired should not be publicly disclosed | 1 = True / 0 = False	1
Total Spent Before Rebates	Decimal	14,2	Total spent before Rebates by the Pharmacy to acquire the drug during the 12-month period prior to the date of the notification to report	1000.00
Total Spent Before Rebates NPTS Indicator	Boolean	1	Indication that Total Spent Before Rebates should not be publicly disclosed | 1 = True / 0 = False	1
Total Rebate Receivable	Decimal	14,2	Total Rebate receivable amount accrued for the drug during the 12-month period prior to the date of the notification to report	1000.00
Total Rebate Receivable NPTS Indicator	Boolean	1	Indication that Total Rebate Receivable should not be publicly disclosed | 1 = True / 0 = False	1
Pricing Units Dispensed	Integer	19	Number of pricing units of the drug dispensed by the Pharmacy during the 12-month period prior to the date of the notification to report	1000
Pricing Units Dispensed NPTS Indicator	Boolean	1	Indication that Pricing Units Dispensed should not be publicly disclosed | 1 = True / 0 = False	1
Total Payment Receivable	Decimal	14,2	Total payment receivable amount accrued for the drug during the 12-month period prior to the date of the notification to report	1000.00

Data Element	Format	Size	Description	Example
Total Payment Receivable NPTS Indicator	Boolean	1	Indication that Total Payment Receivable should not be publicly disclosed | 1 = True / 0 = False	1
Total Rebate Payable	Decimal	14,2	Total Rebate payable amount accrued for the drug during the 12-month period prior to the date of the notification to report	1000.00
Total Rebate Payable NPTS Indicator	Boolean	1	Indication that Total Rebate Receivable should not be publicly disclosed | 1 = True / 0 = False	1
Average Cash Price (Pricing Unit)	Decimal	10,2	Average cash price paid by consumers per pricing unit for prescriptions dispensed where no claim was submitted to a health care service plan or health insurer during the 12-month period prior to the date of the notification to report	1000.00
Average Cash Price NPTS Indicator	Boolean	1	Indication that Average Cash Price should not be publicly disclosed | 1 = True / 0 = False	1
General Comments	Alphanumeric	8000	General comments and/or additional information related to the data submitted for the drug, if applicable	"General Comments"
General Comments NPTS Indicator	Boolean	1	Indication that General Comments should not be publicly disclosed | 1 = True / 0 = False	1

Appendix E – Prescription Drugs of Substantial Public Interest Reporting (PBM)

Data Element	Format	Size	Description	Example
NDC	Alphanumeric	11	NDC of the drug	"00000000000"
Item Description	Alphanumeric	255	Description of the drug to including product name, dosage form, strength, package size	"Drug X Tablets 30MG 30"
Pricing Units Administered	Integer	19	Number of pricing units of the drug filled for which the PBM administered claims during the 12-month period prior to the date of the notification to report	1000
Pricing Units Administered NPTS Indicator	Boolean	1	Indication that Pricing Units Administered should not be publicly disclosed | 1 = True / 0 = False	1
Total Reimbursement Receivable	Decimal	14,2	Total reimbursement receivable amount accrued for the drug during the 12-month period prior to the date of the notification to report	1000.00
Total Reimbursement Receivable NPTS Indicator	Boolean	1	Indication that Total Reimbursement Receivable should not be publicly disclosed | 1 = True / 0 = False	1
Total Admin Fee Receivable	Decimal	14,2	Total administrative fee amount accrued for the drug during the 12-month period prior to the date of the notification to report	1000.00
Total Admin Fee Receivable NPTS Indicator	Boolean	1	Indication that Total Admin Fee Receivable should not be publicly disclosed | 1 = True / 0 = False	1
Total Reimbursement Payable	Decimal	14,2	Total reimbursement payable amount accrued for the drug during the 12-month period prior to the date of the notification to report	1000.00
Total Reimbursement Payable NPTS Indicator	Boolean	1	Indication that Total Reimbursement Payable should not be publicly disclosed | 1 = True / 0 = False	1

Data Element	Format	Size	Description	Example
Total Rebate Receivable	Decimal	14,2	Total Rebate receivable amount accrued for the drug during the 12-month period prior to the date of the notification to report	1000.00
Total Rebate Receivable NPTS Indicator	Boolean	1	Indication that Total Rebate Receivable should not be publicly disclosed | 1 = True / 0 = False	1
Total Rebate Payable	Decimal	14,2	Total Rebate payable amount accrued for the drug during the 12-month period prior to the date of the notification to report	1000.00
Total Rebate Payable NPTS Indicator	Boolean	1	Indication that Total Rebate Payable should not be publicly disclosed | 1 = True / 0 = False	1
General Comments	Alphanumeric	8000	General comments and/or additional information related to the data submitted for the drug, if applicable	"General Comments"
General Comments NPTS Indicator	Boolean	1	Indication that General Comments should not be publicly disclosed | 1 = True / 0 = False	1

Appendix F – Prescription Drug of Substantial Public Interest Reporting (Wholesaler)

Data Element	Format	Size	Description	Example
NDC	Alphanumeric	11	NDC of the drug	"00000000000"
Item Description	Alphanumeric	255	Description of the drug to including product name, dosage form, strength, package size	"Drug X Tablets 30MG 30"
Units Acquired	Integer	19	Number of units of the drug acquired during the 12-month period prior to the date of the notification to report	1000
Units Acquired NPTS Indicator	Boolean	1	Indication that Units Acquired should not be publicly disclosed | 1 = True / 0 = False	1
Total Acquisition Amount	Decimal	14,2	Total spent before Rebates to acquire the drug during the 12-month period prior to the date of the notification to report	1000.00
Total Acquisition Amount NPTS Indicator	Boolean	1	Indication that Total Acquisition Amount should not be publicly disclosed | 1 = True / 0 = False	1
Total Rebate Receivable	Decimal	14,2	Total Rebate receivable amount accrued for the drug during the 12-month period prior to the date of the notification to report	1000.00
Total Rebate Receivable NPTS Indicator	Boolean	1	Indication that Total Rebate Receivable should not be publicly disclosed | 1 = True / 0 = False	1
Units Sold	Integer	19	Number of units of the drug product sold during the 12-month period prior to the date of the notification to report	1000
Units Sold NPTS Indicator	Boolean	1	Indication that Units Sold should not be publicly disclosed | 1 = True / 0 = False	1

Data Element	Format	Size	Description	Example
Gross Revenue	Decimal	14,2	Gross revenue from sales in the United States for the drug during the 12-month period prior to the date of the notification to report	1000.00
Gross Revenue NPTS Indicator	Boolean	1	Indication that Gross Revenue should not be publicly disclosed | 1 = True / 0 = False	1
Total Rebate Payable	Decimal	14,2	Total Rebate payable amount accrued for the drug during the 12-month period prior to the date of the notification to report	1000.00
Total Rebate Payable NPTS Indicator	Boolean	1	Indication that Total Rebate Payable should not be publicly disclosed | 1 = True / 0 = False	1
General Comments	Alphanumeric	8000	General comments and/or additional information related to the data submitted for the drug, if applicable	"General Comments"
General Comments NPTS Indicator	Boolean	1	Indication that General Comments should not be publicly disclosed | 1 = True / 0 = False	1