Prescription Drug Price Transparency: Frequently Asked Questions

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The Frequently Asked Questions (FAQ) document addresses practical approaches to submitting data under the Minnesota Prescription Drug Price Transparency Act (the "Act") (Minnesota Statutes, section 62J.84) and addresses specific circumstances reporting entities may face. The Minnesota Department of Health (MDH) posts responses to questions received from stakeholders and will update the document as new information emerges and additional questions about implementing the Act are received.

For additional resources, go to:

- The **Reporting Resources** page for Form & Manner guidance and other entity-specific information.
- The **Rx Data Portal Resources** page for specific instructions on registration and report submissions.

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Program overview

To increase transparency in prescription drug pricing, the Minnesota Legislature passed the Prescription Drug Price Transparency Act (the "Act") in 2020 and expanded it in 2023 (Minnesota Statutes 62J.84). The Act requires drug manufacturers, wholesale drug distributors, pharmacy benefit managers, and pharmacies to report prescription drug data to the Minnesota Department of Health (MDH).

The Act is implemented through three main components:

1. Reporting entities submit data to MDH on prescription drugs requiring reporting.
2. MDH publishes reported data that is permitted and required to be published under state law.
3. MDH analyzes the reported data and annually submits a report to the Legislature that promotes transparency and supports management of prescription drug spending.

What are important dates for this reporting program?

January 30 of each year. All Reporting Entities are required to register online using the Minnesota Rx Data Portal and must minimally update existing registration information by January 30 of each year. This includes reviewing and updating contact information for the organization and maintaining at least two-three individual contacts to ensure continuous access to data and ability to report, even during staffing transitions.

Sixty days after a price increase or introduction of a drug to the US market. Changes to the price of a prescription drug and new listings of a prescription drug for sale in the United States may trigger reporting, if all reporting criteria are met. The deadline for reporting is 60 days after the price change or introduction occurs.

Sixty days after MDH sends a notification to report on Drugs of Substantial Public Interest. On an ongoing basis no more than quarterly, MDH will produce and post on its Drugs of Substantial Public Interest Lists webpage a list of Prescription Drugs and for which Prescription Drug data sets must be submitted by Reporting Entities. After 30 days or more, MDH will send a notification to reporting entities of their requirement to report. The deadline for reporting is 60 days after the date of notification.

How can reporting entities stay updated on implementation of the Act?

MDH will communicate updates and announcements on its website and through emailed GovDelivery bulletins. Reporting entities can monitor website updates on the Announcements page and can sign up to receive email updates via GovDelivery bulletins.

Entity requirements and registration

Who may be required to report?

Minnesota statute specifies that entities that are licensed to act as a drug manufacturer (MN Statutes 151.252), wholesale drug distributor (MN Statutes 151.47), pharmacy benefit manager (MN Statutes 62W.03), or community/outpatient pharmacy (MN Statutes 151.19, Minnesota Rules part 6800.0100) in the state of Minnesota are subject to the Act.

Manufacturer reporting. Drug manufacturers may be required to report under subdivisions 3, 4, or 11 of the Act if they:

1. Are licensed to operate as a prescription drug manufacturer in Minnesota; and
2. Set the Wholesale Acquisition Cost (WAC) price for brand name, generic, or biosimilar prescription drugs.

Wholesaler reporting. Drug wholesalers may be required to report under subdivision 14 of the Act if they:

1. Are licensed to operate as a wholesale drug distributor in Minnesota; and
2. Distribute prescription drugs, for which they are not the manufacturer, to persons or entities, or both, other than a consumer or patient in Minnesota.

Pharmacy benefit manager reporting. PBMs may be required to report under subdivision 13 of the Act if they:

1. Are licensed to operate as a pharmacy benefit manager in Minnesota; and
2. Fulfill pharmacy benefit management duties for Minnesota residents.

Pharmacy reporting. Pharmacies may be required to report under subdivision 12 of the Act if they:

1. Are licensed to operate as a community-outpatient pharmacy in Minnesota; and
2. Dispense prescription drugs in Minnesota or mail to a Minnesota address.

Entities should review the definitions for these in the RxPT Form and Manner guidance document to assess their reporting responsibility.

Is registration required?

All Reporting Entities are required to register online using the Minnesota Rx Data Portal and must minimally update existing registration information by January 30 of each year. Reporting entities include all licensed drug manufacturers, wholesalers, pharmacy benefit managers, and community/outpatient pharmacies licensed in Minnesota.

What does MDH check when reviewing registration requests?

MDH reviews registration requests to confirm the email domain used to register a reporting entity account is affiliated with an entity licensed in Minnesota. This is to verify the authenticity of the registrant.

Can another entity report on a reporting entity's behalf?

Yes. A reporting entity may delegate reporting authority to another entity (e.g., subsidiaries, contractors, or other third parties) but remains responsible for the accuracy and completeness of any submissions to MDH.

How should a third-party associate intending to report on behalf of a reporting entity register?

Third-party associates should register a "Third Party Associate" account. Once registered, an employee of the reporting entity for which the third-party associate will report may then look up the third-party company within the online system and establish an affiliation (after independently registering a contact for their organization using an email domain associated with the reporting entity). This way, multiple reporting entities may delegate reporting to a single third-party company, and the third-party associate may access and report on behalf of the reporting entity through the Third-Party Associate account. The online system limits access to any given entity's data to only the delegated third-party associate and that reporting entity.

Not public data and trade secrets

How can a reporting entity protect "trade secrets" and other not public data reported to MDH?

Not public data and trade secrets (collectively, "not public data") are defined by Minnesota and Federal Law. If a reporting entity believes any of the data it is required to report is not public, the reporting entity must report the data along with a written statement specifically identifying the data and the factual and legal basis for the designation. MDH will not publicly disclose data a reporting entity demonstrates is not public by a preponderance of evidence (i.e., it is more likely than not the data is not public).

Additionally, a change to the Act in 2025 clarified that MDH will report only aggregated data reported by pharmacies, pharmacy benefit managers, and wholesalers in a manner that prevents the identification of any of these individual reporting entities.

Please see the RxPT Form and Manner guidance, which provides detailed information about the required content of a written statement, the definitions of not public data and trade secrets, and MDH decisions.

If MDH disagrees with a reporting entity's written statement justifying the designation of data as not public or trade secret, will MDH provide a written statement of its reasoning?

Yes. If MDH disagrees with a reporting entity's written statement, MDH must provide the reporting entity written notice that the data will be publicly posted 30 days after the date of the notice. Within this notice, MDH will provide a written explanation of its decision.

Can a reporting entity challenge an MDH decision to publicly report data the reporting entity designated as a trade secret or not public?

A reporting entity that would like to challenge an MDH decision to publish data it believes is not public data may pursue the administrative or civil remedies available in the Minnesota Government Data Practices Act (MGDPA). Because the Prescription Drug Price Transparency Act requires MDH to provide advance notice of 30 days when it disagrees with a reporting entity's written statement, reporting entities have a time-sensitive obligation to pursue a challenge within the notice period and notify MDH. MDH will continue to withhold disputed data until a timely challenge is resolved, unless extraordinary circumstances exist to justify publication.

What will MDH do with the written statements providing the legal basis for withholding data submitted by reporting entities?

MDH is not required to publish reporting entities' written statements that identify not public data, and, currently, MDH does not intend to do so. As required by the Act, MDH will use the information to explain "the nature of the information and the…basis for withholding" any not public data [MN Statutes 62J.84, subd. 6(c)].

However, MDH does have an obligation to respond to requests for written statements made under the Minnesota Government Data Practices Act (MGDPA). Each MGDPA request is evaluated on a case-by-case basis. In general, MDH must disclose written statements in response to an MGDPA request unless the contents are classified by law as not public. MDH is prohibited from disclosing not public data, except when disclosure is specifically authorized by the MGDPA or other federal and state law.

How will MDH protect not public data and trade secrets?

Data reported to MDH that are classified as not public will be safeguarded by technical and operational protections and the requirements of the Minnesota Government Data Practices Act, the Minnesota IT Services Security Controls (based on the National Institute of Standards and Technology Cybersecurity Framework), and applicable Minnesota IT Services security policies. For more detail on Minnesota IT security policies, please visit the Enterprise Information Security Policies and Standards page.

Compliance and enforcement

What is the maximum penalty a reporting entity may face?

The sum daily total of all penalties across one or more administrative penalty orders issued to a reporting entity for violating the Act may not exceed $10,000.

Will there be a grace period for implementing penalties?

No. The Act does not contemplate a grace period for enforcement and civil penalties. Throughout its implementation of the Act, MDH has focused on providing opportunities to gain familiarity with the Act's requirements and to engage in the development of guidance and reporting processes. As a result, MDH is confident that reporting entities are well-prepared to meet the Act's requirements.

How will MDH monitor compliance and communicate with reporting entities about compliance with the Act?

Using reference and other data, including data from Wolters Kluwer's Medi-Span, MDH will monitor for events that may trigger reporting under the law. Using contact information provided by other state agencies, as well as that provided by reporting entities in MDH's registration system, MDH will communicate with reporting entities that may have triggered reporting.

Reporting entities must register in the Minnesota Rx Data Portal.

When a reporting entity notifies MDH that it has corrected a violation or developed a corrective plan according to an administrative penalty order, when can the reporting entity expect a response from MDH?

MDH will ordinarily issue written notice of its determination regarding the sufficiency of corrective action within ten working days after receiving the information from the reporting entity, or within ten working days after the 31st day after MDH issued the penalty order, whichever is later. For more information, see the MDH Plan for the Use of Administrative Penalty Order, Cease and Desist Authority, and Other Enforcement Tools.

How can a reporting entity challenge an enforcement action by MDH?

A reporting entity may challenge an enforcement action taken by MDH by requesting an expedited administrative hearing. Any administrative penalty order or notice of outstanding corrective action sent to a reporting entity will contain a description of the process for requesting an expedited administrative hearing.

Rx Data Portal

Reporting entities must register and submit required reports to MDH exclusively using the Rx Data Portal. Visit the Rx Data Portal Resources page for technical guidance—including how to register and manage accounts in the portal—and video tutorials customized to each reporting entity type.

Once signed into the online Rx Data Portal, how can a reporting entity submit a report?

The reporting template and reporting functionality are in the Minnesota Rx Data Portal. Visit the Rx Data Portal Resources page for specific instructions on registration and report submission.

How should a reporting entity proceed if they are receiving error messages when attempting to upload their reporting spreadsheet?

First consult the video reporting tutorials available on the Rx Data Portal Resources page and then review the checklist and guidance below.

To complete a successful spreadsheet upload, ensure:

- The file is in **.xlsx format**.
- The file contains **no blank cells** in required fields.
- The **file name** has not been altered from the template download.
- The **column names** have not been altered from the template download.
- The **tab names** have not been altered from the template download.

The data elements entered are in the proper **data format** (text, integer, etc.) as outlined in the "Help" tab in the template download. Note the template requires the use of 1 for "True" and 0 for "False" in the non-public and trade secret and NA fields. Entering "NA" as a value is not an accepted response.

If non-formatting related error messages appear, you may continue the upload but must correct or provide explanations for all identified data element errors in subsequent steps in the Rx Data Portal before certifying the submission.

How can reporting entities confirm a report has been successfully submitted to MDH?

Reporting entities submit drug reports to MDH by entering and certifying data in the online Rx Data Portal. For instructions on how to review the status of a drug report and other functions, please visit the Rx Data Portal Resources page.

Can a reporting entity correct their data after it is uploaded and certified?

A reporting entity can correct data that was previously certified only until MDH has completed its review of the item. A record with a status of Submitted can be edited by clicking on the Submitted section, clicking the pencil icon to edit the record, making changes in the Edit Item page, checking the certify checkbox at the bottom of the Edit Item page and clicking Save. Alternatively, if all items need to be edited, the entity can upload an updated template and recertify the items after the upload is complete.

General reporting (all reporting entities)

What drugs meet the requirement for reporting under the Act?

Drugs intended for human use subject to United States Code, title 21, section 353(b)(1) are subject to the Act. These drugs require reporting if they meet price growth or new prescription drug reporting criteria, or if they are included on a list of drugs of substantial public interest (MN Statutes 62J.84, subd. 3-4, 10).

Are orphan or ultra-orphan drugs included in reporting?

Yes. Orphan and ultra-orphan drugs are subject to the same reporting criteria as other drugs.

Are drugs administered by a physician and drugs delivered in an inpatient setting included in reporting?

Yes. Drugs administered by a physician and drugs delivered in an inpatient setting are subject to the same reporting criteria as other drugs. Prescription drugs that meet the definition of "a drug for human use subject to United States Code, title 21, section 353(b)(1)" are subject to reporting requirements under the Act.

What is a drug family and how is it defined?

Minnesota Statutes 62J.84 defines a drug product family as "a group of one or more prescription drugs that share a unique generic drug description or nontrade name and dosage form." Some examples include: abiraterone acetate (unique generic drug description or nontrade name) Tablet (dosage form); and capecitabine (unique generic drug description or nontrade name) Tablet (dosage form).

For what date range should reporting entities compile data for required reporting?

For Drugs of Substantial Public Interest Reporting, all reporting entities must report on data associated with the specific NDCs for **the time period specified in the notification to report**. This time period will also be posted publicly on MDH's Drugs of Substantial Public Interest Lists web page.

For *Manufacturer-Only* Prescription Drug Price Growth Reporting, manufacturers must report data associated with the specific *NDCs during the 12-month period preceding the price increase.*

For *Manufacturer-Only* New Prescription Drug Price Reporting, manufacturers must report on the costs incurred or the assistance it provided *from the first date manufacturing costs were incurred through the date of introduction to market***.**

What types of rebates should be included in the fields on total rebates payable and total rebates receivable?

A reporting entity must report any form of rebate or discounting the entity receives or pays for the drug product during the reporting period. These figures should be inclusive of rebates received and paid out directly, as well as those received by or paid to group purchasing organizations or other external entities negotiating drug rebates to lower the net cost of the drug.

What should a reporting entity do if it is not tracking the information needed for a data element?

Required data are statutorily required, and reporting entities must report the information to the best of their ability. Where necessary, reporting entities may develop estimates and use the General Notes fields to provide context and detail about the methodology used to develop estimates.

What should a reporting entity do if it did not have any transactions for any drugs on the current list for this reporting period?

Reporting entities should enter zeros for drugs with no applicable transactions (produce, distribute, dispense, reimburse, etc.) for the reporting period. This means entering zeros in multiple data fields on the template. Please note that future lists may include drugs that your organization *does* provide.

For pharmacies, wholesalers, and PBMs: for Drugs of Substantial Public Interest reporting, if you did not have *any* applicable transactions for *any* of the drugs on the list for a reporting period, you may submit a "zero report," which allows for expedited reporting when no drugs are applicable.

Directions for submitting a "zero report": You have two options:

1. You may download the 'Download Report Zeros' template in the Rx Data Portal, which is pre-populated with all relevant zeros. If you use the "Download Report Zeros" template, you must still upload that template and certify you did not have any transactions for those drugs for the reporting period.*
2. You may click the "Report Zero" button and follow instructions for certifying your submission.

*If you have transactions for some, but not all, of the drugs on the current list, then you may also use the "zero report" template rather than a blank template as a baseline. Override the zeros for the lines with the drugs for which you do have transactions and leave the zeros in the remaining lines.

Is it possible to submit a consolidated report if a reporting entity—a Minnesota-licensed drug manufacturer, wholesaler, pharmacy benefit manager (PBM), or pharmacy—has multiple sites or if multiple organizations fall under a larger organizational umbrella?

There are options for consolidated reporting in some circumstances. If multiple entities are reporting under the same subdivision and have registered in the Rx Data Portal as parent/child or affiliates, then they may submit a single report that aggregates data for multiple entities. Each entity that is obligated to report must still be identified in the organization registration and as contributing to the consolidated report.

Access the Registration Quick Start Guide (PDF) for tips on how best to register your organization to meet your reporting obligations.

What will MDH do with reported data?

MDH is required to publicly post lists of prescription drugs reported, the manufacturers of those prescription drugs, and information reported to MDH on those prescription drugs aggregated on a per-drug basis in a manner that does not allow identification of a reporting entity that is not the manufacturer of the drug. MDH is also required to synthesize the reported information in an annual report to the Minnesota Legislature.

Manufacturer reporting – general

Please also refer to the section.

Are all reporting obligations currently active?

Yes.

The New Drug and Price Growth provisions of the Act became active in January 2022 and are ongoing. Reporting requirements for these provisions operate on a rolling basis based on the date drug pricing events that meet statutory thresholds (introduction to market or price increase). Reports must be submitted within 60 days of the pricing event.

The Drugs of Substantial Public Interest provision of the Act went into effect in January 2024 and is ongoing. Reporting under this provision is based on lists published periodically by MDH. All lists posted by MDH are available on the Drugs of Substantial Public Interest Lists page.

Are drug manufacturers required to register even if they don't have any current reporting obligations?

Yes. All manufacturers licensed in Minnesota need to register using the Rx Data Portal. For technical guidance on using the Rx Data Portal, including information on how to register and manage accounts, visit the Rx Data Portal Resources page.

How will manufacturers know when and what to report?

For New Drug and Price Growth reporting, manufacturers are responsible for identifying their reporting obligations based on the statutory thresholds. MDH uses reference data to identify potential reporting obligations for compliance outreach.

For Drugs of Substantial Public Interest reporting, MDH publishes the lists of drugs for reporting online and will notify registered manufacturers of the drugs requiring reporting. All lists posted by MDH are available on the Drugs of Substantial Public Interest Lists page.

Where will manufacturers submit reports?

Manufacturers must use the Rx Data Portal for all submissions. Reporting templates are available for download within the portal.

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

The law places the responsibility for reporting with the entity that sets the WAC price. However, other entities such as a third-party associate (TPA) may report on a drug on behalf of the responsible manufacturer (but the manufacturer retains responsibility for accuracy and

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

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

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

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

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

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

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

Entity B may have a reporting responsibility for any price increases that occur after the sale of the drug. Possible reporting responsibilities for Entity B are:

- **No reporting responsibility.** If Entity B acquired the drug and does not increase the price of the drug, Entity B does not have a reporting responsibility.
- **Reporting responsibility on price increase.** If Entity B acquired and increased the price to an amount that meets the reporting criteria on or after the date the acquiring manufacturer begins to sell the drug, Entity B has the responsibility for Prescription Drug Price Growth reporting (MN Statutes 62J.84, subd. 3).
    - Note: This responsibility applies even if Entity A was partially responsible for the price increase. To illustrate, Entity A owned a drug and increased the price by an amount that does not meet price increase reporting criteria before selling the drug to Entity B. On or before the date Entity B began to sell the drug, Entity B further increased the price to an amount that meets price growth reporting criteria. If each of Entity A's and Entity B's price increases occurred within the applicable 12- or 24-month reporting window, Entity B is responsible for reporting all price increase and newly acquired drug data. (MN Statutes 62J.84, subd. 3).

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

If the acquiring manufacturer increased the price of the drug to an amount that meets the price growth criteria on or after the date the acquiring manufacturer begins to sell the drug, the acquiring manufacturer is required to report, even if the selling manufacturer was partially responsible for the price increase.

Please reference Scenario 3 of the previous question (*If multiple prescription drug manufacturers have a relationship to a prescription drug that triggers reporting, which entity has the responsibility to report?*) on manufacturer relationships.

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

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

Should manufacturers report information for the manufacturer providing the report or the contract manufacturer under the "Manufacturing Company Name" and "Manufacturing Company Address" fields?

For the data fields relating to "Manufacturing Company Name" and "Manufacturing Company Address," reporting entities should enter the manufacturer that physically manufactures the product.

What costs may a manufacturer include in the reported amounts for direct costs to manufacture, market, and distribute a drug?

Direct costs may include any costs directly attributable at the drug product level to the manufacturing, marketing, or distributing of the drug. This may include any labor or third-party vendor costs if they are directly attributable at the drug product level.

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

A manufacturer should report any form of financial assistance it provided directly to consumers of the drug, provided the assistance reduced the out-of-pocket cost of the drug to consumers. Examples of financial assistance include discounts in price or waiver of charges (based on income, need, drug availability, emergency response, or other factors), rebates, or other similar

financial assistance provided directly by the manufacturer. Financial assistance does not include benefits to consumers that are not provided directly by the manufacturer, such as government assistance or other benefits that compensate the manufacturer or consumer for the purpose of reducing out-of-pocket costs to consumers.

What date should a manufacturer report if a drug has multiple patents?

Manufacturers should report the date the last patent relating to the reportable drug expires.

For reporting Drugs of Substantial Public Interest, what scope of an organization's business should be included in its reporting?

Manufacturers should submit data based on all their prescription drug business in the United States.

Manufacturer reporting – price growth

Please also refer to the and ***Manufacturer*** sections.

How is price growth calculated?

To assess reporting responsibility for a given price increase to a drug, a manufacturer should reference the new price increase against the price for that drug 12 and 24 months prior (or the first date of sale, if the drug was introduced for sale less than 12 months prior), as appropriate for the drug, to determine whether the change meets the price increase criteria.

Scenario 1. A price increase to a *brand name drug* occurs on January 15, 2022.

For price increases involving brand name drugs, the manufacturer must reference the new price against the price for that drug 12 and 24 months prior to determine whether the change meets the price increase criteria (i.e., increases of 10 percent or more over 12 months, or 16% or more over 24 months). The new price should be compared against the price of the drug on January 15, 2021, and January 15, 2020.

Scenario 2. A price increase to a *generic drug* occurs on January 15, 2022.

For price increases involving generic drugs, the manufacturer must reference the new price against the price for that drug 12 months prior to determine whether the change meets price increase criteria (i.e., increases of 50% or more over that 12-month period). The new price should be compared against the price of the drug on January 15, 2021.

Scenario 3. A price increase to a prescription drug occurs on January 15, 2022, and the drug was acquired within the last 12 months.

If a manufacturer acquires a drug, the process for calculating a price increase remains the same: the price at which the manufacturer begins to sell the drug should be compared to the price of the drug at the applicable 12- and/or 24-month prior to the price increase. For more information on what information an acquiring manufacturer must report, please reference "Scenario 3" in the answer to the question "If multiple prescription drug manufacturers have a relationship to a prescription drug that triggers reporting, which entity has the responsibility to report?"

If a drug had an established wholesale acquisition price, but never sold the drug at that price, and subsequently, the wholesale acquisition price increases, can the new price trigger Prescription Drug Price Growth Reporting?

MDH uses reference data on prescription drug pricing that manufacturers report to drug databases, such as Wolters Kluwer's Medi-Span, to identify required reporting on price

increases. If a manufacturer believes a previously established wholesale acquisition cost should not count toward a calculation of a drug's price increase, the manufacturer should write and provide evidence to MDH supporting why a given price reported to drug databases should not be used in calculating price growth.

Can price increases for biosimilars trigger Prescription Drug Price Growth Reporting?

Yes. As of August 1, 2023, biosimilars that meet the reporting criteria for Prescription Drug Price Growth Reporting require reporting. This followed a change made by the Minnesota Legislature in 2023 to add the word "biosimilar" to the reporting criteria (MN Statutes 62J.84, subd.3).

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

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

Should manufacturers report the chemical name or the name of generic equivalents on the market for the "Generic Nonproprietary Name" data element?

Manufacturers should report the generic or chemical name of the product for the drug.

Manufacturer reporting – new drug

Please also refer to the and ***Manufacturer*** sections.

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

One of the criteria for requiring reporting on new prescription drugs is based on the Centers for Medicare and Medicaid Services Specialty Drug tier threshold for Medicare Part D. This amount is $950 as of January 1, 2025 (Centers for Medicare and Medicaid Services. Contract Year 2026 Final Part D Bidding Instructions. April 1, 2025); this threshold will change as the Specialty Drug tier threshold is updated in the future.

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

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

When does a new NDC for a prescription drug qualify as a New Drug for New Prescription Drug Reporting?

A drug newly approved by the U.S. Food and Drug Administration with no previous Wholesale Acquisition Cost may require New Drug Reporting if it meets the reporting criteria.

If an existing drug is being assigned a new National Drug Code (NDC)—for example, because it is transitioning to a new labeler code—but has had no changes to the drug product, strength, dosage form, or package type, it is considered an existing drug and does not meet the reporting criteria for New Drug Reporting.

- **Note**: Manufacturers should report such NDC transitions to prescription drug databases, such as Medi-Span or First Databank. MDH uses data on NDC transitions to identify which new NDCs are for new drugs, and which are for existing drugs being assigned a new NDC.

How does MDH identify new drugs?

MDH uses reference data on prescription drug pricing that manufacturers report to drug databases, such as Wolters Kluwer's Medi-Span, to identify required reporting on new drugs. Specifically, MDH identifies a new drug by the first date on which a drug had a reported wholesale acquisition cost.

If a manufacturer establishes a wholesale acquisition price for a new drug but has not begun selling the drug in the U.S., does MDH require New Prescription Drug Price Reporting?

MDH uses reference data on prescription drug pricing that manufacturers report to drug databases, such as Wolters Kluwer's Medi-Span, to identify required reporting on price increases. If a manufacturer believes it should not yet be required to report on a new drug, the manufacturer should write and provide evidence to MDH supporting why a given price reported to drug databases should not be used in calculating price growth.

Can a drug that was approved through a supplemental application trigger New Prescription Drug Reporting?

Yes. As of August 1, 2023, all new approvals that meet the criteria for reporting, including supplemental new drug applications and supplemental biologics license applications, require reporting under MN Statutes 62J.84, subd 4. This followed a change made by the Minnesota Legislature in 2023 to remove the word "original" from the definition of a brand drug.

Can the introduction of a new generic drug for sale in the U.S. that does not have a referenced brand drug on the market trigger New Prescription Drug Price Reporting?

No. Currently, the law does not require reporting under the New Prescription Drug Reporting category for a new generic for which there is no referenced brand name drug for sale in the U.S. However, the same generic drug may still trigger Prescription Drug Price Growth Reporting at some later point.

Wholesaler reporting

Please also refer to the section.

How will wholesalers know when and what to report?

For Drugs of Substantial Public Interest reporting, MDH publishes the lists of drugs for reporting online and will notify registered wholesalers of the drugs requiring reporting. All lists posted by MDH are available on the Drugs of Substantial Public Interest Lists page.

Are wholesalers required to register even if they don't have any current reporting obligations?

Yes. All wholesalers licensed in Minnesota need to register using the Rx Data Portal. For technical guidance on using the Rx Data Portal, including information on how to register and manage accounts, visit the Rx Data Portal Resources page.

Where will wholesalers submit reports?

Wholesalers must use the Rx Data Portal for all submissions. Reporting templates are available for download within the portal.

For reporting Drugs of Substantial Public Interest, what scope of an organization’s business should be included in its reporting?

Wholesalers should submit data based on all prescription drugs the wholesaler distributed within or into Minnesota.*

*If distinguishing Minnesota transactions as described here is impossible, reporting entities should provide their best estimates and include their estimation methodology in the general comments field. If an estimate is impossible, reporting entities should describe what data is included in the general comments field. If a Minnesota-licensed entity does not conduct *any* business in Minnesota, then zeros should be entered in applicable data fields and reporting entities should describe this in the general comments field.

Pharmacy benefit manager reporting

Please also refer to the section.

How will pharmacy benefit managers (PBMs) know when and what to report?

For Drugs of Substantial Public Interest reporting, MDH publishes the lists of drugs for reporting online and will notify registered PBMs of the drugs requiring reporting. All lists posted by MDH are available on the Drugs of Substantial Public Interest Lists page.

Are PBMs required to register even if they do not have any current reporting obligations?

Yes. All PBMs licensed in Minnesota need to register using the Rx Data Portal. For technical guidance on using the Rx Data Portal, including information on how to register and manage accounts, visit the Rx Data Portal Resources page.

Where will PBMs submit reports?

PBMs must use the Rx Data Portal for all submissions. Reporting templates are available for download within the portal.

For reporting Drugs of Substantial Public Interest, what scope of an organization's business should be included in its reporting?

PBMs should submit data based on all Minnesota residents for which the PBM fulfilled pharmacy benefit management duties.*

*If distinguishing Minnesota transactions as described here is impossible, reporting entities should provide their best estimates and include their estimation methodology in the general comments field. If an estimate is impossible, reporting entities should describe what data is included in the general comments field. If a Minnesota-licensed entity does not conduct *any* business in Minnesota, then zeros should be entered in applicable data fields and reporting entities should describe this in the general comments field.

How should PBMs report units administered?

PBMs should treat the **standard unit of measure** (mL, g, each) of the drug product as the smallest dispensable unit. PBMs should report the number of milliliters, grams, or capsules/tablets/"each" of each drug product **administered** by your PBM.

- In the general comments section, indicate the following: "Pricing units administered have been evaluated as one unit = one standard unit of measure."
- Examples:

- Simvastatin 20 mg tablet: report number of tablets administered
- NovoLog FlexPen Prefilled Syringe 100 units/mL: report number of mL administered
- Advair Diskus Fluticasone / Salmeterol 250 mcg: report number of grams administered

Pharmacy reporting

Please also refer to the section.

How will pharmacies know when and what to report?

For Drugs of Substantial Public Interest reporting, MDH publishes the lists of drugs for reporting online and will notify registered pharmacies of the drugs requiring reporting. All lists posted by MDH are available on the Drugs of Substantial Public Interest Lists page.

Can a pharmacy request an extension or exemption from reporting?

A pharmacy may request an extension or exemption within the Rx Data Portal if they meet both statutory requirements:

1. Must be a small or independent pharmacy.
2. Must document that reporting would represent a hardship or undue burden on the pharmacy.

If these criteria for an exception are met, a pharmacy may submit an exception request in the Rx Data Portal that affirms they are a small/independent pharmacy and includes a hardship explanation. MDH reviews requests and the exception is not active until MDH has approved.

Note that exemptions are not permanent: a pharmacy must request a new exemption for each Drugs of Substantial Public Interest List that is published.

Portal instructions: In the Rx Data Portal, from the Menu in the upper right, select Public Interest Reporting. Find the current Reporting Period and click on View. Then scroll down to Organization Reporting Status and click on *+ Request Exception*. Select *Exemption* or *Extension*. If requesting an extension, include a requested extension date in the provided field.

Are pharmacies required to register even if they do not have any current reporting obligations?

Yes. All pharmacies licensed in Minnesota need to register using the Rx Data Portal. For technical guidance on using the Rx Data Portal, including information on how to register and manage accounts, visit the Rx Data Portal Resources page.

Are pharmacies required to report even if none of the drugs on a given public interest list are applicable to them?

Yes. All pharmacies licensed in Minnesota are required to report unless they have requested and been approved for an exemption within the portal (see below). Pharmacies should enter zeros for drugs with no applicable transactions in a reporting period. This means entering zeros in multiple data fields on the template.

See the **What should a reporting entity do if it did not have any transactions for any drugs on the current list for this reporting period?** question on page 11 for directions on how to submit a "zero report."

Where will pharmacies submit reports?

Pharmacies must use the Rx Data Portal for all submissions. Reporting templates are available for download within the portal.

For reporting Drugs of Substantial Public Interest, what scope of an organization's business should be included in its reporting?

Pharmacies should submit data on all prescriptions either dispensed in Minnesota or mailed to a Minnesota address.*

*If distinguishing Minnesota transactions as described here is impossible, reporting entities should provide their best estimates and include their estimation methodology in the general comments field. If an estimate is impossible, reporting entities should describe what data is included in the general comments field. If a Minnesota-licensed entity does not conduct *any* business in Minnesota, then zeros should be entered in applicable data fields and reporting entities should describe this in the general comments field.

How do I request an extension to the deadline or an exemption from reporting?

Requests for exceptions—which include extensions and exemptions—are limited to small and independent pharmacies and must be re-applied for each reporting period. If you believe you qualify, request an exception via the Minnesota Rx Data Portal by following the directions below. Include a justification for your status as small or independent pharmacy and justification for your hardship request.

MDH will review and send notice of approval or denial via the Rx Data Portal. All exception requests should be submitted at least 20 calendar days in advance of the reporting deadline to provide adequate time for review.

Note that exemption approvals are applicable only for the current Drugs of Substantial Public Interest List, and new exemption requests must be submitted for future Lists.

Directions: From the Menu dropdown in the upper right, select Public Interest Reporting. From there, click on the View button by the current reporting period. There, you should find an option to request an exception.

How should pharmacies report units acquired and units dispensed?

Pharmacies should report the number of **NDC units** (bottles, packages, pens–whatever the NDC which is being reported on encompasses) **acquired** by your pharmacy.

Pharmacies should treat the **standard unit of measure** (mL, g, each) of the drug product as the smallest dispensable unit. Pharmacies should report the number of milliliters, grams, or capsules/tablets/“each” of each drug product **dispensed** by your pharmacy.

- In the general comments section, indicate the following: “Pricing units dispensed have been evaluated as one unit = one standard unit of measure.”
- Examples:
  - Simvastatin 20mg tablet: report number of tablets dispensed
  - NovoLog FlexPen Prefilled Syringe 100 units/mL: report number of mL dispensed
  - Advair Diskus Fluticasone / Salmeterol 250 mcg: report number of grams dispensed

Revision history

Date	Version	Description
August 2021	1	First draft for public comment
December 2021	2	Added questions and revised selected responses on items raised through Dec. 2021 that focused on compliance and enforcement
February 2022	3	Updates focused on registration and reporting activities
September 2022	4	Added responses to questions raised by reporting entities
November 2025	5	Consolidated and updated responses to all frequently asked questions across distinct documents and provided responses to items raised in a Aug./Sept. 2025 comment period

References

- Minnesota Statutes, section 62J.84 (https://www.revisor.mn.gov/statutes/cite/62J.84)
- Reporting Resources (https://www.health.state.mn.us/Data/rxtransparency/resources/index.html)
- Rx Data Portal Resources (https://www.health.state.mn.us/data/rxresources/index.html)
- Minnesota Rx Data Portal (https://rxpt.health.mn.gov/)
- Drugs of Substantial Public Interest Lists (https://www.health.state.mn.us/data/rxtransparency/pilists.html)
- Announcements (https://www.health.state.mn.us/data/rxtransparency/announcements.html)
- Email updates (https://public.govdelivery.com/accounts/MNMDH/subscriber/new?topic_id=MNMDH_553)
- MN Statutes 151.252 (https://www.revisor.mn.gov/statutes/cite/151.252)
- MN Statutes 151.47 (https://www.revisor.mn.gov/statutes/cite/151.47)
- MN Statutes 62W.03 (https://www.revisor.mn.gov/statutes/cite/62W.03)
- MN Statutes 151.19 (https://www.revisor.mn.gov/statutes/cite/151.19)
- Minnesota Rules part 6800.0100 (https://www.revisor.mn.gov/rules/6800.0100/)
- RxPT Form and Manner guidance document (https://www.health.state.mn.us/data/rxtransparency/docs/rxfandmnov25.pdf)
- Enterprise Information Security Policies and Standards (https://mn.gov/mnit/government/policies/security/)
- Medi-Span (https://www.wolterskluwer.com/en/solutions/medi-span/medi-span)

- MDH Plan for the Use of Administrative Penalty Order, Cease and Desist Authority, and Other Enforcement Tools (https://www.health.state.mn.us/communities/environment/local/docs/ehcib/apoplan2010.pdf)
- United States Code, title 21, section 353(b)(1) (https://www.law.cornell.edu/uscode/text/21/353)
- Registration Quick Start Guide (PDF) (https://www.health.state.mn.us/data/rxtransparency/docs/rxportalregquickstart.pdf)
- Contract Year 2026 Final Part D Bidding Instructions (https://app.clearpol.com/document/92579/)