

Drugs of Substantial Public Interest: Draft Methodology for Public Comment

APRIL 2024

Purpose

The Minnesota Department of Health (MDH) is inviting comments on the draft methodology for the inaugural list of **drugs of substantial public interest**. The comment period will be open for two weeks. MDH will release the formal list of drugs of substantial public interest for data collection in late spring of 2024. For future releases, MDH will seek public input on designating drugs through a variety of approaches, including the standing form for [Public Input on Prescription Drug Price Transparency](#).

This document serves to provide stakeholders and the interested public with detail and background information on the Prescription Drug Price Transparency Act and on the draft methodology for identifying drugs of substantial public interest for the inaugural release.

Background

Many Minnesotans are struggling to afford the high and rising cost of critically important drug therapies. Due to the complexity and lack of transparency of the prescription drug market, patients and policymakers struggle with understanding the factors driving drug prices and how to make the market work more effectively to improve affordability.

Minnesota's Initial Transparency Initiative: In response to these challenges, the Minnesota Legislature passed the bipartisan Minnesota Prescription Drug Price Transparency Act (Minnesota Statutes, section [62J.84](#)) in 2020 and reporting on the initial provisions began in 2022.ⁱ Goals of the Act include promoting transparency of prescription drug pricing trends and developing evidence to inform further policy development.

Drug manufacturers are required to report on new drug introductions and price increases that meet certain thresholds identified in statute. MDH must make this information publicly available and submit [annual reports](#) to the legislature.ⁱⁱ

Drugs of Substantial Public Interest Initiative: Informed by MDH's assessment in the first reports about the limits of focusing just on drug manufacturers and list prices,ⁱⁱⁱ the Minnesota Legislature expanded the Act in 2023 to require a new data reporting mechanism. Under that new requirement, MDH must issue quarterly lists of drugs, beginning in 2024, that the commissioner has determined represent a substantial public interest. In addition to drug manufacturers, wholesalers, pharmacy benefit managers (PBMs), and pharmacies must report

data on rebates, fees and other transactions for drugs that are on these lists. This new reporting and MDH's analysis are intended to provide the legislature and stakeholders with more meaningful and actionable information aimed at promoting a more transparent prescription drug market and improving affordability.

Similar to the initial transparency data reporting streams, the data collected on drugs of substantial public interest will be made public via dashboards and downloadable files on MDH web pages; individual data elements identified as trade secret or not-public by reporting entities will be withheld from public release.^{iv} MDH analysis and assessment of the new reporting will be included in annual legislative reports, beginning with 2025.

Requirements for identifying drugs of substantial public interest

The statute specifies that in designating quarterly lists of drugs “of substantial public interest to Minnesota,” the commissioner must consider information relevant to “providing greater consumer awareness of the factors contributing to the cost of prescription drugs in the state.” In addition, MDH shall consider drugs:

1. That meet the original transparency reporting requirements.
2. For which the claims paid amount exceeds the price of the claims by more than 125%.
3. That are identified by the public.

Once each list is posted, reporting entities have approximately 90 days until reports are due to MDH.

MDH approach to identifying drugs of substantial public interest

The prescription drug industry and supply chain are complex and opaque, with pricing dynamics – and price drivers – differing across brand and generic drugs, new-to-market and established drugs, and biologics and related biosimilar products. Identifying drugs of substantial public interest and collecting data from across the prescription drug supply chain serves the state of Minnesota by enhancing **understanding** and providing **transparency** into the factors contributing to the cost of prescription drugs in the state.

By reaching beyond manufacturers to collect data from four reporting entity types, this initiative is nation-leading and will allow for a system-wide view of pricing for identified drugs. MDH's approach is shaped by the following considerations:

- MDH plans to focus on drug pricing at the **systemic level** or issues that occur across the supply chain, rather than individual market actors or pricing decisions.
- MDH expects that most lists will focus on a **single feature of the supply chain**. However, depending on criteria used for designating future lists, it is possible that some drugs will be included in multiple lists over time.
- MDH anticipates that there may be reasons to **repeat a particular list of drugs** over a period of time. Generally, however, MDH will aim to explore different aspects of the market with each list.

- As directed by statute, MDH will be including **whole drug product families** in the list of drugs of substantial public interest.^v This will allow the public to observe data on particular drugs of interest in the context of pharmaceutically equivalent drugs. It will also permit meaningful comparisons across drug products and an assessment of the effectiveness of market competition.

MDH recognizes that there are other governmental programs, transparency initiatives, research institutes, and individuals that are making significant contributions to the prescription drug research and policy discussions, particularly at the drug level. MDH may leverage some of that existing work to further explore the issue with Minnesota-specific data, but MDH does not specifically aim to replicate other efforts and intends to ensure the lists are a **good fit for the Act's reporting and the Minnesota context**.

As noted, MDH has also developed a [standing online form](#) for receiving **input** into the process to designate drugs of substantial public interest.^{vi} In addition, MDH will be establishing other opportunities for gathering input from stakeholders and the public on future lists, such as feedback periods and direct outreach.

Draft methodology for the inaugural list of drugs of substantial public interest

Significant price increases along the supply chain

The Act directs MDH to consider drugs for which the average total paid amount exceeds the list price (i.e., the wholesale acquisition cost [WAC]) by more than 125%. This difference represents earnings by intermediaries (including wholesalers, PBMs, and pharmacies) paid for by patients and other payers,^{vii} over and above the manufacturer list price, which may already be set at a considerably high price.^{viii}

Draft Methodology

MDH expects the inaugural list of drugs for 2024 to focus on the top 10 drug product families that contain one or more drugs for which the average total claims paid amount was over \$100 and at least 125% higher than the manufacturer's initial list price, or WAC. The list would include all drugs within the identified drug product families for market comparison, with all distinct drugs across all strengths and package sizes; drugs will be listed by their National Drug Code (NDC).

To develop this list, MDH will analyze pharmacy claims in the MN APCD that were incurred in the commercial market during 2022 together with WAC prices from reference data using the following steps:

1. MDH will calculate the total claims paid amount and the total list price amount for each drug for all active retail prescription drugs on a per-drug basis.
2. MDH will divide the total claims paid amount by the total list price amount for each drug to determine the percentage difference between the two values.

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3. Next, MDH will filter the list of drugs to those where the percentage difference between the total claims paid amount and the total list price amount represented an increase of more than 125% and where the average paid amount per claim was greater than \$100.
4. All drugs within the same drug product family as one of the drugs on the resulting list will be grouped and the total claims paid amounts and total list price amounts will be aggregated for each drug family.
5. Finally, MDH will select the top 10 drug product families having the greatest difference between total claims and the total list price for the final list.

Glossary

Drug product families are groups of one or more prescription drugs that share a unique generic drug product description, or nontrade name, and dosage form.

Medi-Span is a suite of data products on prescription drugs maintained by Wolters Kluwer that includes manufacturer list prices.

Minnesota All Payer Claims Database (MN APCD) is a state repository of de-identified health care enrollment and claims data administered by MDH.

NDC is the National Drug Code. It uniquely identifies human drugs in the United States.

Total Claims Paid Amount is the aggregated sum of the insurer paid amount and the patient out-of-pocket amount paid at the point of service. This metric represents the actual payments made by payers for each drug.

Total List Price Amount is the product of WAC per unit value on incurred date and the quantity dispensed for the claim. This metric reflects the price of the drug using Medi-Span drug price data from the past calendar year.

WAC is the Wholesale Acquisition Cost of a prescription drug. It represents the list price established by a manufacturer for each prescription drug product and is available at the National Drug Code level. WAC does not necessarily reflect actual amounts paid to manufacturers but serves as an upper bound for this amount. MDH obtains the WAC from the Medi-span data product.

ⁱ <https://www.revisor.mn.gov/statutes/cite/62J.84>

ⁱⁱ <https://www.health.state.mn.us/data/rxtransparency/reports.html>

ⁱⁱⁱ <https://www.health.state.mn.us/data/rxtransparency/docs/rxleg rpt.pdf>

^{iv} <https://www.health.state.mn.us/data/rxtransparency/dashboards/index.html>

^v <https://www.revisor.mn.gov/statutes/cite/62J.84>

^{vi} <https://forms.office.com/Pages/ResponsePage.aspx?id=RrAU68QkGUWPJriclVmCjJEFDs2GihEt42OkgoSyU1URFFVTE1VWFIFQ1JIMVVRQ09CUkdBWUpTOS4u>

^{vii} Ultimately, consumers tend to finance the total costs, including those borne by payers, through foregone wages, premium payments and taxes.

^{viii} As noted below, manufacturers may offer discounts or rebates off list prices, but they do not apply to the incremental price increases charged across the supply chain by intermediaries after the drugs are acquired by manufacturers.