Drugs of Substantial Public Interest: List Methodology & Summary

JUNE 26, 2024

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 Rx Price Transparency Initiative: In response to these challenges, the Minnesota Legislature passed the bipartisan Minnesota Prescription Drug Price Transparency Act (the Act) (Minnesota Statutes, section 62J.84) in 2020 for which reporting 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 [i.e., the wholesale acquisition cost (WAC)],[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 greater transparency in the prescription drug market and developing the tools for 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 authorizing 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 average claims paid amount is greater than 125% of the list price or WAC.
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 all NDCs within **drug families** in the list of drugs of substantial public interest. 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**.

To support ongoing work related to designating drugs of substantial public interest, MDH has developed a standing online form for receiving stakeholder **input**.[v] In addition, MDH will be establishing other opportunities for gathering input from stakeholders and the public on future lists, including feedback periods and direct outreach.

Overview of the inaugural list of drugs of substantial public interest

Origins

The Act directs MDH to consider drugs for which the average total paid amount is greater than 125% of the list price (WAC). This difference represents earnings by intermediaries (including wholesalers, PBMs, and pharmacies) paid for by patients and other payers,[vi] over and above the manufacturer list price, which may already be set at a considerably high price.[vii]

Methodology

The inaugural List of Drugs of Substantial Public Interest focuses on the top 10 drug families that contain one or more drug products for which the average claim paid amount was over $100 and at least 125% of the manufacturer's list price, or WAC, as of the date the claim was incurred.

To develop this list, MDH analyzed pharmacy claims in the Minnesota All Payer Claims Database (MN APCD) that were incurred in the commercial market during 2022 together with list prices from Medi-Span reference data using the following steps:

1. MDH calculated the total claims paid amount and the total list price amount for each drug product for all active retail prescription drugs on a per-NDC basis.
2. MDH divided the total claims paid amount by the total list price amount for each drug product to determine the percentage difference between the two values.
3. Next, MDH filtered the list of drug products to those where the total claims paid amount was greater than 125% of the total list price amount and where the average amount paid per claim was greater than $100.
4. All drug products within the same drug family as one of the drugs on the resulting list were grouped and the total claims paid amounts and total list price amounts were aggregated for each drug family.
5. Finally, MDH selected the 10 drug families having the greatest dollar amount difference between total claims and the total list price for the final list.

Prevalence of intermediary price increases

Applying steps 1-4 in the outlined methodology, MDH examined the prevalence of intermediary price increases along the supply chain by analyzing pharmacy claims data for retail prescription drug products from commercial claims in the MN APCD and WAC prices from Medi-Span reference data. In 2022, **approximately 37% of all retail drug products dispensed for commercially insured Minnesotans observed in the MN APCD had average claims paid amounts that were more than 125% of the manufacturer list price** (8,164 of 22,079 distinct products dispensed). Minnesota payers (patients and plans) paid approximately $636.2 million for these 8,164 drug products. The aggregate difference between the total WAC and the total claims paid amount for these drug products was **$344.8 million** or **54.2% of the total paid amount**. While this estimate is simplified due to the nature of available data, it suggests that approximately $292.4 million went to drug manufacturers and $344.8 million was earned by intermediaries such as wholesalers, PBMs, and/or pharmacies.

The list

The inaugural List of Drugs of Substantial Public Interest features 10 drug families (see Table 1) containing a total of 364 drug products, listed by their National Drug Code (NDC), from 76 manufacturers. These 10 drug families include all drug products on the market within the family for comparison with pharmaceutically equivalent drug products across all strengths and package sizes.

As illustrated in the methodology above, MDH selected the 10 drug families that have the greatest absolute difference between the total list price and the total claims amount paid. The resulting 10 drug families include those that:

- treat a range of conditions
- are considered “specialty drugs”
- include a mix of generic and brand name drug products

For a complete list of NDCs on the June 2024 list, visit MDH’s web page: Prescription Drug Price Transparency Public Interest Drug Lists.[viii]

Table 1: Drug Families in the List of Drugs of Substantial Public Interest, June 2024

Drug Family	Therapeutic Class	Treatment or Purpose	Count of NDCs	Total Claims	Total of WAC	Total Paid Amount	Difference*
Abiraterone Acetate Tablet	Antineoplastics And Adjunctive Therapies	Cancer	35	5,499	$ 4,884,579	$ 19,237,685	294%
Capecitabine Tablet	Antineoplastics And Adjunctive Therapies	Cancer	39	3,925	$ 437,774	$ 3,087,526	605%
Dimethyl Fumarate Capsule Delayed Release	Psychotherapeutic and Neurological Agents	Multiple sclerosis (MS)	27	3,191	$ 7,293,900	$ 13,192,104	81%
Emtricitabine-Tenofovir Disoproxil Fumarate Tablet	Anti-Infective Agents - Antivirals	HIV, PrEP	26	16,415	$ 1,313,035	$ 13,390,587	920%
Everolimus Tablet	Antineoplastics And Adjunctive Therapies	Immuno-suppressant	38	1,011	$ 7,626,430	$ 9,569,824	25%
Glatiramer Acetate Solution Prefilled Syringe	Psychotherapeutic and Neurological Agents	Multiple sclerosis (MS)	8	7,056	$ 25,300,371	$ 28,836,961	14%
Imatinib Mesylate Tablet	Antineoplastics And Adjunctive Therapies	Cancer	36	3,462	$ 2,949,368	$ 10,543,139	257%
Lacosamide Tablet	Neuromuscular Agents - Anticonvulsants	Anti-seizure	71	22,345	$ 11,486,951	$ 13,638,024	19%
Methylphenidate HCl Tablet Extended Release	Adhd/Anti-Narcolepsy/Anti-Obesity/Anorexiants	ADHD	55	150,624	$ 44,156,967	$ 46,376,225	5%
Pancrelipase (Lipase-Protease-Amylase) Capsule Delayed Release Particles	Gastrointestinal Agents - Digestive Aids	Digestive aid	29	18,205	$ 31,338,420	$ 39,003,881	24%
Total	--	--	**364**	**231,733**	**$ 136,787,795**	**$ 196,875,956**	--

Glossary

Drug families are groups of one or more prescription drug products 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 product.

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/rxlegrpt.pdf

[iv] https://www.health.state.mn.us/data/rxtransparency/dashboards/index.html

[v] https://forms.office.com/Pages/ResponsePage.aspx?id=RrAU68Qk GUWPJricIVmCjJEFDds2GihEt42OkgoSyU1URFFVTE1VWFlFQ1JIMVVRQ09CUkdBWUpTOS4u

[vi] Ultimately, consumers tend to finance the total costs, including those borne by payers, through foregone wages, premium payments, and taxes.

[vii] 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.

[viii] https://www.health.state.mn.us/data/rxtransparency/pilists.html