

Minnesota Prescription Drug Price Transparency

REPORT TO THE MINNESOTA LEGISLATURE

February 2023

Minnesota Prescription Drug Price Transparency: Report to the Minnesota Legislature
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February 21, 2023

To the Honorable Chairs and Ranking Members:

As directed in Minnesota Statutes, Section 62J.84, the Minnesota Department of Health (MDH) has begun implementing the Minnesota Prescription Drug Price Transparency Act (the Act), which requires drug manufacturers to report information to MDH on high and quickly increasing drug prices and for MDH to publicly publish the reported information. Enclosed is the first required legislative report. It represents preliminary analysis of collected data, capturing information reported by manufacturers of prescription drugs from the first half of 2022. The report also includes early takeaways on the impact of the initiative.

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Three key findings from the report include:

- Holding health care use constant, the price increases required to be reported in the first four months of 2022 are likely to impact—at minimum—an estimated 41,000 people living in Minnesota. As a result, health care spending is estimated to increase—at minimum—by \$32 million in 2022.
- Nearly a year after the first required data reporting, data quality and compliance with the statutory reporting requirement are poor. MDH is in the process of addressing data quality concerns with almost all manufacturers (69 manufacturers for 368 reports). Additionally, MDH is working to enforce compliance. Approximately half of expected reports have not been submitted (68 manufacturers for 442 reports).
- Minnesota's legislation has had a positive impact on prescription drug price transparency in the state. Unfortunately, in its current design, the Act's impact is limited because:
 - The focus is on list prices instead of net prices, and therefore does not represent the actual income manufacturers earn from the sale of their products.
 - The focus is only on manufacturers rather than the full supply chain. Other downstream entities—like pharmacy benefit managers, wholesalers, pharmacies, and payers—also contribute to the final price paid by consumers.
 - Reporting requirements treat drug pricing as if there is one market functioning under a single set of practices, which does not reflect the complex factors—such as incentives, economic environments, and business arrangements—driving pricing and rebate practices.
 - The Act broadly protects trade secret information, thereby shielding information from public release.

This report and the publicly available data reported by prescription drug manufacturers will become available on an MDH website (<u>Prescription Drug Price Transparency Home</u> www.health.state.mn.us/data/rxtransparency/).

Questions or comments on the report may be directed to Stefan Gildemeister, the State Health Economist, at (651) 201-4520 or health.Rx@state.mn.us.

Sincerely,

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Executive Summary

In 2020, the Minnesota Legislature passed the Prescription Drug Price Transparency Act or "the Act" (Minnesota Statutes, Section 62J.84) to increase transparency into the pricing of prescription drugs. Drug manufacturers are required to report on prices for new drugs and price increases over specified thresholds (see Table 1). The Act requires submission of several data elements, but the primary reporting element is the Wholesale Acquisition Cost (WAC), or "list price," for a 30-day supply. Requirements for reporting under the Act took effect January 1, 2022.

Overview

MDH identified 798 unique prescription drugs across 137 manufacturers with new drug introductions or price increases above the threshold in the Act that meet the reporting requirements on or before June 30th (this reporting period includes pricing event effective dates between January 1st and May 1st). MDH received about half (368) of the expected reports from 69 manufacturers and is actively seeking compliance for the additional reports not submitted. MDH has determined that virtually all reports covered in this analysis require clarifications or corrections by manufacturers. As a result, the analysis reported here should be considered preliminary.

Preliminary Findings

Among new drugs reported to MDH, the median reported list price at market introduction was \$6,612.

Among drugs reported to MDH due to a *price increase*, the median reported list price after the increase was \$1,062. The median reported percent price increase was 7.9%, ranging from 1.5% to 106.0%.

Based on historical data, MDH estimates that the price increases included in this report (January 1st to May 1st) comprise about 68.0% of all price increases for calendar year 2022. The number of price increases that would have required price increase reporting under Minnesota thresholds has steadily declined over the last five years.



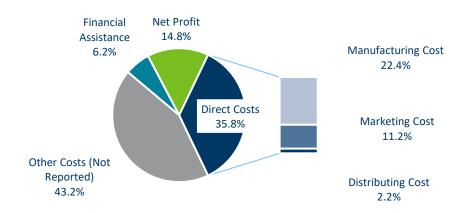


Source: MDH, Health Economics Program summary of data reported under Minnesota's Prescription Drug Price Transparency Act for the period of January 1, 2022, to June 30, 2022.

Based on historical data, MDH estimates the price increases requiring reporting from January 1 to May 1 of 2022 would impact—at a minimum—41,000 people living in Minnesota during 2022 and would generate an additional \$32 million in health care spending in 2022.

As a percentage of gross revenue, on average manufacturers reported 35.8% was spent on direct costs on of manufacturing, marketing, and distributing, 14.8% on profit, and 6.2% on financial assistance.

Distribution of Preliminary Reported Gross Revenue Among Price Increase Reports



Source: MDH, Health Economics Program analysis for preliminary reported data under Minnesota's Prescription Drug Price Transparency Act for the period of January 1, 2022, to June 30, 2022. Note: Other Costs (Not Reported) may include direct costs other than those of manufacturing, marketing, and distributing the prescription drug.

Takeaways and Next Steps

While MDH is not yet positioned to offer definitive and final insights into the efficacy of the Act given the recency of data availability and the need to validate and improve data quality and completeness, early takeaways from the initiative include:

- With the implementation of the Act, transparency in pharmaceutical pricing in Minnesota has distinctly increased.
- To meaningfully impact affordability and sustainability of prescription drug prices, transparency needs to be expanded and paired with stronger oversight and regulation of pricing practices.
- Transparency laws across the nation may have affected patterns of price increases by manufacturers.

MDH is expanding its analytic use and dissemination of reported data as it improves the quality of the data—including by considering other data on prescription drugs collected in Minnesota and by programs in other states and the federal government. As part of these activities, MDH will continue incrementally expanding the data available on the price transparency website as interactive dashboards (Price Transparency Home;; www.health.state.mn.us/data/rxtransparency/).

Introduction

For many people living in Minnesota, drug therapy is a critical component of health care and well-being. Prescription drugs provide many patients with life-saving treatment and improvements in quality-of-life. Yet, many people living in Minnesota face affordability challenges due to high and increasing prescription drug prices and changes in health insurance benefit designs. There is considerable evidence that racial and ethnic minority populations disproportionately experience access barriers to novel and high-cost medications, lower-cost generic therapies, certain emergency use therapies, and preventive or critical care therapies. 3

Prescription drug prices have been shown to cause patients to forego or reduce treatment; and prescription drug prices, as a component of overall out-of-pocket spending, affect the ability of people living in Minnesota to pay their health care bills. ⁴ Not only are there increasing numbers of people living in Minnesota struggling to afford their medications, ⁵ but trends in prescription drug prices also place pressure on public and private payers, as well as employers. ⁶

In response, the Minnesota Legislature passed the Prescription Drug Price Transparency Act or "the Act" (see Appendix A) in 2020 to increase transparency into the pricing of prescription drugs and

¹ In 2013, the most recent year for which a more in-depth analysis was conducted most insured Minnesotans (about 3.2 million or 68.4 percent) filled one or more prescriptions at a pharmacy. This represents nearly 56 million filled pharmacy prescriptions for Minnesota residents that year. (MDH/Health Economics Program and PRIME Institute/Data IQ analysis of Minnesota All Payer Claims Database, 2016; MDH/Health Economics Program (2016) Pharmaceutical Spending and Use in Minnesota: 2009 to 2013, Issue Brief. Pharmaceutical Spending and Use in Minnesota: 2009 - 2013 (www.health.state.mn.us/data/apcd/docs/RxIssueBrief1Proof20161102.pdf); MDH/Health Economics Program and PRIME Institute/Data IQ analysis of Minnesota All Payer Claims Database, 2019.)

² For example, see 46brooklyn (2021). <u>The Rise of the Drug Mix Empire (https://www.46brooklyn.com/research/2020/12/15/the-increasing-irrelevance-of-brand-drug-price-increases).</u>

³ Essien UR; Dusetzina SB; and WF Gellad. A Policy Prescription for Reducing Health Disparities—Achieving Pharmacoequity; JAMA. 2021;326(18)

⁴ In 2021, 5.7 percent of Minnesotans reported not filling a prescription in a 12-month period due to costs. (MDH/Health Economics Program analysis of the Minnesota Health Access Survey. In 2013, about 135,000 insured Minnesotans paid more than \$1,000 in out-of-pocket prescription drug pharmacy costs, with 1,835 Medicare beneficiaries and 1,075 commercially insured Minnesotans having paid \$5,000 or more out of pocket.

⁵ In 2021, 5.7 percent of Minnesotans reported not filling a prescription in a 12-month period due to costs. (MDH/Health Economics Program analysis of the Minnesota Health Access Survey. In 2013, about 135,000 insured Minnesotans paid more than \$1,000 in out-of-pocket prescription drug pharmacy costs, with 1,835 Medicare beneficiaries and 1,075 commercially insured Minnesotans having paid \$5,000 or more out of pocket.

⁶ In 2020, Minnesota spending on retail prescription drugs (less prescription drug rebates) totaled over \$5.9 billion, or 9.8 percent of all health care spending in Minnesota. If one includes estimates of spending on prescription drugs administered in medical settings, like hospitals, infusion centers, and nursling homes, prescription drug spending in Minnesota in 2020 likely reached as high as \$10.2 billion and accounted for 17.0 percent of total spending. (MDH/Health Economics Program (unpublished), "Minnesota Health Care Spending: 2020 Estimates and Ten-Year Projections; Minnesota Department of Health, Health Economics Program, MN APCD Issue Brief: Pharmaceutical Spending and Use in Minnesota: 2009-2013. November 2016. Pharmaceutical Spending and Use in Minnesota: 2009-2013 (https://www.health.state.mn.us/data/apcd/docs/RxIssueBrief1Proof20161102.pdf).

inform future policy through an improved understanding of factors driving prescription drug prices. The Act directs the Minnesota Department of Health (MDH) to develop a system for collecting data from pharmaceutical manufacturers and publicly reporting these data. The Act also requires MDH to annually submit a report to the legislature containing a synthesis of the data and assessment of the impact of the Act.

This is the first legislative report prepared by MDH. It contains:

- An overview of the Act.
- An update of MDH's implementation of the Act, including a summary of submitted information and preliminary analyses of reported data.
- A preliminary discussion of the effectiveness of the Act.

This report covers the reporting period from January 1, 2022⁷ to June 30, 2022.

Minnesota Prescription Drug Price Transparency Act

Overview of Statutory Requirements

The Act has three core requirements:

- 1. **Reporting:** Drug manufacturers must report to MDH a set of specified data elements when a drug's price meets the criteria for reporting. Broadly, reporting is required for higher priced new drugs and certain price increases.
- 2. **Public Posting:** MDH must publicly post data reported by manufacturers.
- 3. **Assessing Impact:** MDH must assess the Act's effectiveness in addressing the three primary statutory goals:
 - a) Promoting transparency in pharmaceutical pricing for the state and other payers.
 - b) Enhancing the understanding of pharmaceutical spending trends.
 - c) Assisting the state and other payers in the management of pharmaceutical costs.

Manufacturer reporting takes place throughout the year and is governed by defined triggering events associated with the introduction of new drugs⁸ and price increases. Table 1 summarizes the

⁷ Under the law, manufacturers have a 60 days after a triggering event (a qualifying price increase or introduction at a qualifying price level) for reporting and the submission of data. MDH received the first submission on March 1, 2022 for a triggering event date of January 1, 2022.

⁸ Minnesota Statutes 62J.84 criteria for reporting new drugs is defined in reference to the Centers for Medicare and Medicaid Services' tier threshold for specialty drugs, which was \$830 in 2022. Centers for Medicare and Medicaid Services. (February 3, 2022). Contract Year 2023 Final Part D Bidding Instructions (https://www.cms.gov/files/document/2023partdbiddinginstructions.pdf).

main criteria for when reporting is required.⁹ Requirements for reporting under the Act took effect January 1, 2022, and manufacturers have 60-days after a triggering event to submit reports. For example, drugs with triggering events on January 1, 2022 must be reported by March 2, 2022. The price metric identified in the Act is the Wholesale Acquisition Cost (WAC),¹⁰ which is defined in federal law, and is a manufacturer's list price.

Table 1: Triggering Events for Prescription Drug Reporting

Trigge Type		Price Minimum	Criteria
Price Increase	Brand ¹¹	Greater than or equal to \$100 WAC	Greater than or equal to 10% increase in WAC over previous 12 months or 16% over previous 24 months
Price Increase	Generic ¹²	Greater than or equal to \$100 WAC	Greater than or equal to 50% increase in WAC over previous 12 months
Price at Market Entry		Greater than \$830 WAC in 2022	Introduction for sale
Price at Market Entry	Generic and	Greater than \$830 WAC in 2022 and is not at least 15% lower than the referenced brand name drug	Introduction for sale

⁹ For more detail on the triggers and criteria for reporting, see the Submission Requirements section of MDH's Form and Manner for Prescription Drug Price Data Sets guidance at: <u>Form and Manner for Prescription Drug Price Data Sets, Feb. 2022</u> (https://www.health.state.mn.us/data/rxtransparency/docs/rxformmanner022322.pdf).

¹⁰ Wholesale acquisition cost is defined in United States Code, title 42, section 1395w-3a(c)(6)(B) as "the manufacturer's list price for a prescription drug to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price."

¹¹ Brand name drug is defined in Minnesota Statutes 62J.84, subdivision 2(c) as "an original, new drug application approved under United States Code, title 21, section 355(c), except for a generic drug as defined under Code of Federal Regulations, title 42, section 447.502; or a biologics license application approved under the United States Code, title 45, section 262(a)(c).

¹² Generic drug is defined in Minnesota Statutes as "a drug that is marketed or distributed pursuant to: an abbreviated new drug application approved under United States Code, title 21, section 355(j); an authorized generic as defined under Code of Federal Regulations, title 45, section 447.502, or a drug that entered the market the year before 1962 and was not originally marketed under a new drug application."

Manufacturers are required to submit a range of data elements for each drug with a triggering event. Table 2 summarizes the data elements by data type (see Appendix B-1 and B-2). Manufacturers may identify certain information as trade secret and as non-public. They must provide a rationale for this designation. When MDH withholds non-public data from publication because they are protected by trade secret laws or other data practices provisions, MDH must describe the nature of information withheld and the basis for withholding the information.

Table 2: Required Data Elements

Data Type	Data Elements
Administrative Information	 Descriptive Drug Information Manufacturer Information Acquisition Information (company, date, price)*
Pricing History and Cost Drivers	 Net Increase Percent (current and previous five years) Factors Contributing to Increase Direct Costs (manufacturing, marketing, distribution) Sales Revenue and Net Profit WAC at Acquisition and Prior Year* (WAC at Introduction**) Year Introduced to Market and WAC at Introduction* WAC Price – Previous Five Years*
Industry Relationships and Market Context	 Financial Assistance Provided to Patient Programs Pay for Delay Agreements Patent Expiration Date Ten Highest Foreign Prices (brand only) Breakthrough Therapy Designation/Priority Review (Y/N)**

^{*}Data element that is required for drugs acquired by a manufacturer within 12 months of triggering a price increase report.

The Act also provides that a manufacturer may be subject to a civil penalty not to exceed \$10,000 per day of violation for failure to submit timely reports, failure to provide required information, or providing inaccurate or incomplete information.

^{**}Data element required only for new drugs.

National Context

With the adoption of the Act, Minnesota joined 17 other states that had passed drug price transparency laws and has been followed by three additional states passing transparency legislation.¹³ Minnesota's law differs in some important ways from those in other states:

- Collection of trade secret information and evaluation of trade secret assertions. Minnesota's law—like many state prescription drug price transparency initiatives—requires reporting of data elements regardless of trade secret status. However, Minnesota is among the few states that require manufacturers justify the reason for their position that data are trade secret and evaluate manufacturer justifications, disclosing them if no legal basis is found.
- Volume of detailed information. State transparency initiatives vary by what types of information, and at what level of specificity or aggregation are required. In Minnesota, manufacturers are required to report data at the drug product level. This means reporting occurs at a national drug code level¹⁴ for all unique combinations of drug name, dosage, strength, and package size. In addition, required data include administrative information, pricing history, cost drivers, industry relationships, and market context.
- Reporting only from manufacturers and focus on list prices. Minnesota's reporting requirement is limited to manufacturers of prescription drugs and the price they set for drugs, which is the WAC or the list price. Other states also collect data from other entities throughout the prescription drug supply chain, including pharmacy benefit managers (PBMs), wholesalers, pharmacies, and health plans. Reporting in other states also aims to collect data on net prices and net expenditures, thereby helping to illustrate the flow of funds through the supply chain and understanding the economic forces shaping pricing.
- Continuous data reporting. While the transparency initiatives in many other states require annual reporting, the Act in Minnesota requires manufacturers report to MDH on an ongoing basis within 60 days of a triggering event. Under this design, manufacturers' price changes may trigger reporting at any point and possibly multiple times in a calendar year.

¹³ National Academy of State Health Policy. "2022 State Legislative Action to Lower Pharmaceutical Costs." <u>NASHP - 2022 State Legislative Action to Lower Pharmaceutical Costs</u> (https://www.nashp.org/rx-legislative-tracker/).

¹⁴ The National Drug Code (NDC) is a unique, three-segment number assignment by the FDA and used as a universal identifier for individual drug products in the United States. The first set of numbers identifies the labeler, such as the drug manufacturer, repackager, or distributer. The second set is the product code, which details the drug strength, dosage form and formulation, and the last set identifies the package size and type. <u>U.S. FDA - National Drug Code Directory (https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory)</u>.

Implementation of the Act

MDH approached implementation of the Act with the goal to balance efficiency in data collection with ensuring that collected data would be timely and of high-quality. To that end, MDH consulted with industry representatives, communicated through GovDelivery announcements and state register notices, and sought feedback from stakeholders. MDH also established a website to host real-time information throughout the implementation process (Prescription Drug Price
Transparency Home (www.health.state.mn.us/data/rxtransparency/); see Appendix C). This website will also be the location where MDH hosts data for public reporting.

MDH drew on the expertise of state officials engaged in prescription drug policy and prescription drug price transparency initiatives in other states, subject matter experts, and the National Academy for State Health Policy (NASHP). Figure 1 provides an overview of four distinct milestones of implementation of the Act.

Establishing Reporting
Guidance & System
(Apr - Dec 2021)

Data Submission &
Review
(Mar 2022 - ongoing)

Public Reporting &

Analysis

May 2022 - ongoing

Figure 1: Implementation Milestones of the Act

Establishing Reporting Guidance

Registration & Reporting

System Goes Live

(Jan - Feb 2022)

MDH sought to ensure that data reporting requirements were sufficiently rooted in industry practices by contracting with subject matter experts at Ten2Eleven Business Solutions, LLC, a firm that provides business technology solutions in the prescription drug space. To develop the reporting guidance, MDH held two public meetings between June and November 2021, at which MDH solicited manufacturer input. The final reporting guidance—which incorporated feedback from manufacturers, their trade associations, and other stakeholders—was released in December of 2021.

Registration & Reporting System

MDH developed an online reporting system for manufacturers to submit required information easily and securely. MDH held a training on the registration portal, responded to questions from manufacturers, and prepared online materials to assist manufacturers in their reporting. 15

Data Submission & Review

Following the statutory reporting timeframes, MDH received its first data submissions in March 2022 for new drug introductions and price increases with triggering events on or after January 1, 2022. MDH staff has reviewed the initially reported data to assess compliance with the Act and reporting accuracy. A detailed analysis of the scope of reporting and state of quality of the data is reported in the section titled Reported Prescription Drugs. MDH is actively working with manufacturers to address the identified concerns and questions with compliance and data quality.

Public Reporting and Analysis

MDH's initial public posting of reported data will be iterative. MDH has prepared interactive displays that present drug-level data and aggregate trends—we refer to them as data dashboards. MDH anticipates releasing the following seven dashboards over time. They are accessible under the following URL: https://www.health.state.mn.us/data/rxtransparency/

- Reporting Snapshot Descriptive tables of the volume and types of data reported to MDH, use
 and spending context for the reported drugs, and an overview of the review and public posting
 status of reported data.
- Price Increase: Five Year Price Analysis Data on average current and cumulative price change percent over the most recent five years.
- Price Increase: Comparative Price Analysis Data comparing the 5-year cumulative price change for a drug product with the cumulative mean price change of equivalent products.
- Price Increase: Reported Revenues, Costs, and Profits Data on direct costs, revenues, and profits of drug products.
- Price Increase: Drug Report List of drugs reported for price increases above statutory thresholds and all data elements that may be publicly posted.
- New-to-market: Drug Report List of new-to-market drugs with prices above statutory thresholds and all data elements that may be publicly posted.

¹⁵ Materials that manufacturers can consult in the process of submitting the required information is available online: <u>Prescription Drug</u> Price Transparency: Information for Reporting Entities (www.health.state.mn.us/data/rxtransparency/rptgentities.html)

Acquired Product Price Impact Analysis – Information about acquired drugs.

Additionally, MDH will make downloadable files available online of all reported data that may be made public. These dashboards and downloadable files will be updated on a rolling basis following the completion of reviews for compliance and accuracy, and remediation by manufacturers.

Reported Prescription Drugs

This section provides a preliminary summary of prescription drug prices reported to the department from manufacturers on or before June 30th, 2022. The data received are incomplete, inconsistent, and a significant portion remain unverified. As noted, MDH is in the process of verifying and reviewing data and is following up with virtually all manufacturers where the quality of data appears suspect or inconsistent with requirements. Additionally, MDH is pursuing compliance checks for manufacturers with incomplete or nonexistent/absent reporting. Therefore, due to data quality and quantity concerns, the summary and analysis presented in this report is preliminary. MDH believes despite the preliminary nature of the data, they lend themselves to exploring high-level takeaways.

To support our analysis and identify what reporting is expected, MDH benefited from a range of reference data—including Wolters Kluwer Medi-Span, ¹⁶ FDA National Drug Code Directory, ¹⁷ and FDA Purple Book. ¹⁸ This information provides MDH the ability to analyze market attributes and pricing trends related to all drugs for which the department expects manufacturer reporting. Appendix D provides a summary of these reference data. Throughout this section, MDH presents the preliminary and unrefined **reported data**—submitted by manufacturers to MDH—in relation to the **data on expected reports** and statistics based on reference data on all drugs for which MDH expected to receive a report.

Overview of Reported Drugs

Manufacturers of drugs that met the triggering event criteria defined in the Act–either a new drug or a price increase–between January 1 and May 1 of 2022 were required to report on or before June 30, 2022.¹⁹ Historical data indicate that the pricing events targeted by the Act happen earlier in the year with 68.0% of all price increases within a typical calendar year occurring within these first four months. As such, the reporting period for this report likely covers most drug reports for the year.²⁰

¹⁶ Additional information about Medi-Span is available at: <u>Medi-Span: Drug Data Solutions for Healthcare</u> (https://www.wolterskluwer.com/en/solutions/medi-span).

¹⁷ U.S. Federal Food and Drug Administration. National Drug Code Directory. Available at: <u>U.S. FDA - National Drug Code Directory</u> (https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory).

¹⁸ U.S. Federal Food and Drug Administration. Purple Book: Database of Licensed Biological Products. <u>U.S. FDA - Purple Book:</u> Database of Licensed Biological Products (https://purplebooksearch.fda.gov/downloads).

¹⁹ This lag is due to the 60 days manufacturers are allowed to submit data after a triggering event. This report includes all data submissions from January 1 to June 30, 2022 and may include some drugs with triggering events after May 1, 2022 that were submitted before June 30th.

²⁰ MDH conducted this analysis using reference data from Walters Kluwer's Medi-Span data for the years 2019 to 2021. Additional information about Medi-Span is available at: Medi-Span: Drug Data Solutions for Healthcare (https://www.wolterskluwer.com/en/solutions/medi-span).

Using reference data, MDH identified 810 triggering events—either new drug introductions or price increases—for 798 unique prescription drugs across 137 manufacturers that were statutorily required to report on or before June 30.²¹ As shown in Table 3, MDH received 368 reports from 69 manufacturers—or 45.4% of expected reports from 50.4% of the manufacturers. (MDH received an additional 108 reports, 21 for new drugs and 87 for price increases, for the same period that were not statutorily required; these reports are included in the analysis in this section.)

Table 3: Expected Reports and Required Reports Received

Measure	Expected	Required and Received	Percentage Received
New Prescription Drug Reports	112	43	38.4%
Prescription Drug Price Increase Reports	698	325	46.6%
Total	810	368	45.4%

Source: MDH, Health Economics Program summary of preliminary data expected and reported under Minnesota's Prescription Drug Price Transparency Act for the period of January 1, 2022, to June 30, 2022. Note: reports not statutorially required are not presented in this table.

New drug introductions and price increases occurred across a wide range of therapeutic classes.²² The ten therapeutic classes with the highest number of reports by report type are included in Table 4 and Table 5.

²¹ Some of these drugs had more than one price increase during this timeframe that triggered required reporting.

²² U.S. Federal Food and Drug Administration. USP Therapeutic Categories Model Guidelines. March 28, 2018. Available at: <u>USP Therapeutic Categories Model Guidelines (https://www.fda.gov/regulatory-information/fdaaa-implementation-chart/usp-therapeutic-categories-model-guidelines)</u>.

Table 4: Top 10 Therapeutic Classes Associated with New Prescription Drug Price Reports

Therapeutic Class	Number of Reports	Percent of Reports Received
Antineoplastics and Adjunctive Therapies	17	26.5%
Hematological Agents – Misc.	8	12.5%
Endocrine and Metabolic Agents – Misc.	5	7.8%
Dermatologicals	5	7.8%
Cardiovascular Agents – Misc.	4	6.3%
Analgesics – Anti-Inflammatory	3	4.7%
Anti-Infective Agents – Misc.	2	3.1%
Antihistamines/Nasal Agents/Cough and Cold/Respiratory/Misc. – Antiasthmatic and Bronchodilator Agents	2	3.1%
Diagnostic Products	2	3.1%
Hematological Agents – Hematopoietic Agents	2	3.1%
Subtotal	50	78.0%

Source: MDH, Health Economics Program summary of preliminary data expected and/or reported under Minnesota's Prescription Drug Price Transparency Act for the period of January 1, 2022, to June 30, 2022.

Table 5: Top 10 Therapeutic Classes Associated with Prescription Drug Price Increase Reports

Therapeutic Class	Number of Reports	Percent of Reports Received
Antineoplastics and Adjunctive Therapies	47	11.4%
Endocrine and Metabolic Agents – Antidiabetics	30	7.3%
Ophthalmic Agents	23	5.6%
Passive Immunizing and Treatment Agents	19	4.6%
Cardiovascular Agents – Antihypertensives	17	4.1%
Analgesics – Opioid	16	3.9%
Dermatologicals	15	3.6%
Anti-Infective Agents – Antivirals	14	3.4%
Nutritional Products – Minerals and Electrolytes	14	3.4%
Endocrine and Metabolic Agents – Misc.	13	3.2%
Subtotal	208	50.5%

Source: MDH, Health Economics Program summary of preliminary data expected and/or reported under Minnesota's Prescription Drug Price Transparency Act for the period of January 1, 2022, to June 30, 2022.

Early Results: New Drugs

Using reference data, MDH identified 112 new drugs that required reporting during the first half of 2022 following their introduction to market at prices that exceeded \$830, the 2022 threshold. Of these, 81 were brand drugs and 31 were generic drugs. MDH received 38.4% of these expected reports by June 30, 2022. MDH identified an additional 44 generic drugs were introduced for sale at prices greater than \$830 but were not required to report because their drug products were introduced at a discount from the reference brand drug product of greater than 15%, or a reference brand drug was not on the market.

The median reported list price at market introduction was \$6,612.50 with half of all introductions priced between \$3,184.59 and \$15,396.47. Manufacturers reported existing patent protection for 64.1% of the submitted new drug reports. Patent protection means that the period during which a manufacturer enjoys market exclusivity where competitor drugs are delayed or cannot be brought to market has not ended. Among these, 28 were reported as having received priority review from the Food and Drug Administration (FDA), and of these, 16 were also indicated as having breakthrough therapy designation. Priority review and breakthrough therapy designation are FDA

approval processes that seek to reduce the development and review time for drugs that may provide a substantial improvement over existing treatment options.

Manufacturers reported information on direct costs attributed to manufacturing, marketing, and distributing. ²³ Table 6 aggregates the average reported direct cost values for each category across new drug introductions. The Act requires collection of these three categories, but the manufacturer is not required to report other direct costs; so, the data represented likely captures only a portion of a manufacturer's total direct costs. ²⁴ The cost of manufacturing and distribution each accounted for nearly half of the reported direct costs and marketing accounted for 6.3% of these costs. This data was inconsistently reported and, again, MDH is in the process of addressing many errors; so, the information presented is not final.

Table 6: Summary of Reported Direct Cost Information for New Drugs

Reported Direct Cost	Average Reported Value (in mill \$)	Percent of Total
Manufacturing	\$127.0	49.0%
Marketing	\$16.4	6.3%
Distribution	\$115.6	44.6%
Total	\$259.0	100.0%

Source: MDH, Health Economics Program summary of preliminary data expected and/or reported under Minnesota's Prescription Drug Price Transparency Act for new prescription drugs for the period of January 1, 2022, to June 30, 2022.

Early Results: Price Increases

MDH identified 698 triggering events for 686 unique drugs that were on the market that required reporting during the first half of 2022 due to exceeding the price and percentage increase criteria established by the Act.²⁵ MDH estimates that a minimum of 41,000 people living in Minnesota would be impacted by these price increases based on prescribing patterns from the first six months of 2021,²⁶ and estimates these increases will raise health care spending, at a minimum, by \$32 million in Minnesota in 2022.

Of the 698 expected price increase reports, only nine were for generic drugs. This disparity partially stems from the difference in reporting criteria in the Act between brand drugs and generic drugs:

²³ In some instances, manufacturers reported the same value for direct costs across multiple items with the same generic ingredient. For this analysis, MDH assumed these values represent total direct cost amounts distributed evenly rather than duplicate values.

²⁴ Direct costs collected by MDH do not include research and development costs.

²⁵ Some of these drugs had more than one price increase during this timeframe that triggered required reporting.

²⁶ MDH reviewed pharmacy claims data collected in its Minnesota All Payer Claims Database (MN APCD) for claims incurred during the first six months of 2021 that relate to the drug products qualified as a triggering event for price increase reporting.

brand drugs must be reported for a price increase of 10% or more over a 12-month period or 16% or more over a 24-month period. Generic drugs that generally have lower prices in the first place need only be reported for a price increase of 50% or more during a 12-month period. If the reporting criteria were the same for generic drugs as they are for brand name drugs, an additional 127 generics drugs would have been required to be reported.²⁷

The median list price after price increase for drugs reported to MDH was \$1,062.35, with half of the prices between \$349.90 and \$3,354.12. Figure 2 provides data for all drugs for which reports should have been submitted. As expected, the range in the prices varied more greatly for brand name drugs compared to generics.

Figure 2: Median and Interquartile Range of List Prices for Expected Price Increase

Drugs



Source: MDH, Health Economics Program analysis of Medi-Span reference data from Wolters Kluwer's Medi-Span Suite of electronic drug data files on expected for price increase reporting for the period of January 1, 2022, to June 30, 2022. Additional information about Medi-Span is available at: Medi-Span: Drug Data Solutions for Healthcare (Medi-Span: Drug Data Solutions for Healthcare (https://www.wolterskluwer.com/en/solutions/medi-span)

Manufacturers reported that 143 of the drugs reported for their price increase retained patent protection.

Price increases for drugs that are the subject of this initial reporting under the Act tend to occur on regular schedules. As shown in Figure 3, this means that price increases build up over time just like compound interest. The median cumulative increase reported by manufactures over the five-year period preceding the current increase, therefore preceding the time the Act was in force, was

²⁷ If statutory pricing criteria were the same for brand and generic drugs, 18.9 percent of brand drugs and 17.1 percent of generic drugs with a price increase of any amount during the review period would have required reporting.

32.4%. Figure 3 shows aggregated preliminary data; once data are validated and corrected, MDH will be able to report these trends for specific drugs (National Drug Code or "NDC"), drug families, and for therapeutic classes.



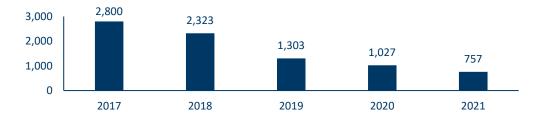
Figure 3: Five-Year Median Price Increase Percent with Cumulative Impact

Source: MDH, Health Economics Program summary of preliminary data reported under Minnesota's Prescription Drug Price Transparency Act for the period of January 1, 2022, to June 30, 2022.

For illustration, Figure 4 presents a review of reference data that shows the number of price increase events over the previous five years that would have met the Act's requirements for reporting. Note that this is solely for reference as the reporting requirement was not in force in Minnesota until 2022. The number of significant price increases, as defined by the Act, has steadily declined. Several factors may have influenced this change in pricing dynamics, including:

- Increased competition resulting from a significant number of blockbuster drugs becoming generically available between 2010 and 2020.²⁸
- Implementation of price transparency laws requiring manufacturer reporting of significant price.
- Operational and financial decisions influenced by the COVID-19 pandemic in 2020 and 2021.

Figure 4: Estimated Number of Price Increase Events that Would Have Met Minnesota's Reporting Thresholds for the Five Years Prior to Implementation



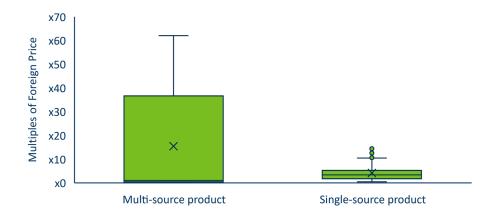
²⁸ DeRuiter, Jack, and Holston, Pamela L. "Drug Patent Expirations and the 'Patent Cliff.'" Published June 20, 2012. U.S. Pharmacist. <u>U.S. Pharmacist - Drug Patent Expirations and the "Patent Cliff" (https://www.uspharmacist.com/article/drug-patent-expirations-and-the-patent-cliff).</u>

Source: MDH, Health Economics Program analysis of Medi-Span reference data from Wolters Kluwer's Medi-Span Suite of electronic drug data files. Additional information about Medi-Span is available at: Medi-Span Suite of electronic drug data files. Additional information about Medi-Span is available at: Medi-Span Suite of electronic drug data files. Additional information about Medi-Span is available at: Medi-Span Suite of electronic drug data files. Additional information about Medi-Span is available at: Medi-Span Suite of electronic drug data files. Additional information about Medi-Span is available at: Medi-Span Suite of electronic drug data files. Additional information about Medi-Span is available at: Medi-Span Suite of Electronic drug data files. Medi-Span Suite drug data files. Medi-Span Su

As part of the Act's requirements, manufacturers reported the top ten foreign prices for 21% of reported drugs. ²⁹ MDH is following up with manufacturers to ensure that drug-specific reporting on international prices is complete, accurate, and posted publicly; at this point these data have significant gaps and several manufacturers are claiming trade secret protection over these data. Analyzing data as submitted, MDH finds U.S. list prices overall exceed the reported international prices by substantial amounts. Although U.S. prices for a few reported drugs are below international list prices, U.S. prices on average are nearly three times larger than their international counterparts. ³⁰

As shown in Figure 5 (which distinguishes between single-source³¹ and multi-source drugs³²) the U.S. list prices for most drugs significantly exceed international prices, sometimes 60-times larger. Price differences in foreign countries for single source brand drug products were less significant, suggesting that brand drug prices for multisource drug products may recognize more rapid price reductions as generic products are introduced to the market in foreign countries.

Figure 5: U.S. WAC as a Multiple of the Foreign Price: Full Range, Interquartile Range and Median for Price Increase Drugs



²⁹ Some manufacturers have indicated that they have not reported prices in other countries because drugs are not being sold in equivalent package sizes. MDH has communicated to manufacturers that they must estimate respective prices in these circumstances.

³⁰ The median percentage that WAC was reported priced above foreign prices was 260.6 percent during the previous calendar year.

³¹ Single-source drugs are drugs that do not face competition from generic drugs rated as therapeutically equivalent under the Food and Drug Administration.

³² Multi-source drugs are drugs for which there Is at least one other drug product that is rated as therapeutically equivalent by the Food and Drug Administration and is sold or marketed in the United States.

Source: MDH, Health Economics Program analysis for preliminary reported data under Minnesota's Prescription Drug Price Transparency Act for the period of January 1, 2022, to June 30, 2022.

One benefit of increasing prescription drug transparency is to better understand how price increases are related to the direct costs manufacturers experience and the revenue and profits the drugs generate. Manufacturers that provided data across all revenue, cost, and profit data elements, reported that average reported direct costs (manufacturing, marketing, and distribution) accounted for 35.8% of gross revenue and the average profit margin amounted to 14.8%, as shown in Figure 6. Only 6.2% of gross revenue for reported drugs was devoted to financial assistance.³³

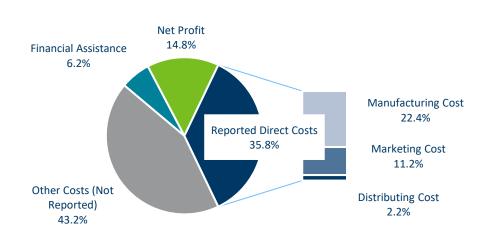


Figure 6: Distribution of Preliminary Reported Gross Revenue Among
Price Increase Reports

Source: MDH, Health Economics Program analysis for preliminary reported data under Minnesota's Prescription Drug Price Transparency Act for the period of January 1, 2022, to June 30, 2022. Note: Other Costs (Not Reported) may include direct costs other than those of manufacturing, marketing, and distributing the prescription drug.

Manufacturers are required to submit narratives describing the factors contributing to the price increase, from which Minnesota expected to learn about what dynamics drive price increases and how they differ across products, manufacturers, drug classes, and drug characteristics. From the relatively brief and universal narrative descriptions submitted by manufacturers, MDH noted the following preliminary trends:

 Each manufacturer provided essentially the same justification language for all their reported drug products, rather than identifying drug-specific factors.

³³ Other Costs (Not Reported) represents the difference between reported gross revenue reduced by direct costs and financial assistance and the value reported as net profit.

- Many manufacturers referred to "costs and market dynamics" and "patient value" as key factors without indicating what that meant specifically.
- Some manufacturers referenced "marketing and distribution costs" as reasons for price increases—again without noting what underlying factors drove changes in these direct costs and ultimately drove price increases.
- Some manufacturers noted that drug prices as reported are needed to finance operations related to innovation, oversight, and patient access.

Data Considerations

As noted in the introduction to this section, the analysis reported here should be considered preliminary because of concerns about the quality and completeness of the data. Users of these data should be aware of the following considerations:

The reported data contain suspected inaccuracies and are incomplete. MDH has determined that virtually all reports covered in this analysis require clarifications or corrections by manufacturers. Common reasons include that:

- Reported data do not match reference data.
- Data were reported at an aggregated level rather than an NDC-specific level.
- Required data fields were not completed.
- Reports did not adhere to reporting requirements.

MDH is assessing these data on an ongoing basis and is following-up with manufacturers to address these issues.

The narrative descriptions of factors contributing to price increases often lacked meaningful, drug-specific information. Our understanding of the intent of this requirement was to better understand the factors responsible for price increases—such as manufacturing capacity, input price trends, formulary design considerations, or product competition. However, information submitted by manufacturers lacked significant detail or specificity that would generate meaningful and actionable insights. Furthermore, manufacturers frequently reported the same written narrative description of factors contributing to price increases regardless of the magnitude of a price increase or the drug product. Without drug-specific information, this data element holds little utility in understanding the distinct factors behind drug prices and their market environments. The narrative descriptions of the factors contributing to price increases suggested that manufacturers set list prices based on several other factors in addition to costs.

Many data elements reported to MDH were designated as not public and/or trade secret by manufacturers, which may prevent these data from being publicly reported. Not public and/or trade secret designations must be accompanied by written statements from the manufacturer that

substantiate the assertions by showing that each designated data element is supported by law as not public data or by citing applicable federal or state law and relevant legal authority. MDH must review these assertions to determine whether elements should be withheld from publication.

Virtually all (90%) of submitted reports included at least one data element designated by manufacturers as not public and/or trade secret. The data elements with the highest share of not public designation were those that contained financial information, including:

- Gross revenue and net profit.
- Direct costs incurred (manufacturing, distributing, and marketing).
- The estimated amount of financial assistance provided.

Many not-public assertions declare that disclosure of the data would provide competitors, customers, insurers, pharmacy benefit managers, and/or marketers with information that could be used to impact the ability to negotiate purchase and rebate agreements, and/or increase the leverage that consumers may have over the manufacturer.

Assessing the Effectiveness of the Act

Early Takeaways

One of the requirements of the Act is for MDH to assess its impact on three outcomes: (1) promoting transparency in pharmaceutical pricing, (2) enhancing Minnesota's understanding of pharmaceutical spending trends, and (3) assisting the state and other payers in the management of pharmaceutical spending.

While MDH is not yet positioned to offer definitive insights into the efficacy of the Act given the recency of data availability and the need to validate and improve data quality and completeness, MDH is presenting early takeaways on the first two items based on the data MDH has reviewed, the analysis MDH has conducted, and the experience MDH has gained from observing transparency initiatives in other states. In the coming months, MDH will assess the Act's effectiveness more comprehensively, including by:

- Analysis of Clean Data: Working with a representative set of data for which the review has been successfully concluded. This will likely take several months of engagement with manufacturers.
- Obtaining Stakeholder Perspectives: Engaging with stakeholders—such as payers, patient representatives, and experts—to consider their insights on the effectiveness of the Act to accomplish the legislative goals.

In the meantime, the following are our early takeaways:

Transparency in pharmaceutical pricing in Minnesota has distinctly increased. Pharmaceutical prices and the factors that drive pricing in the U.S. have long been shielded from public scrutiny. Initiatives in Minnesota and other states are illuminating pricing elements (the individual elements that contribute to the total price) and market incentives that influence drug costs in the country. As high-quality data become available, stakeholders will be able to gain substantial new insights from:

- Analyzing patterns in list prices for new drug introductions and drugs with price increases.
- Assessing market competition by comparing prices of select high-cost drugs to those of equivalent drugs available in the pharmaceutical market.
- Assessing U.S. prices in the context of international prices.
- Weighing the impact of price increases within the context of drug use and spending in Minnesota.
- Monitoring revenue and profits associated with certain drugs relative to certain direct spending, such as marketing and manufacturing costs.

The impact of the Act is limited in multiple ways. Prescription drug price transparency—like all transparency initiatives—is an essential first step to transforming systems. Price transparency Minnesota Prescription Drug Price Transparency

always needs to evolve and, ultimately, be paired with specific policies providing reimbursement oversight and regulation to meaningfully impact affordability and sustainability of prescription drug prices. Here are several of the Act's limiting factors:

- a. The focus is on list prices instead of net prices. Manufacturers grant substantial discounts from list prices, so the manufacturer list prices do not represent the actual income manufacturers earn from the sale of their products. These discounts are shaped by a complex set of market factors—including the degree of competition, the business interests of intermediaries in the supply chain, and the benefits of influencing product placement on insurance benefit formularies. As such, list prices alone are not sufficiently suited to evaluating the financial performance of individual drugs. Trends in net prices (which can directionally differ from those of list prices) offer more meaningful insight to amounts paid by payers and overall trends in the market. Other states have demonstrated that these data can be collected in a way that preserves manufacturers' business interests and produces powerful value to state policy making.³⁴
- b. The focus is only on manufacturers rather than the full supply chain. Manufacturers have a key role in determining the prices of pharmaceutical products through price setting and determining discounts. The Act only focuses on the earliest stage of the pharmaceutical price setting by requiring reporting from pharmaceutical manufacturers. It does not consider the pricing dynamics by downstream supply chain entities such as wholesalers, pharmacy benefits managers (PBMs), pharmacies, and payers (see Figure 7 for a conceptual model of the prescription drug supply chain). These downstream entities further impact the price paid by consumers by applying additional discounts, fees, and markups to drug products. Studying rebates and markups along the whole supply chain would reveal who retains the cost reductions and rebates provided by manufacturers. It will also assist in evaluating where along the supply chain pricing power leads to the excess prices that have contributed to considerable affordability concerns among payers and patients.
- c. Reporting requirements treat drug pricing as if there is one market functioning under a single set of practices. The Act considers the market for prescription drugs as functioning under a single, standardized market strategy for all products. The pharmaceutical market is extremely complex and the factors driving pricing and rebate practices differ between brand and generic products.³⁵ Transparency across the broad spectrum of prescription

³⁴ Van Nuys, K; Ribero, R; Ryan, M and N. Sood. Estimation of the Share of Net Expenditures on Insulin Captured by US Manufacturers, Wholesalers, Pharmacy Benefit Managers, Pharmacies, and Health Plans From 2014 to 2018. JAMA Health Forum. 2021 Nov; 2(11); based on Jones, S.; Thompson, P; Tucker, J; Mitchell H; McKnight TJ; Wallace H and K Devine. Drug Transparency Report, 2019 Essential Diabetes Drugs. Nevada Department of Health and Human Services, 2019.

³⁵ See for example: Prescription Drug Transparency Report, Maine Health Data Organization, Jan. 2022; MDHO Prescription Drug Transparency Report 2022 (https://mhdo.maine.gov/pdf/MHDO%20Rx%20Transparency%20Report%20220120%20Final.pdf)

- drugs requires the collection of data—across the supply chain and across drugs within a class—that take those differences into account.
- d. The Act broadly protects trade secret information. Among states with transparency initiatives, Minnesota's is somewhat unique in that it requires the reporting of business information that manufacturers consider trade secret. In our initial analysis, virtually all submitted reports included at least one data element designated by manufacturers as not public. This designation indicates that manufacturers are seeking to shield from public reporting drug-specific reporting of net profits, gross revenue, direct costs, or comparisons between international and U.S. prices. The existing broad protection of data as trade secret paired with the state's limited resources and expertise devoted to evaluating legal arguments for trade secret, significantly limits developing a more informed public understanding of pricing patterns and restricts policymakers from identifying levers to improve affordability and management of drug spending.

Manufacturer Formulary payments. Drugs market share Preferred payments | Wholesaler placement performance Copay on incentives, Payment Drugs formulary rebates J I assistance Negotiated payment Pharmacy Benefit Manager Pharmacy Managed Share of rebates from drug Copay Payment | Drugs benefits **I**manufacturer Rx Drug Health Plan coverage Beneficiary Premium Premium Flow of funds Plan Sponsors Flow of Rx drugs Services

Figure 7: Conceptual Model of the Prescription Drug Supply Chain

Source: Sood, N; Shih, ; Van Nuys, K; and Goldman D. Flow of Money Through the Pharmaceutical Distribution System. June 6, 2017. <u>USC Schaeffer Center - Flow of Money Through the Pharmaceutical Distribution System (https://healthpolicy.usc.edu/research/flow-of-money-through-the-pharmaceutical-distribution-system/)</u>.

Transparency *may* have affected patterns of price increases by manufacturers. The National Academy of State Policy (NASHP) recently issued a report finding that since enactment of the first state price transparency laws in 2016, price increases that trigger reporting under these laws have decreased. Though there are many factors potentially accounting for the change in the number of

price increases, the number of states in the U.S. requiring some price reporting associated with prescription drugs rose to nearly two dozen by 2022. This has focused significant attention on pricing patterns and trends, thereby possibly affecting the number and rate of price increases.³⁶

Next Steps

Price transparency initiatives have the potential to affect industry behavior on pricing, to provide an evidence base for policy makers toward strengthening affordability, and to inform discussions between consumers and their care team about prescribing options. As noted, extending existing provisions in the Act in scope and scale would further support these outcomes.

Yet, transparency legislation and pricing data alone are unlikely to guarantee that drugs are accessible to all the people who need—in other words, ensuring equal access. Identifying future policies that are effective at reducing price growth *and* overcoming disparities in access to novel treatments and essential prescription drugs requires examining prescription drug prices, market behavior, utilization, and costs—for individuals and the overall system—within a broader context.

Some key dynamics to consider in this broader context include:

- Assessing the relationships between health insurance benefit design, drug use, health care costs, patient cost-sharing, and foregone care for prescription drugs.
- Estimating which market dynamics contribute to high cost sharing and explore how to address them through regulatory reforms.
- Exploring patterns of prescribing and the relative therapeutic and economic value of prescribed drugs (e.g., brand vs. generic, chronic vs. acute care, treatments choices across alternative therapies) across demographics, coverage types, and prescriber characteristics.

Over the next twelve months, MDH will be working with partners, stakeholders and experts—locally and nationally—to generate a research agenda, identify available and additional needed data, and study approaches to consider broader questions of prescription drug pricing, access, affordability, and disparities.

More narrowly, as it concerns continuing to implement the transparency initiative, MDH will pursue the following activities:

³⁶ Butler J and J. Reck. National Academy for State Health Policy. (January 10, 2022). <u>Drug Price Transparency Laws Position States to Impact Drug Prices (https://www.nashp.org/drug-price-transparency-laws-position-states-to-impact-drug-prices/)</u>.

Assessing data designations: Over the next several months, MDH will continue to review and make determinations on the not public/trade secret assertions made by manufacturers over data elements included in required reporting. Unlike many other state prescription drug price transparency initiatives, Minnesota's law requires manufacturers to report information they believe to be trade secret and grants MDH the authority to review and assess the validity of trade secret claims. When MDH agrees with a manufacturer's assertion, those data elements will be withheld from public posting and MDH will instead post a description of the nature of the data and the basis for withholding it. When MDH disagrees with a manufacturer's assertion, MDH will provide the manufacturer written notice 30 days in advance of posting the data to allow manufacturers the opportunity to challenge MDH's determination.

Enforcement: MDH will continue pursuing enforcement of the drug price reporting requirements. This includes three activities: (1) to conduct ongoing review of new data submissions, (2) to communicate with manufacturers on data quality and noncompliance issues, and (3) to implement enforcement actions against manufacturers—including, as applicable, the assessment of penalties as authorized under the law.

Public posting and analysis of reported data: MDH has posted an initial set of interactive displays or data dashboards online (https://www.health.state.mn.us/data/rxtransparency/). Over the next few months, MDH will be incrementally expanding the scale and scope of data available online, including through input from stakeholders and content experts. We will also be expanding our own analytic use and dissemination of analysis as MDH improves the quality of the data. Along the way, MDH expects to make use of other available data on prescription drugs—such as the Department of Commerce's transparency reporting by pharmacy benefit managers; data from the Minnesota All Payer Claims Database (MN APCD) about prescription drug prices and utilization; as well as initiatives in other states and the federal government.

Conclusion

The passage of the Prescription Drug Price Transparency Act in 2020 provided people living in Minnesota and MDH with better sight lines into pharmaceutical pricing. However, more work is needed to meaningfully impact affordability of prescription drugs and the sustainability of total spending. MDH is actively seeking to improve the data we do have by working with manufacturers to fully report required information and clarify and correct submitted information. MDH is also exploring ways to better examine how drug prices are situated within the broad context of health care and how this may inform future policy discussions.

Expanding transparency in Minnesota—focusing on net prices, collecting data from entities throughout the supply chain, supporting public disclosure of reported information, evaluating prices against data on clinical outcomes, and analyzing the downstream health equity effects of prescription drug prices—would also enhance the value of these data to researchers and the public. It would position MDH to more fully answer the statutory charge to assist in the management of pharmaceutical costs and better equip Minnesota to move beyond transparency and develop targeted and effective policy.

MDH is looking forward to working with the legislature and stakeholders on strengthening this initiative and supporting ideas for making prescription drugs more affordable for patients and the total spending on prescription drugs sustainable.

Appendix A: Minnesota Statutes, Section 62J.84

MINNESOTA STATUTES 2021

62J.84

62J.84 PRESCRIPTION DRUG PRICE TRANSPARENCY.

1

Subdivision 1. Short title. This section may be cited as the "Prescription Drug Price Transparency Act."

- Subd. 2. Definitions. (a) For purposes of this section, the terms defined in this subdivision have the meanings given.
- (b) "Biosimilar" means a drug that is produced or distributed pursuant to a biologics license application approved under United States Code, title 42, section 262(K)(3).
 - (c) "Brand name drug" means a drug that is produced or distributed pursuant to:
- (1) an original, new drug application approved under United States Code, title 21, section 355(c), except for a generic drug as defined under Code of Federal Regulations, title 42, section 447.502; or
 - (2) a biologics license application approved under United States Code, title 45, section 262(a)(c).
 - (d) "Commissioner" means the commissioner of health.
 - (e) "Generic drug" means a 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 45, 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.
 - (f) "Manufacturer" means a drug manufacturer licensed under section 151.252.
- (g) "New prescription drug" or "new 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.
- (h) "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.
 - (i) "Prescription drug" or "drug" has the meaning provided in section 151.441, subdivision 8.
- (j) "Price" means the wholesale acquisition cost as defined in United States Code, title 42, section 1395w-3a(c)(6)(B).
- Subd. 3. Prescription drug price increases reporting. (a) Beginning January 1, 2022, a drug manufacturer must submit to the commissioner the information described in paragraph (b) for each prescription drug for which the price was \$100 or greater for a 30-day supply or for a course of treatment lasting less than 30 days and:
- for brand name drugs where there is an increase of ten percent or greater in the price over the previous 12-month period or an increase of 16 percent or greater in the price over the previous 24-month period; and
- (2) for generic drugs where there is an increase of 50 percent or greater in the price over the previous 12-month period.

- (b) For each of the drugs described in paragraph (a), the manufacturer shall submit to the commissioner no later than 60 days after the price increase goes into effect, in the form and manner prescribed by the commissioner, the following information, if applicable:
 - (1) the name and price of the drug and the net increase, expressed as a percentage;
 - the factors that contributed to the price increase;
 - (3) the name of any generic version of the prescription drug available on the market;
- (4) the introductory price of the prescription drug when it was approved for marketing by the Food and Drug Administration and the net yearly increase, by calendar year, in the price of the prescription drug during the previous five years;
- (5) the direct costs incurred by the manufacturer that are associated with the prescription drug, listed separately:
 - (i) to manufacture the prescription drug;
 - (ii) to market the prescription drug, including advertising costs; and
 - (iii) to distribute the prescription drug;
 - (6) the total sales revenue for the prescription drug during the previous 12-month period;
- (7) the manufacturer's net profit attributable to the prescription drug during the previous 12-month period;
- (8) the total amount of financial assistance the manufacturer has provided through patient prescription assistance programs, if applicable;
- (9) any agreement between a manufacturer and another entity contingent upon any delay in offering to market a generic version of the prescription drug;
 - (10) the patent expiration date of the prescription drug if it is under patent;
 - (11) the name and location of the company that manufactured the drug; and
- (12) if a brand name prescription drug, the ten highest prices paid for the prescription drug during the previous calendar year in any country other than the United States.
- (c) The manufacturer may submit any documentation necessary to support the information reported under this subdivision.
- Subd. 4. New prescription drug price reporting. (a) Beginning January 1, 2022, no later than 60 days after a manufacturer introduces a new prescription drug for sale in the United States that is a new brand name drug with a price that 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 a new generic or biosimilar drug with a price that 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 and is not at least 15 percent lower than the referenced brand name drug when the generic or biosimilar drug is launched, the manufacturer must submit to the commissioner, in the form and manner prescribed by the commissioner, the following information, if applicable:
 - (1) the price of the prescription drug;

- (2) whether the Food and Drug Administration granted the new prescription drug a breakthrough therapy designation or a priority review;
- (3) the direct costs incurred by the manufacturer that are associated with the prescription drug, listed separately:
 - (i) to manufacture the prescription drug;
 - (ii) to market the prescription drug, including advertising costs; and
 - (iii) to distribute the prescription drug; and
 - (4) the patent expiration date of the drug if it is under patent.
- (b) The manufacturer may submit documentation necessary to support the information reported under this subdivision.
- Subd. 5. Newly acquired prescription drug price reporting. (a) Beginning January 1, 2022, the acquiring drug manufacturer must submit to the commissioner the information described in paragraph (b) for each newly acquired prescription drug for which the price was \$100 or greater for a 30-day supply or for a course of treatment lasting less than 30 days and:
- for a newly acquired brand name drug where there is an increase of ten percent or greater in the price over the previous 12-month period or an increase of 16 percent or greater in price over the previous 24-month period; and
- (2) for a newly acquired generic drug where there is an increase of 50 percent or greater in the price over the previous 12-month period.
- (b) For each of the drugs described in paragraph (a), the acquiring manufacturer shall submit to the commissioner no later than 60 days after the acquiring manufacturer begins to sell the newly acquired drug, in the form and manner prescribed by the commissioner, the following information, if applicable:
 - (1) the price of the prescription drug at the time of acquisition and in the calendar year prior to acquisition;
- (2) the name of the company from which the prescription drug was acquired, the date acquired, and the purchase price;
- (3) the year the prescription drug was introduced to market and the price of the prescription drug at the time of introduction;
 - (4) the price of the prescription drug for the previous five years;
- (5) any agreement between a manufacturer and another entity contingent upon any delay in offering to market a generic version of the manufacturer's drug; and
 - (6) the patent expiration date of the drug if it is under patent.
- (c) The manufacturer may submit any documentation necessary to support the information reported under this subdivision.
- Subd. 6. Public posting of prescription drug price information. (a) The commissioner shall post on the department's website, or may contract with a private entity or consortium that satisfies the standards of section 62U.04, subdivision 6, to meet this requirement, the following information:

- 4
- (1) a list of the prescription drugs reported under subdivisions 3, 4, and 5, and the manufacturers of those prescription drugs; and
 - (2) information reported to the commissioner under subdivisions 3, 4, and 5.
- (b) The information must be published in an easy-to-read format and in a manner that identifies the information that is disclosed on a per-drug basis and must not be aggregated in a manner that prevents the identification of the prescription drug.
- (c) The commissioner shall not post to the department's website or a private entity contracting with the commissioner shall not post any information described in this section if the information is not public data under section 13.02, subdivision 8a; or is trade secret information under section 13.37, subdivision 1, paragraph (b); or is trade secret information pursuant to the Defend Trade Secrets Act of 2016, United States Code, title 18, section 1836, as amended. If a manufacturer believes information should be withheld from public disclosure pursuant to this paragraph, the manufacturer must clearly and specifically identify that information and describe the legal basis in writing when the manufacturer submits the information under this section. If the commissioner disagrees with the manufacturer's request to withhold information from public disclosure, the commissioner shall provide the manufacturer written notice that the information will be publicly posted 30 days after the date of the notice.
- (d) If the commissioner withholds any information from public disclosure pursuant to this subdivision, the commissioner shall post to the department's website a report describing the nature of the information and the commissioner's basis for withholding the information from disclosure.
- (e) To the extent the information required to be posted under this subdivision is collected and made available to the public by another state, by the University of Minnesota, or through an online drug pricing reference and analytical tool, the commissioner may reference the availability of this drug price data from another source including, within existing appropriations, creating the ability of the public to access the data from the source for purposes of meeting the reporting requirements of this subdivision.
- Subd. 7. Consultation. (a) The commissioner may consult with a private entity or consortium that satisfies the standards of section 62U.04, subdivision 6, the University of Minnesota, or the commissioner of commerce, as appropriate, in issuing the form and format of the information reported under this section; in posting information pursuant to subdivision 6; and in taking any other action for the purpose of implementing this section.
- (b) The commissioner may consult with representatives of the manufacturers to establish a standard format for reporting information under this section and may use existing reporting methodologies to establish a standard format to minimize administrative burdens to the state and manufacturers.
- Subd. 8. Enforcement and penalties. (a) A manufacturer may be subject to a civil penalty, as provided in paragraph (b), for:
 - failing to submit timely reports or notices as required by this section;
 - (2) failing to provide information required under this section; or
 - (3) providing inaccurate or incomplete information under this section.
- (b) The commissioner shall adopt a schedule of civil penalties, not to exceed \$10,000 per day of violation, based on the severity of each violation.

- (c) The commissioner shall impose penalties under this section as provided in section 144.99, subdivision 4.
- (d) The commissioner may remit or mitigate civil penalties under this section upon terms and conditions the commissioner considers proper and consistent with public health and safety.
 - (e) Civil penalties collected under this section shall be deposited in the health care access fund.
- Subd. 9. Legislative report. (a) No later than May 15, 2022, and by January 15 of each year thereafter, the commissioner shall report to the chairs and ranking minority members of the legislative committees with jurisdiction over commerce and health and human services policy and finance on the implementation of this section, including but not limited to the effectiveness in addressing the following goals:
 - (1) promoting transparency in pharmaceutical pricing for the state and other payers;
 - (2) enhancing the understanding on pharmaceutical spending trends; and
 - (3) assisting the state and other payers in the management of pharmaceutical costs.
- (b) The report must include a summary of the information submitted to the commissioner under subdivisions 3, 4, and 5.

History: 2020 c 78 s 1; 2021 c 30 art 3 s 5-9

Appendix B-1, Data Elements Descriptions: Prescription Drug Price Increase Reporting

Data Element Description

NDC	NDC of the drug
Drug Description	Description of the drug to including product name, dosage form, strength, package size
WAC at Introduction	WAC price of the drug at introduction to market
Year of Introduction	Year of introduction to market
WAC Last Day 1 Year Prior	WAC price of the drug on the last day of the year one calendar year preceding the price increase
WAC Last Day 2 Year Prior	WAC price of the drug on the last day of the year two calendar years preceding the price increase
WAC Last Day 3 Year Prior	WAC price of the drug on the last day of the year three calendar years preceding the price increase
WAC Last Day 4 Year Prior	WAC price of the drug on the last day of the year four calendar years preceding the price increase
WAC Last Day 5 Year Prior	WAC price of the drug on the last day of the year five calendar years preceding the price increase
Generic Delay Agreement	Indication of the existence of an agreement between a manufacturer and any other entity contingent upon any delay in offering to market a generic version of the drug 1 = True / 0 = False
Patent Expiration Date	Patent expiration date of the drug if it is under patent
WAC at Acquisition	If the manufacturer acquired a drug and the price meets the above reporting criteria on the

Data Element Description

	day the manufacturer begins to sell the drug, the WAC on the date of acquisition
WAC Year Prior to Acquisition	If the manufacturer acquired a drug and the price meets the above reporting criteria on the day the manufacturer begins to sell the drug, the WAC on the date one calendar year prior to the acquisition
Company Acquired From	If the manufacturer acquired a drug and the price meets the above reporting criteria on the day the manufacturer begins to sell the drug, the name of the company from which the drug was acquired
Date of Acquisition	If the manufacturer acquired a drug and the price meets the above reporting criteria on the day the manufacturer begins to sell the drug, the date the drug was acquired
Acquisition Price	If the manufacturer acquired a drug and the price meets the above reporting criteria on the day the manufacturer begins to sell the drug, the acquisition price of the drug
WAC Effective Date	Effective date of WAC increase
WAC After Increase	WAC after the price increase
Percent Increase Over Previous WAC	Percentage increase over previous WAC
Price Increase Factors	Factors that contributed to the price increase
Generic Nonproprietary Name	Nonproprietary name of any generic version of the drug available on the market, if applicable
Manufacturing Cost	Direct costs incurred to manufacture the drug during the 12-month period preceding the price increase or cumulatively since the direct cost was first incurred

Data Element Description

Marketing Cost

Direct costs incurred to market the drug, including advertising costs, during the 12-month period preceding the price increase or cumulatively since the direct cost was first incurred

Distributing Cost

Direct costs incurred to distribute the drug during the 12-month period preceding the price increase or cumulatively since the direct cost was first incurred

Gross Revenue from Sales

Total gross revenue from sales of the drug during the 12-month period preceding the price increase

Net Profit

Net profit attributable to the drug during the 12month period preceding the price increase

Financial Assistance Provided

Total amount of financial assistance provided through Patient Assistance Programs during the 12-month period preceding the price increase or cumulatively since the financial assistance was first provided

Manufacturing Company

Name of the company that manufactured the drug

Manufacturing Company Address

Address of the company that manufactured the drug

Brand Foreign Prices

If a brand name drug, the ten highest prices paid for the drug during the calendar year prior to the price increase in any country other than the United States. Prices should represent the WAC equivalent in the country and be expressed in dollars according to the current exchange rate

General Comments

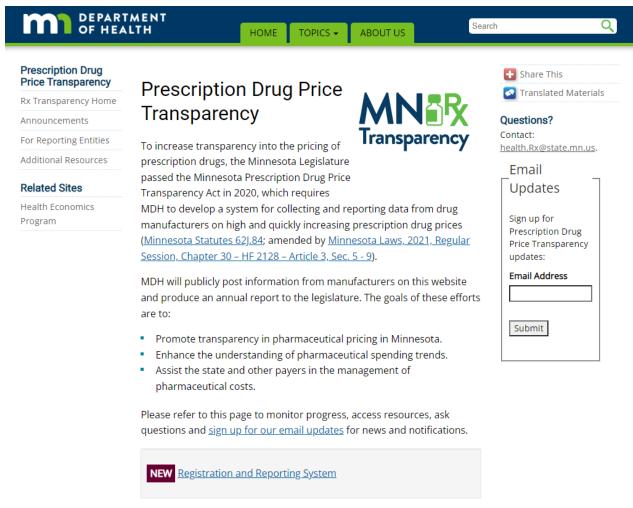
General comments and/or additional information related to the data submitted for the drug, if applicable

Appendix B-2, Data Elements Descriptions: New Prescription Drug Price Reporting

Data Element Description

	•
NDC	NDC of the drug
Drug Description	Description of the drug to including product name, dosage form, strength, package size
Date of Introduction	Date of introduction for sale in the United States
WAC at Introduction	WAC price of the drug at introduction to market
Breakthrough Therapy Designation	Indication of whether the drug was granted breakthrough therapy designation by the federal Food and Drug Administration 1 = True / 0 = False
Priority Review	Indication of whether the drug was granted priority review by the federal Food and Drug Administration 1 = True / 0 = False
Manufacturing Cost	Direct costs incurred to manufacture the drug
Marketing Cost	Direct costs incurred to market the drug, including advertising costs
Distributing Cost	Direct costs incurred to distribute the drug
Patent Expiration Date	Patent expiration date of the drug if it is under patent
General Comments	General comments and/or additional information related to the data submitted for the drug, if applicable

Appendix C: Online Presence of the Minnesota Prescription Drug Price Transparency Act



Available at: Prescription Drug Price Transparency Home (www.health.state.mn.us/data/rxtransparency).

Appendix D: Summary Statistics on Drugs with Expected Price Increase Reports

Category Value	NDC Count	WAC After Increase		Current Increase		12-Month Increase		24-Month Increase	
		Median	IQR	Median	IQR	Median	IQR	Median	IQR
By Brand/Generic									
Brand Drug	689	\$950.80	\$371.90 - \$3,685.50	7.9%	5.0% - 9.5%	10.1%	9.0% - 14.5%	16.7%	14.5% - 20.8%
Generic Drug	9	\$320.85	\$300.00 - \$600.00	90.0%	75.0% - 125.3%	113.7%	90.0% - 166.7%	113.7%	90.0% - 166.7%
By Years on the Market									
<= 5 Years	277	\$1,113.00	\$436.37 - \$4,604.05	8.5%	5.0% - 15.8%	13.1%	10.2% - 23.2%	17.6%	23.2% - 23.3%
6 – 10 Years	158	\$1,231.20	\$462.40 - \$6,272.80	6.0%	5.0% - 9.0%	10.1%	7.9% - 14.5%	16.7%	14.5% - 20.0%
11 – 15 Years	94	\$1,441.85	\$476.78 - \$3,262.13	7.0%	5.0% - 9.4%	10.0%	9.4% - 13.4%	18.8%	13.4% - 21.1%
16 – 20 Years	74	\$509.38	\$157.99 - \$1,731.29	9.0%	6.0% - 9.4%	9.4%	8.5% - 9.4%	19.1%	9.4% - 19.7%
Over 20 Years	95	\$339.27	\$225.25 - \$823.20	9.0%	9.0% - 9.7%	9.0%	9.0% - 10.0%	16.6%	10.0% - 19.1%
By WAC Price									
<= \$500.00	245	\$256.11	\$193.00 - \$374.12	9.0%	6.0% - 9.9%	9.9%	9.0% - 15.4%	16.6%	15.4% - 20.8%
\$500.01 - \$1700.00	195	\$883.59	\$623.69 - \$1,169.05	9.0%	5.0% - 10.0%	10.0%	9.4% - 15.0%	19.1%	15.0% - 21.2%
>= \$1700.01	258	\$5,704.80	\$2,899.93 - \$12,129.88	6.5%	5.0% - 8.9%	11.3%	9.4% - 14.5%	16.3%	14.5% - 19.7%
Top 10 Therapeutic Classes									
Allergenic Extracts/Biologicals Misc.	62	\$533.57	\$321.95 - \$1,079.04	23.2%	23.2% - 23.4%	23.2%	23.2% - 23.4%	23.2%	23.4% - 23.4%
Antineoplastics and Adjunctive Therapies	58	\$9,741.43	\$4,172.71 - \$16,357.52	6.5%	5.5% - 7.0%	12.2%	11.3% - 14.5%	14.5%	14.5% - 17.9%
Passive Immunizing and Treatment Agents	51	\$950.80	\$437.90 - \$2,012.10	4.8%	4.0% - 9.0%	12.4%	10.0% - 13.1%	14.5%	13.1% - 16.3%
Nutritional Products – Minerals and Electrolytes	44	\$176.96	\$141.11 - \$234.54	9.0%	9.0% - 9.0%	9.0%	9.0% - 9.0%	16.6%	9.0% - 16.6%
Analgesics – Opioid	35	\$1,362.29	\$423.98 - \$2,523.00	9.4%	9.4% - 15.0%	9.4%	9.4% - 15.0%	19.7%	15.0% - 26.4%
Endocrine and Metabolic Agents – Misc.	34	\$14,602.56	\$2,970.60 - \$14,602.56	5.0%	5.0% - 5.0%	11.4%	10.3% - 11.8%	15.2%	11.8% - 17.5%
Endocrine and Metabolic Agents – Antidiabetics	32	\$1,564.20	\$521.40 - \$3,476.00	5.0%	5.0% - 5.0%	10.1%	10.1% - 10.1%	10.1%	10.1% - 10.1%
Ophthalmic Agents	29	\$317.61	\$242.51 - \$532.30	6.0%	6.0% - 6.0%	6.0%	6.0% - 6.0%	19.1%	6.0% - 19.1%
Nutritional Products – Nutrients	23	\$231.47	\$171.09 - \$287.80	9.0%	9.0% - 9.0%	9.0%	9.0% - 9.0%	16.6%	9.0% - 16.6%
Cardiovascular Agents – Misc.	22	\$1,231.20	\$623.69 - \$1,871.09	6.0%	6.0% - 6.8%	6.0%	6.0% - 12.4%	19.1%	12.4% - 19.1%

Source: MDH, Health Ecohomics Program analysis of Medi-Span reference data from Wolters Kluwer's Medi-Span Suite of electronic drug data files. Additional information about Medi-Span is available at: Medi-Span: Drug Data Solutions for Healthcare (https://www.wolterskluwer.com/en/solutions/medi-span). IQR stands for Inter-Quartile Range.

Minnesota Prescription Drug Price Transparency: Report to the Minnesota Legislature

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