

# **340B Covered Entity Report**

**REPORT TO THE LEGISLATURE** 

November 25, 2024

#### 340B Covered Entity Report: Report to the Minnesota Legislature

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As requested by Minnesota Statute 3.197: This report cost approximately \$35,000 to prepare, including staff time, printing and mailing expenses.

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Protecting, Maintaining and Improving the Health of All Minnesotans

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The Honorable Tim O'Driscoll, Ranking Member, 2<sup>nd</sup> Floor, State Office Building

November 2024

To the Honorable Chairs and Ranking Members:

As directed in <u>Minnesota Statutes 62J.461 (https://www.revisor.mn.gov/statutes/cite/62J.461</u>), the Minnesota Department of Health (MDH) collected and aggregated data from Minnesota providers that participate in the federal 340B Drug Pricing Program.

Enclosed is the first required legislative report analyzing and summarizing data from these providers known as Covered Entities—on their 2023 participation in the 340B program. Consistent with the requirements in statute, the primary focus of this report is on the volume of net 340B revenue generated under the program. The reporting does not include information on how net 340B revenue is used nor to what extent patients are benefiting. It also does not include the impact to other areas of the health care system. The findings from this nation-leading initiative provide much needed transparency to the 340B program. MDH considers this first-year reporting successful with more than 90% of 204 identified Covered Entities reporting. Data show that the 340B program provides a significant amount of funding in Minnesota, but aggregated results should be considered a substantial underestimate as they do not include revenue generated from many high-cost drugs—those administered in office-based settings for most entities. MDH took extensive steps to ensure data quality and worked directly with nearly all entities, however, it is possible these first-year reported data include unidentified errors or inconsistencies. Statutory changes and MDH efforts should address these issues in 2025 and beyond.

Key findings from this report include:

- MDH determined that Minnesota providers participating in the federal 340B Drug Pricing Program earned a **collective net 340B revenue of at least \$630 million** for the 2023 calendar year. Based on national data, MDH believes this figure may represent as little as half of the actual total 340B revenue for Minnesota providers.
- The state's largest 340B hospitals benefitted most from the 340B program, representing 80%—more than \$500 million—of the statewide net 340B revenue. Conversely, Safety-Net Federal Grantee clinics generated the least net 340B revenue.
- A sizable volume of net 340B revenue was generated from Minnesota Health Care Programs—Medical Assistance/Medicaid and MinnesotaCare—totaling approximately \$87 million.
- Payments to contract pharmacies and third-party administrators were over \$120 million, representing approximately \$16 out of for every \$100 of gross 340B revenue generated paid to external parties.

This report is available online: <u>340B Drug Pricing Program Reporting Home</u> (https://www.health.state.mn.us/data/340b/index.html).

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,

/s/ Brooke Cunningham

Brooke Cunningham, MD, PhD Commissioner P.O. Box 64975 St. Paul, MN 55164-0975

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# **Executive summary**

The 340B Drug Pricing Program (340B) is a more than \$66 billion federal program that is aimed at supporting safety-net health care providers. In an environment of high and rising drug costs, it allows qualified providers— or "Covered Entities"—to purchase outpatient drugs at discounted prices from manufacturers but does not limit the payments that covered entities can receive from insurers or other payers. This means most Covered Entities can generate revenue through their participation in the program or, for some providers, reduce losses.

Despite its size and significance, the program is not well understood—little is known about how much revenue entities generate from the program and how these revenues are used. In 2023, Minnesota was the first state to pass legislation to collect and share data on participating 340B providers. This is the first legislative report presenting findings from Minnesota 340B Covered Entity data reported to the Minnesota Department of Health (MDH); no such report exists nationally.

Consistent with the requirements in statute, the focus of this report is on net 340B revenue, with breakouts by entity type, payer type, and some drug-level reporting. The reporting does not include information on how net 340B revenue is used nor to what extent patients are benefiting. Moreover, the report does not assess impacts of the 340B program on the health care system, including its potential influence on drug manufacturer pricing.

Finally, data presented in the report should be considered a significant underestimate. Future reports will produce more complete data following statutory clarifications passed during the 2024 session.

# **Reporting and data quality**

MDH considers this first-year reporting successful with more than 90% of Covered Entities reporting data. However, nearly every submission had data quality issues requiring MDH to conduct extensive follow-up efforts with reporting entities. MDH identified three major data challenges:

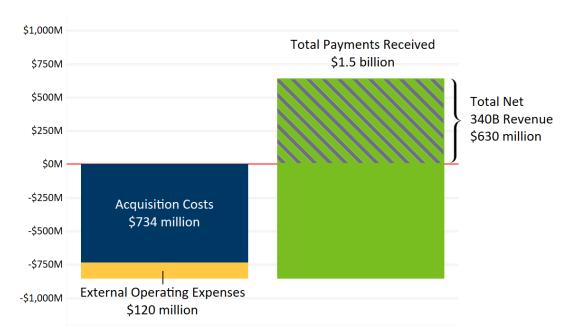
- 1. The inability of some Covered Entities to report the required information.
- 2. Data quality concerns with submitted data that affected MDH's ability to report detailed information across all data points.
- 3. Most importantly, the failure by most entities to report data for office-administered drugs (dispensed to a provider and administered in an outpatient setting). These drugs are estimated to account for about 80% of all 340B drug spending;<sup>1</sup> data presented in this report may therefore represent as little as half of total 340B revenues.

# **Findings**

Based on the reported data, MDH determined that Minnesota providers participating in the federal 340B Drug Pricing Program earned a **collective net 340B revenue of at least \$630 million** for the 2023 calendar year. This

<sup>&</sup>lt;sup>1</sup> Spending in the 340B Drug Pricing Program, 2010 to 2021 (https://www.cbo.gov/system/files/2024-06/60339-340B-Drug-Pricing-Program.pdf)

value is the difference between the payments received for discounted drugs (\$1.5 billion), and the cost of acquiring those drugs (\$734 million) plus payments to external administrators (\$120 million). Figure 1 summarizes the relationship between these reported values.



#### Figure 1: Summary of net 340B revenue and its components in Minnesota, 2023

Source: MDH, Health Economics Program analysis of 2023 data reported by Covered Entities under the Minnesota 340B Covered Entity Report.

Many distinct health care provider types participate in the 340B program—from general acute care hospitals and Critical Access Hospitals to disease-specific and safety-net clinics—and the reported data reveal notable variation between entity types.

- The state's **largest 340B hospitals benefitted most from the 340B program**, accounting for only 13% of the reporting entities but representing approximately 80%—or about \$500 million—of the statewide net 340B revenue. These large hospitals reported the largest volume of prescription fills and received the most net 340B revenue per drug fill on average.
- Conversely, Safety-Net Federal Grantee clinics—which include Federally Qualified Health Centers (FQHCs), their lookalikes, and tribal health centers—generated the least net 340B revenue.

Additionally, there was significant variation between Covered Entities within the same entity type.

When examining payer types from which Covered Entities receive payments—and therefore generate net 340B revenue—commercial and Medicare are the largest categories, but there was also a sizable volume of **net 340B revenue generated from Minnesota Health Care Programs—Medical Assistance/Medicaid and** MinnesotaCare—totaling approximately \$87 million, or 14% of the total \$630 million, in net 340B revenue generated statewide. Reports also included data on payments made to external entities to help Covered Entities operate their programs—these are typically contract pharmacies and third-party administrators. These **external operational expenses were more than \$120 million**. This means that for every \$100 of gross 340B revenue generated, Covered Entities paid approximately \$16 to external parties to administrate and operate areas of their 340B programs.

# Conclusion

Since its inception, the 340B program has lacked transparency. The program's importance is evidenced by its growth, size, and the degree to which it is ingrained in the U.S. health care system. However, policymakers, the public, and other stakeholders have not known the volume of net 340B revenue providers generate, the drivers of these revenues, how entities use the revenue, and the role and impact of intermediaries in the program. There are many open questions about the 340B program.

The Minnesota 340B Covered Entity Report provides new transparency into the ways in which Covered Entities participate in and benefit from the program. It also contributes to the legislature's path towards greater health care market transparency. Future reporting cycles and reports will provide additional insights and more complete data. However, important questions remain about the 340B program and its use that transparency alone will not resolve.

# Introduction

The federal 340B Drug Pricing Program (340B) is a more than \$66 billion initiative aimed at supporting safety-net health care providers. In an environment of high and rising drug costs, it allows qualified providers—or "Covered Entities"—to purchase outpatient drugs at discounted prices from manufacturers but does not limit the payments that covered entities can receive from insurers or other payers. This means most Covered Entities can generate revenue or, for some providers, reduce their losses through their participation in the program. There are no direct requirements on how Covered Entities use revenues generated under the 340B program. The program has evolved significantly since it was originally established in 1992 and has grown particularly quickly in the past 10 years. Nationally, drug purchases through the 340B program increased by over \$12 billion in 2023— an increase of more than 22% compared to 2022.<sup>2</sup> (For additional background on the 340B program, see <u>Appendix 3</u>.)

Despite its size and significance, the program is not well understood and lacks transparency—little is known about how much revenue entities generate from the program, how these revenues are used, and who benefits most.<sup>3</sup> In 2023, Minnesota was the first state to pass legislation to collect and share data from participating 340B providers. This is the first legislative report presenting findings from Minnesota 340B Covered Entity data from 2023 reported to the Minnesota Department of Health (MDH); no such report exists nationally.

Consistent with the requirements in statute, the focus of this report is on net 340B revenue generated under the program with breakouts by entity type, payer type, and some drug-level reporting. The reporting does not include information on how net 340B revenue is used nor to what extent patients are benefiting. Moreover, the report does not assess impacts of the 340B program on the health care system, including the potential influence of the 340B program on drug manufacturer pricing (manufacturers agree to offer discounts as a condition of their Medicaid participation).

Despite the significant contribution the data in this report represent, this first-year reporting has limitations: some of the reporting is inconsistent, and data are missing. One major area of missing data is office-administered drugs (dispensed to a provider and administered in an outpatient setting), which are estimated to account for approximately 80% of all 340B drug spending.<sup>4</sup> The aggregated results in this report should therefore be interpreted as a significant underestimate.

<sup>&</sup>lt;sup>2</sup> 2023 340B Covered Entity Purchases (https://www.hrsa.gov/opa/updates/2023-340b-covered-entity-purchases)

<sup>&</sup>lt;sup>3</sup> To date, researchers have relied on a mix of public and proprietary data to estimate the volume of 340B drugs and 340B revenue.

<sup>&</sup>lt;sup>4</sup> Spending in the 340B Drug Pricing Program, 2010 to 2021 (https://www.cbo.gov/system/files/2024-06/60339-340B-Drug-Pricing-Program.pdf)

# **Minnesota 340B Covered Entity Report**

The Minnesota 340B Covered Entity Report (<u>Minnesota Statutes, chapter 62J.312, subd. 6</u> (<u>https://www.revisor.mn.gov/statutes/cite/62J.312#stat.62J.312.6</u>)) was established by the Legislature in 2023 for annual data reporting to begin in 2024.<sup>5</sup> The statute directs MDH to:

- Specify and communicate the form and manner for reporting.
- Receive data from Covered Entities.<sup>6</sup>
- Aggregate results in an annual report to the Legislature.

The statute was modified by the Legislature in 2024 (<u>Minnesota Laws of 2024, chapter 127</u> (<u>https://www.revisor.mn.gov/laws/2024/0/Session+Law/Chapter/127/</u>)</u>, article 59, section 2).<sup>7</sup> These modifications included several technical changes and a provision to ensure that the annual report includes a list of net 340B revenue by Covered Entity for entities with a significant share of total Minnesota net 340B revenue, as defined by MDH (see <u>Appendix 5</u>).

# **Overview of data**

The data reported by Covered Entities to MDH and aggregated in this report include several data elements that summarize each entity's 340B transactions for the 2023 calendar year. Covered Entities that operate as "parent" entities were directed to include data for child sites operating under the parent's 340B identification number, contract pharmacies paid to distribute 340B drugs, and third-party administrators (TPAs) paid to manage accounting and inventory. Data were reported by five major payer types. Hospitals additionally submitted data at the drug product level for the top 50 most dispensed drugs (see <u>Drug-level findings</u> and <u>Appendix 7</u> for summaries of these data).<sup>8</sup> This section summarizes all the data elements required and referenced in this report.

#### **Required data elements**

• Acquisition costs: The total dollar amount a Covered Entity paid—directly or indirectly—to purchase 340B drugs from drug manufacturers at 340B discounted prices.<sup>9</sup>

<sup>6</sup> The submitted data are classified as nonpublic.

<sup>&</sup>lt;sup>5</sup> Minnesota Statutes, chapter 62J.312, subd. 6 (https://www.revisor.mn.gov/statutes/cite/62J.312#stat.62J.312.6)

<sup>&</sup>lt;sup>7</sup> <u>Minnesota Laws of 2024, chapter 127, article 59, section 2</u> (https://www.revisor.mn.gov/laws/2024/0/Session+Law/Chapter/127/)

<sup>&</sup>lt;sup>8</sup> Drug products are those that can be identified by a unique National Drug Code (NDC).

<sup>&</sup>lt;sup>9</sup> The acquisition cost is based on the 340B discount, which is set in statute. Sometimes Covered Entities purchase 340B drugs at an additional discount known as a sub-ceiling discount.

- **Payments received:** Total payments a Covered Entity received—directly or indirectly—from patients and their insurers for 340B drugs that the entity prescribed to their patients. These are often referred to as reimbursements. This includes payments facilitated by contract pharmacies.
- **Contract pharmacy costs:** Total fees and other payments Covered Entities paid to contract pharmacies to distribute 340B drugs. These are often assessed on a per-prescription basis.
- Number of fills: Total number of prescriptions filled for 340B drugs.<sup>10</sup>

#### **Optional data elements**

MDH sought feedback from stakeholders, including Covered Entities in the state, to develop and implement this nation-leading reporting initiative. Covered Entities were interested in having their administrative burden appropriately accounted for. In response to this feedback, MDH offered Covered Entities the opportunity to voluntarily report the following data elements to reflect these administrative costs:<sup>11</sup>

- **Other external costs:** Total of any other costs paid to external entities (not the Covered Entity or a child site) related to administering a 340B program. This predominately includes fees paid to third-party administrators (TPAs) to perform accounting and distribution functions for Covered Entities.
- **Other internal costs:** Total of all other internal costs for administering a 340B program. This could include staffing or IT costs.<sup>12</sup>

#### **Calculated data elements**

- External operational costs: The sum of payments to contract pharmacies and intermediaries for program administration (e.g., fees charged by TPAs). It is the sum of *contract pharmacy costs* and *other external costs*.
- **Gross 340B revenue:** Funds generated by Covered Entities, which is the value of total *payments received* less *acquisition costs*. Gross 340B revenue does not reflect expenditures incurred by the Covered Entity to operate the program.
- Net 340B revenue: Net 340B revenue equals *gross 340B revenue* minus *external operational costs*. It is payments received minus the sum of acquisition costs, contract pharmacy costs, and other external costs (e.g. TPA fees). Net 340B revenue indicates the full financial impact to a Covered Entity of participating in the 340B program. Other names for net 340B revenue used across industry, government, and research include "340B savings," "340B spread," and "340B profits."

<sup>&</sup>lt;sup>10</sup> The statute identifies number of claims. However, "claims" implies an insurance payment, which is not always the case for 340B. Given the data that was submitted, as described by reporting entities, "fills" is the more accurate term and is what is used in this report.

<sup>&</sup>lt;sup>11</sup> Both optional data fields were included in the 2024 amendments to statute and will be required beginning in 2025.

<sup>&</sup>lt;sup>12</sup> MDH excluded these data in this first-year reporting because data lacked integrity—it included a mix of internal and external administrative expenses, programs funded by net 340B revenue, and personnel costs.

#### **Payer types**

- **Commercial:** This refers to any private health insurance carrier.
- **Medicare:** This is a federal health insurance program for people aged 65 or older and certain younger people with disabilities.
- **Minnesota Health Care Programs (MHCP)**: This payer type includes Medical Assistance (Medicaid) and MinnesotaCare.<sup>13</sup> These programs serve low-income children and parents, older adults, people with disabilities, adults without children, and people who are income-eligible and unable to access affordable employer-sponsored health insurance.
- **Other:** This includes all other payment types, including a combination of special payment programs and cash payments from uninsured and insured patients (self-pay).<sup>14</sup>

# **Reporting and data quality**

MDH identified 204 Covered Entities in Minnesota subject to reporting, and nearly all submitted data (191 Covered Entities reported for a reporting rate of 94%).<sup>15</sup> MDH considers this an extremely successful response rate for the first year of reporting, stemming in part from strong collaboration between Minnesota providers and MDH. Most of the entities that failed to report were smaller clinics and their exclusion does not meaningfully affect findings. Table 1 illustrates Covered Entity reporting and the number of submissions of sufficient quality to be included in the analysis (see <u>Appendix 2</u> for detail on Covered Entity groupings).

To be eligible for the 340B program, providers must not operate as for-profit and must meet the requirements for at least one of the Covered Entity types outlined in Section 340B(a)(4) of the Public Health Service Act (<u>Appendix 2</u>). Many Minnesota providers do not qualify for 340B or do not participate and were therefore not required to report under this initiative. Notable examples include Mayo Clinic Rochester and Park Nicollet Methodist Hospital.

<sup>&</sup>lt;sup>13</sup> Medical Assistance and MinnesotaCare were separated in data collection but are grouped for this report.

<sup>&</sup>lt;sup>14</sup> Many entities communicated that they included insured patient out-of-pocket costs in this grouping instead of the respective insurer grouping.

<sup>&</sup>lt;sup>15</sup> Covered Entities affected by the reporting requirement were identified through the Health Resources and Services Administration (HRSA) Outpatient Pharmacy Affairs Information System (OPAIS). OPAIS contains registration and termination dates for all Covered Entities participating in the program as well as the addresses of child sites and contract pharmacies registered underneath them.

Major Entity Type	Covered Entity Grouping	Expected to Report	Reported	Sufficient Data to Include in Analysis
Hospital	General Acute Care Hospitals (DSH)	24	24	24
Hospital	Critical Access Hospitals (CAH)	74	73	72
Hospital	Other Hospitals	8	8	8
Grantee	Disease-Specific Federal Grantees	78	67	66
Grantee	Safety-Net Federal Grantees	20	19	19
	Total	204	191	189

## Table 1: Summary of 2023 Minnesota Covered Entity reporting

Source: MDH, Health Economics Program analysis of 2023 data reported by Covered Entities under the Minnesota 340B Covered Entity Report.

Although the first-year reporting rate was excellent and all entities certified their reported data, many issues with the data were identified in nearly all submissions by Covered Entities. MDH worked with nearly every data submitter and at times went to extraordinary lengths to ensure the best data was submitted. MDH identified three major data challenges (see <u>Appendix 4</u> for additional summary of data quality issues):

- 1. Inability of some covered entities to report the required information.
- 2. Data quality concerns with submitted data that affected MDH's ability to report detailed information across all data points.
- 3. Failure by most entities to report data for office-administered drugs.

The most significant and impactful of these data quality concerns is the failure of most Covered Entities to report office-administered drugs. Because of some ambiguity in the statute that the legislature corrected in 2024, most Covered Entities believed they met reporting requirements in the first year by only reporting data for retail drugs directly dispensed to patients (pharmacy-dispensed drugs). This is a significant limitation as office-administered drugs represent over 80% of spending in the 340B program and include many high-cost drugs, including chemotherapy drugs, that are infused or injected in a physician's office or other outpatient clinic setting.<sup>16</sup>

<sup>&</sup>lt;sup>16</sup> Spending in the 340B Drug Pricing Program, 2010 to 2021 (https://www.cbo.gov/system/files/2024-06/60339-340B-Drug-Pricing-Program.pdf)

Due to the absence of reliable national 340B reporting, there is no definitive data on how much of an underestimate this first year of Minnesota reporting represents. Using information from the Congressional Budget Office (CBO), the underreporting on office-administered drugs suggests the findings in this report are likely about half of actual total net 340B revenues—and may even represent as little as one third of actual net 340B revenue.<sup>17</sup>

# **Future reporting**

The Minnesota Covered Entity Report—the data submission and the MDH report aggregating the data—is an annual requirement. As such, the 2024 statutory changes modifying certain data elements will apply to 2024 data due to MDH on April 1, 2025. MDH will subsequently deliver an updated report by November 15<sup>th</sup>, 2025.

In preparation for data submissions in 2025, MDH plans to conduct focus groups with some Covered Entities that faced challenges in reporting to better understand reporting issues and to improve compliance and data quality. MDH expects that any remaining data reporting issues—including the omission of administered drugs—will be addressed in 2025 reporting.

MDH also plans to conduct follow-up research with the existing data and reference data to bring additional insights to stakeholders and policymakers.

# **Findings**

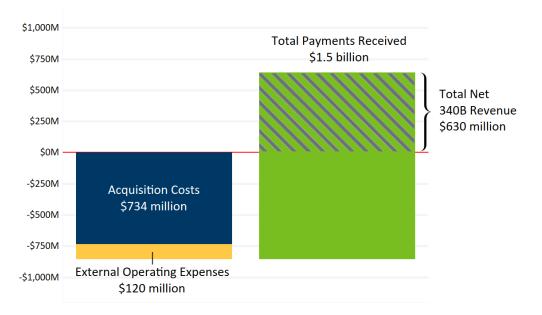
## **Overview**

Based on the first year of reported data, MDH determined that Minnesota providers that participate in the federal 340B Drug Pricing Program, or "Covered Entities," earned a **collective net 340B revenue of at least \$630 million** for the 2023 calendar year. This value is the difference between the payments received for discounted drugs (\$1.5 billion) and the cost of acquiring those drugs (\$734 million) plus paying external entities to administer certain aspects of the program (\$120 million). Figure 1 summarizes the relationship between these reported values. This revenue was generated from over 4.6 million filled prescriptions. As noted, \$630 million in net 340B revenue is a substantial underestimate due to the data limitations mentioned above. (See <u>Appendix 5</u> for a listing of net 340B revenue by entity for select entities.)

Covered Entities benefit from the reduced-price 340B drugs in one of two ways: 1) the discounts offset the uncompensated costs associated with providing free or reduced-price drugs to uninsured or under-insured patients, or 2) the discounts provide a source of revenue when payers reimburse providers for the drugs above

<sup>&</sup>lt;sup>17</sup> Congressional Budget Office data shows total 340B spending is about 20% for pharmacy-dispensed drugs and about 80% for office-administered drugs. Assuming MDH effectively received all data on pharmacy-dispensed drugs and a small portion of office-administered drugs, it is possible that MDH received data on drugs that only represent about one-third of total 340B spending.

the 340B acquisition price—this is typically from insured patients. The net revenue estimates for Minnesota also include 340B entities that do not generate net 340B revenue—meaning they break even or operate at a net loss.



#### Figure 1: Summary of net 340B revenue and its components in Minnesota, 2023

Source: MDH, Health Economics Program analysis of 2023 data reported by Covered Entities under the Minnesota 340B Covered Entity Report.

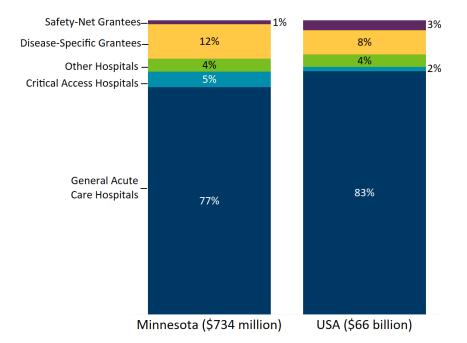
These topline findings from Minnesota reporting are roughly comparable to available 2023 national trend information in two ways:

- The Health Resources and Services Administration (HRSA) reported a total nationwide acquisition cost for the 340B program of at least \$66 billion for 2023.<sup>18</sup> Assuming proportional state participation in 340B, Minnesota 340B drug acquisition costs are estimated to be \$1.12 billion as Minnesota's population represents approximately 1.7% of the total United States population. Minnesota's reported 2023 total 340B acquisition costs of \$734 million is therefore roughly half of national figures; this is not surprising when considering the under-reporting of office-administered drugs.
- The distribution of acquisition costs across provider types (Covered Entity groupings) in Minnesota was likewise comparable to the national distribution from HRSA (see Figure 2).

An important difference between Minnesota and the rest of the country is the role of Critical Access Hospitals in the state. Critical Access Hospitals account for only 2% of 340B acquisition costs nationwide but Minnesota's analysis shows Critical Access Hospitals account for 5% of the total 340B acquisition costs statewide, which reflects their relative importance in the state.

<sup>&</sup>lt;sup>18</sup> Health Resources & Services Administration. (2024, October). 2023 340B Covered Entity Purchases (https://www.hrsa.gov/opa/updates/2023-340b-covered-entity-purchases)

## Figure 2: Distribution of 340B acquisition costs for 2023 by Covered Entity grouping, Minnesota and United States



Source: MDH, Health Economics Program analysis of 2023 data reported by Covered Entities under the Minnesota 340B Covered Entity Report and 2023 data from the Health Resources & Services Administration

# Findings by Covered Entity grouping

There are a range of distinct criteria that make health care provider entities eligible to participate in the 340B program (see <u>Appendix 2</u>); by extension there are many different types of 340B Covered Entities in Minnesota. The range of services they provide (and drugs they prescribe), differences in the patients they serve, and the ways they operate their 340B program all affect their net 340B revenue.

Table 2 summarizes net 340B revenue and its components by Covered Entity groupings. It shows the significant variation across entity types with large hospitals that qualify under the 340B program's Medicare Disproportionate Share Hospital (DSH) designation generating by far the largest net revenues (as a group and individually). This grouping, which includes many of the state's largest non-profit and public general acute care hospitals [hereafter referred to as General Acute Care Hospitals (DSH)], accounts for only 13% of the reporting entities but represents 80% of the net 340B revenue. These hospitals also have the largest volume of prescription fills and receive the most net 340B revenue per prescription filled on average. Conversely, Safety-Net Federal Grantee clinics—which include Federally Qualified Health Centers (FQHCs), so called FQHC-lookalikes, and tribal health centers—generate the least net 340B revenue.

This variation is also driven by reimbursement structures for different Covered Entities. When a Covered Entity receives a market rate payment for a 340B drug—such as an insurance reimbursement or cash payment—it will generally generate net 340B revenue, that is, revenue exceeds the acquisition cost. However, if a Covered Entity

is providing the drugs for free or at reduced rates—as is the case for certain clinics that serve a high number of uninsured or sliding fee scale patients—it may lose money even at these discounted rates. Here, an entity is reducing their costs rather than generating revenue; this means that some 340B entities experience a net loss even at the reduced prices the program provides. Table 2 aggregates all entities together, and the losses of some are offset by the large net revenues of others. There were 41 entities (ten hospitals and 31 federal grantees) that generated \$0 in net 340B revenue or operated their 340B programs at a net loss.

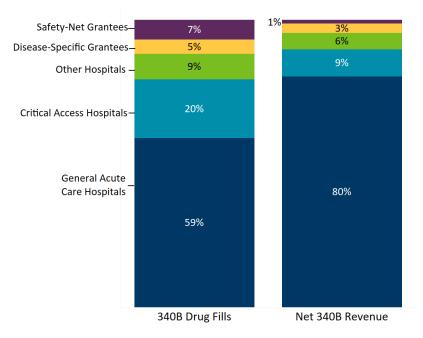
Major Entity Type	Covered Entity (CE) Grouping	Covered Entities (count)	Drug Fills (Count)	Acquisition Costs (\$)	External Operating Costs (\$)	Payments Received (\$)	Net 340B Revenue (\$)	Average Net 340B Revenue per CE (\$)	Average Net 340B Revenue per Drug Fill (\$)
Hospital	General Acute Care Hospitals (DSH)	24	2,707,505	566,390,065	86,038,210	1,158,173,156	505,744,881	21,072,703	187
Hospital	Critical Access Hospitals	72	940,380	39,684,338	12,493,446	111,802,360	59,624,576	828,119	63
Hospital	Other Hospitals	8	406,605	32,011,520	5,937,312	74,252,756	36,303,924	4,537,990	89
Grantee	Disease Specific Federal Grantees	66	232,763	86,270,048	11,488,781	118,490,487	20,731,659	314,116	89
Grantee	Safety-Net Federal Grantees	19	314,324	9,193,241	4,072,928	21,123,482	7,857,313	413,543	25
	Total	189	4,601,577	733,549,211	120,030,677	1,483,842,241	630,262,352	3,334,721	137

## Table 2: Summary by Covered Entity groupings, 2023

Source: MDH, Health Economics Program analysis of 2023 data reported by Covered Entities under the Minnesota 340B Covered Entity Report.

The variation between entity types shown in Table 2 is driven by which services—specifically which drugs—a Covered Entity provides. Both drug volume and drug price are significant drivers of total net 340B revenue. As the 340B discount is based on percent formulas, the more expensive the drug, the greater the discount and the opportunity for generating revenue. As mentioned, the General Acute Care Hospitals (DSH) have the largest volume of 340B drugs—responsible for approximately 60% of 340B drug fills—but their revenue share of 80% is disproportionately larger, as shown in Figure 3. By contrast, Critical Access Hospitals (CAH) generated a smaller share of the state's net 340B revenue (9%) relative to their share of 340B fills (20%); thus, this grouping generates a smaller amount of revenue per prescription filled on average. Safety-Net Grantees, given their financial structure, generated only 1% of the state's net 340B revenue despite accounting for 7% of 340B fills. Figure 3 shows the relationship between drug fills and net 340B revenue. (<u>Appendix 7</u> provides more detail on the relationship between net 340B revenue and volume at a drug level.)

# Figure 3: Distribution of 340B drug fills versus net 340B revenue by Covered Entity grouping, 2023



Source: MDH, Health Economics Program analysis of 2023 data reported by Covered Entities under the Minnesota 340B Covered Entity Report.

The magnitude of net 340B revenue varies across Covered Entity groupings. Additionally, there is significant variation between entities *within* groupings. Figures 4 and 5 show the variation in net 340B revenue for hospitals

and grantees, respectively. These figures use the statistical concept of percentiles to show how individual values relate to others in a group.<sup>19</sup>

The wide interval between the 10<sup>th</sup> and 90<sup>th</sup> percentile for General Acute Care Hospitals (DSH) in Figure 4 indicates substantial variation in net revenue across these facilities. Although the average net 340B revenue is \$21 million per Covered Entity (not shown in Figure 4; see Table 2), half of these entities generated \$7 million or less (those entities below the 50<sup>th</sup> percentile, or median). The top 10% of General Acute Care Hospitals (DSH), or those at the 90<sup>th</sup> percentile, generated \$65 million or more in net 340B revenue, bringing the average up significantly. (See Appendix 5 for a list of net 340B revenue by entity for select entities.)

Safety-Net Federal Grantees also display substantial variation, as seen in Figure 5. The bottom 10% (indicated by the 10<sup>th</sup> percentile) reported a negative net 340B revenue (with losses of approximately \$170,000 or more), while half of Safety-Net Federal Grantees generated \$63,000 or less in net 340B revenue. However, the top 10%, (indicated by the 90<sup>th</sup> percentile level) generated a net 340B revenue of \$1 million or more. Critical Access Hospitals (CAH) display little variation in net 340B revenues, while other groupings have moderate variation, as shown.

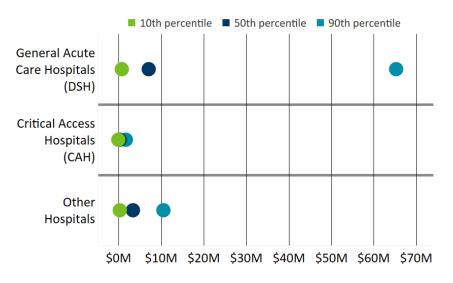
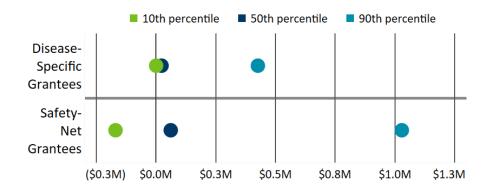


Figure 4: Net 340B revenue distribution by hospital type, 2023

Source: MDH, Health Economics Program analysis of 2023 data reported by Covered Entities under the Minnesota 340B Covered Entity Report.

<sup>&</sup>lt;sup>19</sup> A value at the 10th percentile means that 10% of the other values are smaller and 90% are larger; likewise, a value at the 90th percentile means 90% of the other values are smaller, and only 10% are larger. A value at the 50th percentile is at the median, which means half of the values are larger and half are smaller.



#### Figure 5: Net 340B revenue distribution by grantee type, 2023

Source: MDH, Health Economics Program analysis of 2023 data reported by Covered Entities under the Minnesota 340B Covered Entity Report.

# Findings by payer type

Covered Entities also reported data by payer type revealing the variation in how entities generate revenue (see *Payer types* on page 13 for a review of the payer types). Table 3 presents the distribution of 340B metrics by the four main payer types. <u>Appendix 6</u> contains additional information on payer type by Covered Entity grouping.

Payer Type	Drug Fills (Count)	% of Drug Fills	Payments Received (\$)	Net 340B Revenue (\$)	% of Net 340B Revenue	Average Net 340B Revenue Per Drug Fill (\$)
Commercial	1,921,639	42%	908,854,110	343,236,687	54%	179
Medicare	1,107,475	24%	351,595,699	197,064,198	31%	178
Minnesota Health Care Programs (MHCP)	932,441	20%	169,854,222	86,587,184	14%	93
Other	640,023	14%	53,538,210	3,374,283	1%	5
Total	4,601,577	100%	1,483,842,241	630,262,352	100%	137

#### Table 3: Summary by payer type grouping, 2023

Source: MDH, Health Economics Program analysis of 2023 data reported by Covered Entities under the Minnesota 340B Covered Entity Report.

Note: The "Other" category includes all other payment types, including a combination of special payment programs and cash payments from uninsured and insured patients (self-pay).

Although the majority of net 340B revenue was generated from commercial and Medicare payers, net 340B revenue generated from Minnesota Health Care Program (MHCP) (Medical Assistance/Medicaid and MinnesotaCare) was also significant. Covered Entities generated \$87 million—or 14% of the statewide net 340B revenue—on drugs for patients covered by MHCPs. To prevent duplicate discounts with the Medicaid Drug Rebate Program, contract pharmacies cannot distribute 340B drugs to MHCP enrollees in Minnesota in most cases. This limits the opportunities for generating 340B revenue from MHCP patients.

Comparing net 340B revenue to the overall distribution of health care coverage by payer type in Minnesota, net 340B revenue generated from providing drugs to patients covered by commercial insurance and Medicare was roughly proportional to the health care coverage distribution in Minnesota. Slightly less than three quarters of the population is covered by these payers.<sup>20</sup> The proportion of net 340B revenue generated from MHCPs (about 14%) was proportionally smaller than the coverage distribution in Minnesota (about 20%)—which may in part be due to the limited use of contract pharmacies noted above.

## **Payments to external entities**

Another significant element to a Covered Entity's net 340B revenue is the cost of administering 340B programs, which is primarily outsourced to external entities. Many Covered Entities pay contract pharmacies to distribute 340B drugs and pay third-party administrators (TPAs) to manage accounting and inventory. Contract pharmacy costs is a required data element, and approximately 60% of entities reported making payments to contract pharmacies. Reporting on external costs—including payments to TPAs—was not explicitly required in law but was included as an optional reporting field based on input from stakeholders so entities could more fully represent their costs. As a result, only 24 Covered Entities reported any data for this field.

MDH used these two fields to calculate the external operational costs—which represents total payments to external entities for program operations—incurred by Covered Entities. Table 4 displays the number of Covered Entities by grouping who reported any external operational costs. The external costs reporting field was optional and many entities chose not to report for this data element. Additionally, submissions for the contract pharmacy fees field may have included other costs (See <u>Appendix 4</u>). It is therefore unclear whether the reported external operational costs represent an overestimate or underestimate of true external operational costs.<sup>21</sup> It is clear, however, that **Covered Entities make significant payments to external entities, including contract pharmacies and TPAs, that directly reduce net 340B revenues.** 

<sup>&</sup>lt;sup>20</sup> Health Economics Program. Available in <u>Chartbook Section 2</u> (<u>https://www.health.state.mn.us/data/economics/chartbook/docs/section2.pdf</u>)

<sup>&</sup>lt;sup>21</sup> Internal administrative expenses was also an optional field, but this was fully excluded from analysis due to poor data quality and inconsistency. See *Overview of data* on page 9 for additional detail.

Entity Type Grouping	Count of Reported Covered Entities	Count of Reported External Operational Costs	Percentage Reporting External Operational Costs
General Acute Care Hospitals (DSH)	24	21	88%
Critical Access Hospitals (CAH)	72	54	75%
Other Hospitals	8	8	100%
Disease-Specific Grantees	66	14	21%
Safety-Net Grantees	19	13	68%
Total	189	111	58%

## Table 4: Percentage of Covered Entities reporting external operational expenses, 2023

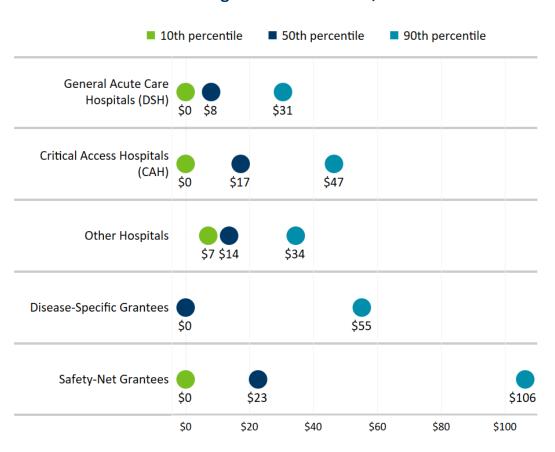
Source: MDH, Health Economics Program analysis of 2023 data reported by Covered Entities under the Minnesota 340B Covered Entity Report.

As with other reported metrics, external operational costs varied significantly across Covered Entity groupings. Figure 6 illustrates the distribution of external operational costs as a share of \$100 of gross 340B revenue by Covered Entity grouping.<sup>22</sup> Across most groupings, the 10% of Covered Entities with the lowest external operational costs (indicated by the 10<sup>th</sup> percentile) paid \$0 for every \$100 dollars of gross 340B revenue generated. However, the payments made by the 10% of Covered Entities with the *highest* external operational costs (indicated by the 90<sup>th</sup> percentile) were quite significant. For every \$100 dollars of gross 340B revenue generated:

• The top 10% (the 90<sup>th</sup> percentile) of Covered Entities in *all groupings* lost about one third of their gross 340B revenue to administrators and contract pharmacies.

<sup>&</sup>lt;sup>22</sup> There were 41 entities that generated \$0 or less in gross 340B revenue; these entities were excluded from the analysis presented in Figure 6 as MDH could not determine their external operational costs as a share of their gross 340B revenue. The median of external operational costs for these 41 entities was \$0, although the mean (average) of external operational costs was approximately \$90,000.

- The top 10% (the 90<sup>th</sup> percentile) of Critical Access Hospitals (CAH) and Disease-Specific Grantees lost at least half of their gross 340B revenue to administrators and contract pharmacies.
- The top 10% (the 90<sup>th</sup> percentile) of Safety-Net Grantees lost more than all of their gross 340B revenue to administrators and contract pharmacies indicating that although these entities generated positive gross 340B revenue, they operated at a net loss as a result of their high external operational costs



# Figure 6: External operational expenses as a share of \$100 of gross 340B revenue, 2023

Source: MDH, Health Economics Program analysis of 2023 data reported by Covered Entities under the Minnesota 340B Covered Entity Report.

# **Drug-level findings**

The Minnesota 340B Covered Entity Report required hospitals participating in 340B to report on their top 50 dispensed drugs by volume. These data were reported at a drug product—or national drug code (NDC)—level.<sup>23</sup>

<sup>&</sup>lt;sup>23</sup> The NDC identifier allows for distinguishing between drugs with different manufacturers, ingredients, strength, dosage form, route of administration, and packaging. For this analysis, MDH uses drugs families to group similar drug products together. Drug families are groups of one or more prescription drug products (NDCs) that share a unique generic drug product description, or nontrade name, and dosage form. When "drug" is used, it refers to a drug family, which may include brand and/or generic products from multiple manufacturers.

Altogether, these "top 50 hospital drugs" comprise about 1 million prescription fills, or 25% of the total reported 340B drug fills at Minnesota hospitals (about 4 million fills) and 22% of all reported 340B drug fills statewide (about 4.6 million fills). These data are also missing office-administered drugs for most hospitals—which are some of the highest priced drugs—and are therefore missing a significant share of hospital drug fills both in terms of volume and potential net 340B revenue. (See <u>Appendix 7</u> for a continuation of this analysis.)

Drug-level data show that net 340B revenue is driven by high-priced drugs. MDH analyzed the 17 drug families whose net 340B revenue was greater than 1% of the total net 340B revenue of the "top 50 hospital drugs" (<u>Appendix Table 7</u>). These top 17 drug families by net 340B revenue accounted for only 6% of fills yet made up nearly 70% of the drug-level net 340B revenue. By contrast, the top 17 drug families by number of fills accounted for 46% of total fills yet made up only 15% of total drug-level net 340B revenue.

Of these 17 drug families, most are high-profile brand name drugs such as Ozempic, Wegovy, and Trikafta. Many of these high-cost pharmaceuticals are purchased through specialty distribution channels and are considered "specialty drugs." While there is no standardized definition of a specialty drug, they are generally characterized by their high-cost and treatment of chronic conditions such as cancer or autoimmune diseases. Many of these drugs are designated as "biologics" by the Food & Drug Administration (FDA).<sup>24</sup>

Notably, adalimumab (brand name Humira) generated the most net 340B revenue at over \$12 million (13% of total "top 50 hospital drugs" net 340B revenue) on 3,600 fills; this is an average net 340B revenue per fill of over \$3,400. Apixaban (brand name Eliquis) generated the third most net 340B revenue at almost \$10 million (10% of total "top 50 hospital drugs" net 340B revenue) on 17,000 fills; this is an average net 340B revenue per fill of \$558.

This analysis underscores that although the volume of prescriptions filled affects net 340B revenue it is the volume of high-cost specialty drug fills that most impacts a hospital's net 340B revenue.

# Conclusion

Since the inception of the 340B program—a program that was created to strengthen the health care safety net in an environment of high and rising drug costs—it has lacked transparency. The program has grown immensely and has become ingrained into U.S. health care, and thousands of Covered Entities nationwide rely on the revenue of the program. But much has been unknown to policymakers: the volume of net 340B revenue providers generate; the drivers of these revenues; how entities use the revenue; how the discounts offered through the 340B program possibly impact prescribing patterns, manufacturer pricing decisions, or payer reimbursement rates; and the role and impact of intermediaries.

<sup>&</sup>lt;sup>24</sup> Food & Drug Administration (November 2024) Biological Product Definitions (https://www.fda.gov/files/drugs/published/Biological-Product-Definitions.pdf)

This nation-leading initiative takes a critical first step for 340B transparency in Minnesota. It is yet another step in the legislature's path towards greater health care market transparency alongside other efforts from 2023 like monitoring health care spending, establishing oversight over health care market transactions, and providing insights into the high drug prices Minnesotans are paying relative to other countries through prescription drug price reporting. The findings in this report move the state toward having the information necessary to have more transparency in health care system financing, resulting in more meaningful policy discussions.

With this advancement in transparency, policymakers are learning about the size of the program, the distribution of metrics across providers and payers, the role of intermediaries, and how certain drugs impact net 340B revenues for hospitals—the largest benefactors of 340B in Minnesota. However, some important questions remain:

- How do 340B benefits extend to patients?
- How do providers use net 340B revenue and how does it relate to other financing?
- How do the 340B benefits compare with different safety-net providers' financial needs?
- What is the impact of program expansion versus rising drug prices on national growth in 340B spending?
- What incentives does the program create across the prescription drug market and broader health care system? For example, do drug manufacturers raise prices to help offset the discounts they offer to 340B Covered Entities or are there impacts to prescribing patterns?
- What is the impact on net 340B revenue and other metrics when all office-administered drugs are included?
- Are there more efficient ways to administer the program in order to reduce the reliance on external parties' administrative services which lead to lower net revenues?

For the 2025 reporting cycle, MDH will build on the collaboration with providers from the first year of reporting to close some of the gaps in data quality and reporting. MDH, together with experts, will also work to bring broader context and additional insights to the program and its impact in Minnesota.

While the impact of this 340B transparency initiative is a significant contribution to transparency, transparency alone will not meaningfully alter the complex, patchwork health care financing system of safety net services that have come to sustain intermediaries, consultants, and administrators and that have simultaneously reduced the resources needed by patients and communities. Nonetheless, this report may contribute to intentional discussion about health care financing in Minnesota.

# Acknowledgement

MDH extends sincere gratitude to Professor Sayeh Nikpay, PhD., at the University of Minnesota School of Public Health and her team of terrific research assistants. Professor Nikpay, a national expert on the 340B program, supported the project with subject matter expertise and pharmaceutical market insight. The contribution by Professor Nikpay and her team on data cleaning and analysis was essential to making this report possible.

# **Appendix 1: Acronyms & glossary**

## Acronyms

- CMS Centers for Medicare and Medicaid Services
- DSH Disproportionate Share Hospital
- FQHC Federally Qualified Health Center
- HEP Health Economics Program
- HRSA Health Resources and Services Administration
- MDH The Minnesota Department of Health
- MHCP Minnesota Health Care Programs
- MN APCD Minnesota All Payer Claims Database
- NDC National Drug Code
- **OPAIS Office of Pharmacy Affairs Information System**
- TPA Third-Party Administrator

### Glossary

**340B discount:** The price reduction that applies to outpatient drugs purchased by Covered Entities participating in the 340B program. The 340B discounted price is set in federal statute and is referred to as the "ceiling price." (See <u>Appendix 3</u> for more detail.)

**340B drugs:** Outpatient drugs that are purchased at discounted prices and dispensed in retail settings or dispensed to a provider and administered in an outpatient setting. 340B Drugs do not include inpatient drugs. (See <u>Appendix 2</u> for more detail.)

**Child site:** An off-site outpatient facility under the management of a parent 340B Covered Entity that can administer or dispense the Covered Entity's 340B drugs to patients on behalf of the parent.

**Contract pharmacy:** A pharmacy that dispenses a Covered Entity's 340B drugs to the Covered Entity's patients that is not part of the Covered Entity. Contract pharmacies are off-site retail pharmacies (e.g., CVS, Walgreens).

**Covered Entity:** A hospital or clinic that is eligible and approved by HRSA to participate in the 340B drug discount program under Section 340B(a)(4) of the Public Health Service Act (42 U.S.C. § 256b(a)(4).

**Drug families:** Groups of one or more drugs that share a unique generic product description, nontrade name, and dosage form. Drug families are subsets of therapeutic classes.

**Health Resources and Services Administration (HRSA)**: An agency of the U.S. Department of Health and Human Services and the entity that is responsible for administering the 340B Drug Pricing Program.

**National Drug Code (NDC)**: The three-segment code maintained by the federal Food and Drug Administration that includes a labeler code, a product code, and a package code for a drug product.

**Office-administered drugs:** Drugs dispensed to a provider and administered to patients in a clinic or other outpatient setting. These are often injection or infusion drugs such as chemotherapy medications.

**Outpatient Pharmacy Administration Information System (OPAIS):** A database maintained by HRSA to record information on eligible Covered Entities, their contract pharmacies, and child sites.

Pharmacy-dispensed drugs: Drugs distributed to patients directly from a pharmacy.

**Reporting Entities:** Parent 340B Covered Entities in Minnesota that are required to report under the Minnesota 340B Covered Entity Report statute. The parent Covered Entities are required to include data for all child and associated sites and any other entity doing business on their behalf related to 340B.

**Therapeutic Drug Class**: Grouping of individual drug families with similar chemical structures or mechanisms of action that are used to treat similar diseases.

# **Appendix 2: Covered Entity groupings**

MDH grouped HRSA 340B Covered Entity types into groupings that were used for analysis. Appendix Table 2 provides 340B Covered Entity types and definitions and the corresponding categories used by MDH. Although HRSA lists 16 Covered Entity types, there are some types that do not have any providers in Minnesota such as Black Lung Clinics and Freestanding Cancer Hospitals.<sup>25</sup> Appendix Table 2 only includes Covered Entity types in Minnesota.

340B Covered Entity Type	Entities in Minnesota (count)	Description	Covered Entity Grouping	Major Covered Entity Grouping
Comprehensive Hemophilia Disease Treatment Center	3	Hemophilia Treatment Centers receive federal grants to care for individuals with hemophilia and other bleeding disorders. This category includes both hospitals and non-hospitals.	Disease- Specific Federal Grantee	Federal Grantee
Children's Hospital	2	Nonprofit hospitals that serve individuals through the age of 18 years of age and certified children's hospitals by CMS. 340B children's hospitals must also provide a minimum amount of inpatient care to Medicaid and low-income Medicare patients. These hospitals became eligible for 340B participation under the Affordable Care Act of 2010.	Other Hospital	Hospital

#### Appendix Table 2: Covered Entity grouping crosswalk

<sup>&</sup>lt;sup>25</sup> Health Resources & Services Administration. 340B Eligibility (https://www.hrsa.gov/opa/eligibility-and-registration)

340B Covered Entity Type	Entities in Minnesota (count)	Description		Major Covered Entity Grouping
Critical Access Hospital	74	Critical Access Hospitals are designated by CMS. They must have less than 25 beds and are generally located in rural areas. These hospitals became eligible for 340B participation under the Affordable Care Act of 2010.	Critical Access Hospital	Hospital
Disproportionate Share Hospital (DSH)	24	Disproportionate Share Hospitals are general acute care hospitals that receive Medicare DSH payments and are designated based on a calculation that includes Medicaid and Medicare inpatient stay days, hospital size, and geographic location. DSH entities can be nonprofit, for-profit, or public hospitals, but for-profit entities cannot participate in 340B.	General Acute Care Hospitals (DSH)	Hospital
Health Center Program Award Recipient	15	These are Federally Qualified Health Centers (FQHCs), which are community-based health care providers that are designated by CMS and receive funds from the federal government to provide primary care services in underserved areas.	Safety-Net Federal Grantee	Federal Grantee
Health Center Program Look- Alike	2	These are community-based health care providers that meet the requirements to be an FQHC, but do not receive federal funding.	Safety-Net Federal Grantee	Federal Grantee
Ryan White HIV/AIDS Program Grantee	9	A health care organization that receives federal funding to provide HIV/AIDS treatment and related services to people living with HIV/AIDS who are uninsured or under-insured under the Ryan White Act. These Covered Entities may include hospitals or non-hospitals.	Disease- Specific Federal Grantee	Federal Grantee

340B Covered Entity Type	Entities in Minnesota (count)	Description		Major Covered Entity Grouping
Sexually Transmitted Disease Clinic	63	Clinics that diagnose and treat sexually transmitted diseases and receive funding from their state and local health departments through the federal Sexually Transmitted Disease Control Program administered by the Centers for Disease Control and Prevention.		Federal Grantee
Sole Community Hospital	6	Sole Community Hospitals is located more than 35 miles from other hospitals and is designated by the CMS. Sole Community hospitals must also provide a minimum amount of inpatient care to Medicaid and low-income Medicare patients. These hospitals became eligible for 340B participation under the Affordable Care Act of 2010.		Hospital
Title X Family Planning Clinic	1	Title X family planning clinics receive federal funding to provide contraceptive services, counseling, and reproductive health-related preventive services, with priority given to low-income people.	Disease- Specific Federal Grantee	Federal Grantee
Tribal / Urban Indian Health Center	3	Tribal Contract or Compact Health Centers are operated by Tribes or Tribal organizations and Urban Indian Health Centers and are outpatient health care programs that specialize in caring for American Indians and Alaska natives.		Federal Grantee
Tuberculosis Clinic	2	Clinics that receive funding from their state tuberculosis control offices to prevent, diagnose and treat tuberculosis. The Centers for Disease Control and Prevention administers the program.	Disease- Specific Federal Grantee	Federal Grantee

# Appendix 3: 340B background

# Origins and purpose of the 340B Program

The 340B program was passed in 1992 to "stretch scarce federal resources" by providing safety-net providers with significant discounts on outpatient drugs.<sup>26</sup> At this time, Congress was responding in multiple ways to the impact of rising drug costs in the United States on government programs, providers, and individuals. The program is administered by the Health Resources and Services Administration (HRSA), an agency of the U.S. Department of Health and Human Services.

Although the program aims to indirectly increase access for these patients by increasing the financial stability of the safety-net organizations that serve them, there has never been an explicit requirement that 340B revenue be used in a certain way, including to increase access to care for patients who are uninsured or underinsured.

# Organizations eligible to participate in 340B

Federal law identifies which health care providers are eligible to participate in 340B, labeling these organizations "Covered Entities." Originally, Covered Entities only included federally funded safety-net clinics, federally funded disease or condition-specific clinics, and certain public and non-profit hospitals. Hospitals who receive this designation must receive federal Medicare Disproportionate Share Payments and provide a minimum share of inpatient care to Medicaid patients and low-income Medicare patients.<sup>27</sup> Later, under the Affordable Care Act, the list of Covered Entities was expanded to include additional types of non-disproportionate share hospitals (Critical Access Hospitals, Sole Community Hospitals, rural referral centers, Children's hospitals, and free-standing cancer hospitals).

According to HRSA's Outpatient Pharmacy Administration Information System (OPAIS), the number of Covered Entities has increased over time from fewer than 300 in 1992 to nearly 10,000 in 2023. The number of contract pharmacies and child sites where 340B-discounted drugs are eligible to be administered or dispensed also increased, from roughly 70,000 in 1992 to almost 1 million in 2023.

<sup>&</sup>lt;sup>26</sup> <u>340B Drug Pricing Program (https://www.hrsa.gov/opa)</u> Note that according to the Government Accountability Office (GAO), the Public Health Service Act does not explicitly state the purpose of the 340B program—see <u>U.S. GOA Drug Pricing</u> <u>Program (https://www.gao.gov/assets/gao-21-107.pdf)</u>

<sup>&</sup>lt;sup>27</sup> Note that these hospitals are called "DSH hospitals" in the program, however they are not the same as Medicaid DSH hospitals as Minnesota defines them. Specifically, there are 35 Medicaid DSH hospitals in the state but only 25 340B DSH hospitals. All but one of these 25 hospitals received Medicaid DSH payments over the period covered by the report.

# 340B eligible drugs

340B discounts only apply to outpatient drugs, which include drugs dispensed in retail settings (pharmacydispensed) or dispensed to a provider and administered in an outpatient setting (office-administered drugs) to patients of the Covered Entity (as defined by HRSA).<sup>28</sup> Examples of office-administered drugs include infused chemotherapy medications, while examples of pharmacy-dispensed drugs include oral medications taken by patients. 340B discounts are not available for drugs used in the inpatient setting, even if that same drug could also be provided as an outpatient drug. Typically, office-administered drugs are more expensive than those that are dispensed.<sup>29</sup>

## 340B discounts

Manufacturers who participate in Medicaid agree to also offer discounted drugs to 340B Covered Entities as a condition of their Medicaid participation. The 340B-discounted prices are based on a formula defined in the federal statute that created the 340B program. The discounts—known as the "ceiling price"—are not public. Little is known about the discounted prices, nor how large they are relative to reimbursements received from insurers. One estimate comes from office-administered drugs reimbursed through the Medicare program. The Federal Office of the Inspector General found that 340B acquisition costs of office-administered drugs were between 25% and 50% off the Medicare's payment for these drugs.<sup>30</sup> It is unclear how manufacturers finance the provision of drugs at reduced prices—they may take a reduction in profit or build the losses into their calculations for standard prices. As an added complexity, sometimes Covered Entities purchase 340B drugs at an additional discount known as a sub-ceiling discount.

# **Benefits of the 340B Program for Covered Entities**

#### **Reduce operating losses**

When 340B Covered Entities administer or dispense drugs to uninsured patients for free or a reduced price, the 340B program can help them lower their operating losses. For example, without 340B, if a Covered Entity provides a \$100 drug for free to an uninsured patient, it loses \$100 (see Appendix Table 3.1). However, with 340B, if the Covered Entity can reduce its acquisition cost, for example by paying only \$60 for the \$100 drug, the discount lowers the entity's operating loss.

<sup>&</sup>lt;sup>28</sup> <u>Health Resources and Services Administration. (November 2024) 340B Patient Definition Compliance Resources</u> (https://www.hrsa.gov/opa/educational-resources/patient-definition-resources)

<sup>&</sup>lt;sup>29</sup> Sachs, R. & Varcie, J. (2024, June). <u>Spending in the 340B Drug Pricing Program, 2010 to 2021. [PowerPoint Slides].</u> <u>Congressional Budget Office. (https://www.cbo.gov/system/files/2024-06/60339-340B-Drug-Pricing-Program.pdf)</u>

<sup>&</sup>lt;sup>30</sup> Murrin, S. (2015, November). <u>Part B Payments for 340B-Purchased Drugs. Department of Health and Human Services</u> <u>Office of Inspector General. OEI-12-14-00030. (https://oig.hhs.gov/documents/evaluation/3180/OEI-12-14-00030-</u> <u>Complete%20Report.pdf</u>)

Uninsured Patients	Without 340B	With 340B
Drug Cost	-\$100	-\$60
Payment Received	+\$0	+\$0
340B Operating Costs	\$0	-\$4
Operating Loss	-\$100	-\$64

#### Appendix Table 3.1: Example of how 340B reduces operating losses

#### **Generate revenue**

When 340B Covered Entities administer or dispense drugs to insured patients in exchange for payments from insurers, the program can provide a source of revenue to fund care. For most payers (Medicare, Commercial, Medicaid managed care) the payments to providers do not differ by whether a 340B drug was used or not.<sup>31</sup> Covered Entities realize financial gains because their drug acquisition costs are significantly lower than without 340B. 340B revenue is therefore the difference between payments received (from insurers in the form of reimbursements and from patients in the form of cost sharing) and the discounted price.

Appendix Table 3.2 illustrates how 340B revenue is generated with an example. Without 340B, the Covered Entity might buy a drug at a \$100 cost. After dispensing this drug to patients, the Covered Entity collects \$95 in reimbursement from the insurer and a \$5 in cost-sharing from the patient. In this scenario, the Covered Entity would not make any revenue from this transaction. However, with 340B, the Covered Entity can now buy the same drug at a significantly lower price (\$60). Collecting the same amount of reimbursement from insurers and patients, the Covered Entity now generates \$36 in net 340B revenue after accounting for program costs.

<sup>&</sup>lt;sup>31</sup> An important exception to this fact is Medicaid fee-for-service payments, which since 2017 have been required to reflect 340B discounts based on federal law. However, Medicaid managed care is not required to differentiate payments by whether a 340B drug was used or not. Another important exception is Federally Qualified Health Centers (FQHCs), for which all Medicaid payments for drugs in either Medicaid fee-for-service and managed care must reflect the 340B price.

Insured Patients	Without 340B	With 340B
Drug Cost	-\$100	-\$60
Payment received (reimbursement + co-payment)	+\$100	+\$100
340B Operating Costs	\$0	-\$4
Net 340B Revenue	\$0	+\$36

#### Appendix Table 3.2: Example of how 340B generates revenue

# Flow of 340B drugs & operations

Once 340B drugs are purchased, they can be dispensed to patients at the Covered Entity's in-house pharmacies or administered to patients in the Covered Entity's clinics within the hospital. Drugs can also be dispensed or administered at locations off the parent organization's campus and potentially not wholly owned by the parent. These locations can include "child site" clinics under contract with a Covered Entity or independent, community pharmacies under contract with a Covered Entity, called "contract pharmacies."

Covered Entities typically contract with companies who are third-party administrators (TPAs) to help with a variety of administrative or operational functions, including monitoring drug transactions for billing purposes, assisting with negotiations with contract pharmacies, and facilitating the remittance of 340B revenue from contract pharmacies.

## 340B operational expenses

Gross 340B revenue (the difference between payments received for 340B drugs and the discount cost of those drugs) is intended to provide Covered Entities with an unrestricted source of revenue. However, contract pharmacies and TPAs typically charge Covered Entities fees for their services. These fees lower the amount of net 340B revenue available to Covered Entities.

Although fees are not publicly reported, analyses from the Government Accountability Office (GAO) demonstrates that fees can include flat per-contract fees, per drug dispensing fees, or a percentage of the 340B revenue generated from the transitions. Examples from the GAO's analysis of 30 Covered Entity's contract

pharmacy arrangements included flat fees of \$15 per branded prescription to \$1,750 per specialty prescription, and a percentage of payment from insurers for discounted drugs between 8% and 20%.<sup>32</sup>

## 340B: Ongoing program perspectives

The 340B program is large, significant, and impacts many parts of the health care system. There are several key perspectives—sometimes controversial—discussed in the national policy dialogue about the program:

- Lack of program transparency. There are no publicly available data to quantify the financial benefits of the 340B program to Covered Entities—neither for reducing operating losses from providing drugs to the uninsured nor net 340B revenue. Recently, HRSA has published the dollar value of discounted purchases by Covered Entity type.<sup>33</sup> In 2023, Covered Entities purchased \$66 billion worth of discounted drugs, with over 80% (\$42 billion) of those purchases made by public and non-profit hospitals qualifying as Medicare DSH hospitals. Measuring the aggregate acquisition costs from HRSA against an estimate from consulting company IQVIA on the prices insurers might have reimbursed Covered Entities for these drugs (\$106 billion) suggests that if Covered Entities did not provide any free or discounted drugs, gross 340B revenue could be as high as \$52 billion.
- **Mixed evidence on whether 340B benefits patients directly.** As stated by HRSA, the goal of the program is to "reach more eligible patients and provide more comprehensive services." However, several peer-reviewed studies of hospitals participating in the program find little to no increase in safety-net care provided after Covered Entities begin participating in the program.<sup>34, 35</sup> The exception to this finding is public hospitals, which appear more likely to offer certain unprofitable, yet high-community value, services—such as obstetrics, burn care, psychiatric care, and substance abuse treatment.<sup>36</sup> New evidence on non-hospital Covered Entities, such as Federally Qualified Health Centers

<sup>&</sup>lt;sup>32</sup> U.S. Government Accountability Office. (2018, June). <u>Drug Discount Program: Federal Oversight of Compliance at 340B</u> <u>Contract Pharmacies Needs Improvement. GAO-18-480. (https://www.gao.gov/products/gao-18-480)</u>

<sup>&</sup>lt;sup>33</sup> Health Resources & Services Administration. (2023, September). <u>2022 340B Covered Entity Purchases.</u> (https://www.hrsa.gov/opa/updates/2022-340b-covered-entity-purchases)

<sup>&</sup>lt;sup>34</sup> Nikpay, S. S., Buntin, M. B., & Conti, R. M. (2020). Relationship between initiation of 340B participation and hospital safety-net engagement. *Health services research*, *55*(2), 157-169.

<sup>&</sup>lt;sup>35</sup> Desai, S., & McWilliams, J. M. (2021). The 340B Drug Pricing Program and Hospital Provision of Uncompensated Care. *The American journal of managed care*, *27*(10), 432.

<sup>&</sup>lt;sup>36</sup> Owsley, K. M., Hasnain-Wynia, R., Rooks, R. N., Tung, G. J., Mays, G. P., & Lindrooth, R. C. (2024, May). US Hospital Service Availability and New 340B Program Participation. In *JAMA Health Forum* (Vol. 5, No. 5, pp. e240833-e240833). American Medical Association.

(FQHCs), suggests that 340B revenues may increase care to low-income patients, patients with special needs, and increase preventative health screening.<sup>37</sup>

- Drug affordability problems for patients. Although 340B is considered a safety-net program, it may not address patients' drug affordability challenges. Because sharing discounts with insured patients who experience affordability problems decreases the amount of 340B revenue the Covered Entity may generate, there is a disincentive to provide discounted or free care to this group of patients. The Government Accountability Office's analysis of Covered Entities contracts suggests that over half of hospitals' contracts did not include a provision requiring pharmacies to share discounts with uninsured or underinsured patients.<sup>38</sup>
- Increased Costs for the Medicaid Program. Since 1991, state Medicaid programs have used the Medicaid Drug Rebate Program to reduce the cost of financing drugs for Medicaid beneficiaries. These rebates are paid by manufacturers to states and reduce the amount Medicaid agencies paid for drugs from \$64 billion to \$30 billion in 2022 nationally.<sup>39</sup> The "duplicate discount provision" of the 340B program prohibits the use of a Medicaid drug rebate *and* a 340B discount on the same drug. As such, the federal government does not allow Covered Entities to generate 340B revenue from beneficiaries enrolled in the Medicaid fee-for-service program. However, states vary significantly in whether they allow Covered Entities to use 340B discounts on beneficiaries enrolled in Medicaid managed care. In Minnesota, most Covered Entities (except for Federally Qualified Health Centers) are allowed to generate 340B revenue from Medicaid rebates. Minnesota does prohibit the use of contract pharmacies for both managed care and fee for service when Covered Entities claim a 340B discount for patients covered by a Minnesota Health Care Program (Medical Assistance/Medicaid and MinnesotaCare).
- Possible impact on drug prices. Little is known about how manufacturers set launch prices in the U.S. or establish price increases. It is well understood, however, that prices in the U.S. market tend to be higher than in other industrialized nations and that, in general, manufacturers of prescription drugs enjoy considerable pricing power. As such, it is possible that drug manufacturers increase launch prices in response to offering 340B discounted prices, which are formulaic and percentage based, or that they consider the discount as they post regular price increases. While there are no studies that specifically test this theory—largely because pricing data is not typically accessible—evidence from other federally sponsored drug discount programs suggests that 340B could increase prices for all consumers.

<sup>&</sup>lt;sup>37</sup> Watts, E., McGlave, C., Quinones, N., & Nikpay, S. (2023, June). Association of 340B Participation and Revenue with Safety-Net Engagement Among Federally Qualified Health Centers, 2014-2021. American Society of Health Economists Meeting.

<sup>&</sup>lt;sup>38</sup> Government Accountability Office. (2018, June). Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement. GAO-18-480.

<sup>&</sup>lt;sup>39</sup> Kaiser Family Foundation. (June 2019). <u>Understanding the Medicaid Prescription Drug Rebate Program.</u> (https://www.kff.org/medicaid/issue-brief/understanding-the-medicaid-prescription-drug-rebate-program/)

- Significant program growth, especially since 2010. The number of Covered Entities and contract pharmacies grew substantially since 2010. The Affordable Care Act made six new types of hospitals eligible for the program and the number of hospitals participating in the program increased from roughly 1,000 before 2011 to almost 2,500 by 2021.<sup>40</sup> Much of this growth was driven by the addition of Critical Access Hospitals to the list of eligible Covered Entities. Also in 2010, HRSA issued guidance allowing Covered Entities to have an unlimited number of contract pharmacies, increasing the number from roughly 800 retail pharmacies before 2010 to more than 27,000 by 2022, or roughly 40% of US retail pharmacies.<sup>41</sup> Seventy percent of these pharmacies are large chains such as CVS, Walgreens, Walmart, or Rite Aid.<sup>42</sup> In addition to the growth in number of participating entities, drug spending—and subsequent opportunity for net 340B revenue—has also grown significantly. HRSA reports that total drug spending under 340B grew an incredible 22% from 2022 to 2023 for a national total of \$66 billion in drug acquisitions. And, since drug prices are a significant driver of net 340B revenue, rising manufacturer drug prices have also contributed to growing spending and net 340B revenue.
- Contract pharmacy restrictions. In response to significant contract pharmacy growth, many drug
  manufacturers have begun restricting discounts to a single contract pharmacy per Covered Entity. This
  has limited 340B revenue generated through contract pharmacies, although by how much is unknown.
  An analysis by IQVIA suggests 340B revenue from contract pharmacies fell slightly in the years after the
  restrictions went into effect.<sup>43</sup> Multiple states, including Minnesota, have passed legislation since 2020
  requiring the manufacturers provide discounts through contract pharmacies.

<sup>&</sup>lt;sup>40</sup> Owsley et al. (2024).

<sup>&</sup>lt;sup>41</sup> Nikpay, S., McGlave, C. C., Bruno, J. P., Yang, H., & Watts, E. (2023, August). Trends in 340B Drug Pricing Program contract growth among retail pharmacies from 2009 to 2022. In *JAMA Health Forum* (Vol. 4, No. 8, pp. e232139-e232139). American Medical Association.

<sup>&</sup>lt;sup>42</sup> McGlave, C., Bruno, J. P., Watts, E., & Nikpay, S. (2024). 340B Contract pharmacy growth by pharmacy ownership. *Health Affairs*, *2*(1), 1-4.

<sup>&</sup>lt;sup>43</sup> Martin, R. (2022, April). <u>340B Program Continues to Grow While Contract Pharmacy Restrictions Take Effect. IQVIA.</u> (https://www.iqvia.com/locations/united-states/blogs/2022/04/340b-program-continues-to-grow-while-contractpharmacy-restrictions-take-effect)

# **Appendix 4: Data limitations**

MDH reviewed each report individually for reporting compliance and data quality. Approximately 90% of reports required MDH to follow-up with or seek clarification with the Covered Entity at least once.<sup>44</sup> MDH used information from Covered Entities to inform data cleaning steps, which are noted where applicable. MDH observed six primary types of data quality issues:

### 1. Reporting of office-administered vs. pharmacy-dispensed drugs

The 340B Covered Entity Report applies to all 340B drugs (which are all outpatient drugs), and Covered Entities were required to report both office-administered and pharmacy-dispensed drugs. However, the statutory language was somewhat ambiguous, and stakeholders indicated that office-administered drug transactions are more difficult to identify. MDH followed-up with nearly every Covered Entity to clarify which drugs were included in their reporting. Most Covered Entities reported only pharmacy-dispensed drugs purchased through the 340B program and not office-administered drugs. A small number of entities reported data for only office-administered drugs, and a small number reported data for both.

### 2. Contract pharmacy fees: inconsistent methodologies

Covered Entities were required to report the fees they paid to contract pharmacies to dispense 340B drugs. This is important because these costs can be significant (and are often assessed on a per-prescription basis), cutting into the net 340B revenues Covered Entities see from acquiring 340B drugs. Some Covered Entities reported the total payments they made to contract pharmacies, which included drug acquisition costs. Others reported a net amount of payments to contract pharmacies and reimbursements to pharmacies from payers. MDH reached out to Covered Entities to clarify what they reported when this field value was greater than their reported acquisition costs and made corresponding adjustments during the data cleaning phase to include only fees paid to contract pharmacies. This information was used to allocate contract pharmacy fees to the appropriate category.

### 3. Payer type

Statute requires Covered Entities to report their costs and revenues by payer type (commercial insurance, Medicare, Medical Assistance, and MinnesotaCare, and Other). Some entities were not able to disaggregate their 340B data at this level. For hospital Covered Entities with this issue, MDH applied their annual payer mix by patient days to allocate totals. Payer mix by patient day was calculated using MDH's standardized hospital report data and the most recent year available.<sup>45</sup>

#### 4. Child versus parent site

Covered Entities were required to report at the 340B parent level, meaning the level of the organization that qualifies for 340B. As such, data from all child sites and contract pharmacies should have been included in the parent's report. However, some child sites and contract pharmacies reported independently. MDH reached out

<sup>&</sup>lt;sup>44</sup> As an indication of the 1<sup>st</sup>-year reporting challenges, two entities notified MDH of significant errors in their reporting within the two days prior to this report's legislative deadline despite having certified their submissions.

<sup>&</sup>lt;sup>45</sup> Standard Hospital Data Sets (https://www.health.state.mn.us/data/economics/hccis/data/stndrdrpts.html)

to these entities to determine whether the data from these child sites were included in the parent's report or needed to be added.

#### 5. Other

Several entities had unique data reporting issues. MDH communicated with these entities individually to clarify questions or help them resubmit in the most accurate manner possible.

# Appendix 5: Net 340B revenue by entity by select entities

There were 26 Covered Entities that together generated the top 90% of statewide net 340B revenue in Minnesota. However, as noted throughout this report, reported data are incomplete as most entities reported only pharmacy-dispensed drugs instead of both office-administered and pharmacy-dispensed drugs. Therefore, the list and any associated rankings presented in Appendix Table 5 do not represent full information, and entities that submitted complete data (both administered and dispensed drugs) are likely attributed a greater percentage of statewide net 340B revenue than if all entities had reported office-administered drugs.

Scope of Reported Data	Covered Entity Name	340B Covered Entity Type	City	Net 340B Revenue (\$)	% of Statewide Net 340B Revenue	% of Entity's 340B Net Revenue attributed to Minnesota Health Care Programs
Dispensed Only	M Health Fairview University of Minnesota Medical Center	Disproportionate Share Hospital	Minneapolis	\$129,598,482	21%	1%
Dispensed Only	Hennepin Healthcare	Disproportionate Share Hospital	Minneapolis	\$70,211,917	11%	54%
Dispensed Only	Essentia Health Duluth	Disproportionate Share Hospital	Duluth	\$53,538,103	8%	0%
Dispensed Only	Abbott Northwestern Hospital	Disproportionate Share Hospital	Minneapolis	\$31,773,835	5%	24%
Dispensed Only	CentraCare - St. Cloud Hospital	Disproportionate Share Hospital	St. Cloud	\$27,310,115	4%	12%

### Appendix Table 5: Net 340B revenue by select entities, 2023

Scope of Reported Data	Covered Entity Name	340B Covered Entity Type	City	Net 340B City Revenue (\$)		% of Entity's 340B Net Revenue attributed to Minnesota Health Care Programs
Dispensed Only	Sanford Bemidji Medical Center			\$26,862,989	4%	6%
Dispensed Only	Regions Hospital	Disproportionate Share Hospital	St. Paul	\$18,123,342	3%	17%
Dispensed Only	Children's Minnesota	Comprehensive Hemophilia Disease Treatment Center	Minneapolis	\$13,911,529	2%	84%
Dispensed Only	Fairview Range	Disproportionate Share Hospital	Hibbing	\$12,979,661	2%	0%
Dispensed Only	Essentia Health-St. Joseph's Medical Center	Sole Community Hospital	Brainerd	\$11,012,509	2%	0%
Dispensed Only	Grand Itasca Clinic and Hospital	Sole Community Hospital	Grand Rapids	\$10,323,143	2%	20%
Dispensed Only	United Hospital Disproportio Share Hosp		St. Paul	\$8,586,866	1%	0%
Dispensed Only	Children's Minnesota	Children's Hospital	Minneapolis	\$6,382,884	1%	42%
Dispensed Only	Essentia Health Virginia	Disproportionate Share Hospital	Virginia	\$6,146,068	1%	0%
Dispensed Only	Welia Health	Critical Access Hospital	Mora	\$5,651,223	0.9%	0%
Dispensed Only	Sanford Thief River Falls Critical Acce Medical Center Hospital		Thief River Falls	\$5,133,589	0.8%	0%
Dispensed Only	St. Mary's Regional Health Center	Disproportionate Share Hospital	Detroit Lakes	\$5,123,631	0.8%	0%
Dispensed Only	Mercy Hospital	Disproportionate Share Hospital	Coon Rapids	\$4,880,819	0.8%	0%

Scope of Reported Data	Covered Entity Name	340B Covered Entity Type	City	Net 340B Revenue (\$)	% of Statewide Net 340B Revenue	% of Entity's 340B Net Revenue attributed to Minnesota Health Care Programs
Dispensed Only	M Health Fairview St. John's Hospital	Disproportionate Share Hospital	Maplewood	\$4,462,704	0.7%	0%
Dispensed Only	Ne-Ia-Shing Clinic	Tribal / Urban Indian Health Center	Onamia	\$4,078,326	0.6%	75%
Dispensed Only	Hutchinson Health	Disproportionate Share Hospital	Hutchinson	\$3,736,395	0.6%	0%
Administered & Dispensed	North Memorial Health Hospital	Disproportionate Share Hospital	Robbinsdale	\$80,071,766	13%	7%
Administered & Dispensed	Olmsted Medical Center	Disproportionate Share Hospital	Rochester	\$8,632,687	1%	5%
Administered & Dispensed	Maple Grove Hospital	Disproportionate Share Hospital	Maple Grove	\$7,992,600	1%	1%
Administered & Dispensed	Stevens Community Medical Center	Critical Access Hospital	Morris	\$7,150,970	1%	0%
Administered & Dispensed	Winona Health Services	Sole Community Hospital	Winona	\$3,578,644	0.6%	0%

Source: MDH, Health Economics Program analysis of 2023 data reported by Covered Entities under the Minnesota 340B Covered Entity Report.

Note: Minnesota prohibits the use of contract pharmacies for both managed care and fee for service when Covered Entities claim a 340B discount for patients covered by a Minnesota Health Care Program (Medical Assistance/Medicaid and MinnesotaCare).

# Appendix 6: Net 340B revenue by Covered Entity grouping and payer type

### Appendix Table 6: Net 340B revenue by Covered Entity grouping and payer type, 2023

Covered Entity Major Type	Covered Entity Grouping	Commercial	Medicare	Minnesota Health Care Programs (MHCP)	Other	Total
Hospital	General Acute Care Hospitals (DSH)	\$285,731,927	\$152,163,749	\$61,997,487	\$5,851,718	\$505,744,881
Hospital	Critical Access Hospitals	\$30,490,124	\$26,820,534	\$1,544,339	\$769,578	\$59,624,576
Hospital	Other Hospitals	\$17,908,641	\$13,274,728	\$4,707,268	\$413,286	\$36,303,924
Grantee	Disease Specific Federal Grantees	\$6,606,228	\$1,191,455	\$14,415,465	-\$1,481,489	\$20,731,659
Grantee	Safety-Net Federal Grantees	\$2,499,767	\$3,613,733	\$3,922,624	-\$2,178,810	\$7,857,313
	Total	\$343,236,687	\$197,064,198	\$86,587,184	\$3,374,283	\$630,262,352

Source: MDH, Health Economics Program analysis of 2023 data reported by Covered Entities under the Minnesota 340B Covered Entity Report.

# **Appendix 7: Drug-level findings (continued)**

As presented, reporting included drug-level data from hospitals on their top 50 dispensed drugs by volume of prescription fills (see *Drug-level findings* on page 25). This appendix includes a more detailed analysis of these drug-level data.

## By acquisition cost

Recently, HRSA published the top 10 drugs in terms of national 340B acquisition costs (provider spending on 340B drug purchases) for 2023.<sup>46</sup> Spending on these 10 drugs represented approximately one-third of all drug spending for the 340B program nationwide. Most of these drugs are high-cost pharmaceuticals purchased through specialty distribution channels—or "specialty drugs." While there is no standardized definition of a "specialty drug," it is often the notably higher price that leads to the "specialty" designation. Of note, many of these drugs are in the biologics class of drugs or are office-administered drugs. Specialty drugs represent a growing share of total 340B acquisition costs; HRSA noted that although they represented only 36% of total 340B acquisitions *by volume* they accounted for over 60% (\$40 billion of \$66 billion) of 340B *acquisition costs* in 2023.<sup>47</sup>

In Minnesota, it appears that specialty drugs are also a significant driver of total 340B acquisition costs. Three of the drugs that appeared on HRSA's "Top 10" list were also within the top 10 drugs by acquisition cost in Minnesota. These three drugs account for approximately 57% of 340B acquisition costs of the 2023 "top 50 hospital drugs" reported by Minnesota 340B hospitals:

- Trikafta (elexacaftor-tezacaftor-ivacaftor), a cystic fibrosis drug, ranks sixth on HRSA's list and first on Minnesota's list of greatest acquisition costs.
- Humira (adalimumab), an immunology drug, ranks seventh on HRSA's list and second on Minnesota's list.
- Biktarvy (bictegravir-emtricitabine-tenofovir alafenamide fumarate), an anti-viral drug, ranks second on HRSA's list and sixth on Minnesota's list.

It is possible that there will be greater overlap between drugs families on HRSA's and Minnesota's lists of largest 340B acquisition costs once Minnesota receives more office-administered drug reporting in 2025 and beyond.

<sup>&</sup>lt;sup>46</sup> HRSA's top 10 list identifies brand names for these drugs and likely includes multiple dosage forms and equivalent generic products, similar to the drug families identified in this report.

<sup>&</sup>lt;sup>47</sup> 2023 340B Covered Entity Purchases (https://www.hrsa.gov/opa/updates/2023-340b-covered-entity-purchases)

## By volume

When ranked by volume or the number of prescription fills, oxycodone was the most frequently filled drug for which 340B discounts were applied in hospitals. In total, there were over 80,000 fills of oxycodone, generating approximately \$100,000 in net 340B revenue. Fentanyl was ninth by volume with over 20,000 fills and a net revenue of approximately \$360,000. According to Minnesota's All Payer Claims Database (MN APCD), opioids are the 10<sup>th</sup> most filled therapeutic class in the state. Overall, analgesics (pain relief) represent many of the most filled 340B drugs, which may reflect post-operative prescribing for Minnesota hospital patients.

The top 10 most filled drug families account for about one-third of all filled drugs in the "top 50 hospitals drugs" and include common drug families: acetaminophen, sodium chloride, omeprazole, atorvastatin calcium, albuterol sulfate, propofol, ibuprofen, and ondansetron. <sup>48</sup> These drug families all generate between \$1 and \$30 in net 340B revenue per fill, and none totals more than \$1 million in net 340B revenue. In other words, the most prescribed 340B drugs reported for 2023 do not significantly drive net 340B revenues.

## By net 340B revenue

MDH analyzed the 17 drug families whose net 340B revenue represented at least 1% of the total net 340B revenue of the "top 50 hospital drugs" (Appendix Table 7). (See *Drug-level findings* on page 25 for notable findings from these data.)

<sup>&</sup>lt;sup>48</sup> 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.

Rank by net 340B revenue	Drug family	Brand name(s)	Biologic	Primary indication	Total fills (count)	Total net 340B revenue (\$)	Average net 340B revenue per fill (\$)
1	Adalimumab	Humira	Yes	Immunology	3,593	12,233,752	3,405
2	Elexacaftor-Tezacaftor- Ivacaftor	Trikafta	No	Cystic fibrosis	2,465	9,737,952	3,950
3	Apixaban	Eliquis	No	Blood thinner	17,335	9,679,212	558
4	Semaglutide	Ozempic	No	Anti-diabetic	11,201	6,373,377	569
5	Etanercept	Enbrel	Yes	Immunology	578	3,899,862	6,747
6	Dornase Alfa	Pulmozyme	Yes	Cystic fibrosis	988	3,740,182	3,786
7	Somatropin	Norditropin	Yes	Growth hormone	1,219	3,459,801	2,838
8	Avalglucosidase Alfa-ngpt	Nexviazyme	Yes	Pompe disease	68	2,662,632	39,156
9	Semaglutide (Weight Management)	Wegovy	No	Weight loss	2,051	2,433,566	1,187

## Appendix Table 7: Greatest net 340B revenue by drug family, 2023

Rank by net 340B revenue	Drug family	Brand name(s)	Biologic	Primary indication	Total fills (count)	Total net 340B revenue (\$)	Average net 340B revenue per fill (\$)
10	Rivaroxaban	Xarelto	No	Blood thinner	3,586	2,010,046	561
11	Insulin Glargine	Lantus, Toujeo, Basaglar	Yes	Insulin	4,293	1,741,279	406
12	Pancrelipase (Lipase- Protease-Amylase)	Creon, Zenpep	Yes	Digestive aid	460	1,649,312	3,585
13	Anakinra	Kineret	Yes	Immunology	181	1,459,936	8,066
14	Insulin Aspart	NovoLOG	Yes	Insulin	2,496	1,342,748	538
15	Empagliflozin	Jardiance	No	Anti-diabetic	2,060	1,131,083	549
16	Dulaglutide	Trulicity	Yes	Anti-diabetic	2,550	1,013,215	397
17	Eteplirsen	Exondys 51	No	Muscular dystrophy	251	962,570	3,835

Source: MDH, Health Economics Program analysis of 2023 data reported by Covered Entities under the Minnesota 340B Covered Entity Report and reference data from Wolters-Kluwer's Medi-Span.