Recent Reports Shed Light On Section 340B's Effectiveness

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In April, the majority staff of the <u>U.S. Senate</u>'s Health, Education, Labor, and Pensions Committee, under leadership of Chairman Bill Cassidy, R-La., released a report on the Section 340B Drug Discount Program.¹

The Section 340B program mandates that drug manufacturers provide steep discounts on their products to many healthcare providers.²

Based on an extensive review that included two high-volume 340B hospitals, two large and for-profit pharmacy chains that act as 340B contract pharmacies, and data from four manufacturers, the HELP report concluded that those hospitals "each generated hundreds of millions of dollars in 340B ... revenue," but "do not pass 340B discounts directly to patients" at the pharmacy counter.³

As a consequence, the HELP report called for program reform designed to "ensure that manufacturer discounts actually benefit 340B-eligible patients." While Section 340B advocates were quick to dismiss the HELP report and its findings, the report's conclusion that the Section 340B program fails to provide meaningful assistance for patients at the pharmacy counter is consistent with questions raised by another recent report, which echoes Chairman Cassidy's concerns and underscores the need for reform.



Only a few months before the HELP report was issued, the <u>Minnesota Department</u> of <u>Health</u> issued its first Section 340B transparency report, providing substantial insight into the operations of the Section 340B program in the state.⁶

Together, the HELP and MDH reports support some of the concerns about the Section 340B program frequently raised by policy researchers, reform advocates, patient groups and other Section 340B critics. While limited to one state and with important limitations, Minnesota's data collection effort appears to highlight a disconnect between where the Section 340B program concentrates its benefits and the needs of patients at the pharmacy counter.

The debate about whether the Section 340B program provides meaningful assistance to patients is not just an important policy issue. It also is a central issue in the ongoing litigation engulfing the program.

Litigation related to Section 340B has followed efforts by drug manufacturers to limit covered entities' use of contract pharmacies⁷ and to effectuate Section 340B prices through rebates, rather than upfront discounts.⁸

In opposing these policies, advocates for entities covered by Section 340B contend that such policies hinder covered entities' ability to share Section 340B discounts with needy patients at the pharmacy counter in the form of free or discounted care.

Manufacturers and other critics have disputed this claim, pointing to the dramatic growth of the program coupled with a corresponding decline in charity care provided by Section 340B hospitals. They contend that this trend demonstrates that patients at the pharmacy counter do not sufficiently benefit from the covered entities' increasing profits generated by the program.⁹

In particular, a prior study found that Section 340B discounts are shared with patients for only 1.4% of all prescriptions filled at contract pharmacies, on average. Significantly, there are over 33,000 unique contract pharmacy locations and more than 194,000 relationships between Section 340B hospitals or clinics and contract pharmacies. Hospitals or clinics and contract pharmacies.

Charity care includes both free care and discounted care provided to uninsured and underinsured individuals who lack the financial means to pay for the care they receive, including pharmaceuticals.

As such, charity care levels can serve as an indicator of the extent to which Section 340B covered entities provide financial assistance at the pharmacy counter, although such covered entities may also provide charity care for nonpharmaceutical items and services. Accordingly, only a portion of reported hospital charity care is, as a general matter, devoted to Section 340B-eligible patients at the pharmacy counter.

As noted in both the HELP and MDH reports, concerns about the lack of transparency of the Section 340B program have been widely raised since its inception.¹²

The MDH report does not specifically address how much financial assistance is provided to Section 340B patients at the pharmacy counter, or how much those patients pay out of pocket — contributing to the profits of Section 340B covered entities.

However, it does shed light on the relationship between 340B benefits and charity care, and, by extension, the likelihood that needy patients receive assistance at the pharmacy counter, thus reinforcing the concerns articulated in the HELP Report.

An analysis of 23 Minnesota hospitals that received the lion's share of Section 340B discounts and benefits discussed in the MDH report indicates that the average charity care ratio among these hospitals in 2022 was quite low.¹³

Specifically, the charity care ratio for those hospitals — including charity care provided to patients at the pharmacy counter — was only 0.91%, substantially lower than the national average of 2.35% among non-Section 340B hospitals. ¹⁴

This analysis underscores the need for further evaluation of the extent to which the Section 340B program benefits patients at the pharmacy counter and raises important questions about whether legislative reform should be enacted — just as the HELP report did.

In the following sections, we first summarize the patient assistance debate underlying the ongoing Section 340B litigation. We then present important findings from the MDH report and from our own analysis of charity care provided by selected Section 340B covered entities in Minnesota relative to state and national benchmarks.

The Litigation Debate

Whether the billions in Section 340B discounts translate into meaningful charity care, including at the pharmacy counter, has been an issue that has increasingly played into the framing of Section 340B litigation disputes.

Manufacturers, who doubt that such a connection exists in any meaningful way, see it as a means to portray the program as having strayed from its purpose of assisting entities that provide direct care to underinsured and uninsured patients.¹⁵

Section 340B covered entities, conversely, argue that the connection is real and substantial, and contend that it is an important way in which the program benefits patients in need.

In an amicus brief in the <u>U.S. Court of Appeals for the Fifth Circuit</u>, for instance, the <u>American Hospital Association</u> supported a challenge to manufacturer contract pharmacy policies.

In Novartis v. Fitch on Nov. 15, 2024, the AHA argued that the manufacturer policies operate "at the expense of hospitals and the patients they serve." The brief asserted that the effect of manufacturer policies is to force patients to lose "savings that hospitals directly pass on to them," including assistance at the pharmacy counter. 17

Later in the brief, in seeking to support that argument, it alleged that the manufacturer policies have prevented a covered entity from offering "more direct patient financial assistance and charity care."

18

Similarly, in discussing another covered entity, the brief attempted to support its argument by stating that the manufacturer policies mean patients "will not be able to receive discounts." In other words, the amicus repeatedly implies that the Section 340B program results in discounts being shared directly with patients at the pharmacy counter. 20

Manufacturers and other critics, including a growing number of patient advocacy groups, on the other hand, see the issues of charity care and benefit to the patient at the pharmacy counter quite differently.²¹

In a challenge to Minnesota's law prohibiting manufacturer contract pharmacy policies, for example, <u>AstraZeneca PLC</u> argued in AstraZeneca Pharmaceuticals v. Ellison last year that although "Congress originally intended for the 340B program to benefit the underserved communities," including "'low-income and rural persons," covered entities have "realized that if they didn't pass on" those discounts to patients, "they could use the Program to generate arbitrage 'revenue'" for their own benefit.²²

In that same case, another manufacturer, <u>AbbVie Inc.</u>, asserted that "[c]overed entities and commercial pharmacies reap windfalls" under the 340B program, "but uninsured and underinsured patients are not benefitting."²³

Courts have, to date, generally seen the issue of charity care and patient benefit at the pharmacy counter as Section 340B covered entities have presented it. The <u>U.S. Court of Appeals for the Eighth Circuit</u>, in upholding the Arkansas law prohibiting manufacturer contract pharmacy restrictions, premised its decision in PhRMA v. McClain last year, in part, on the assertion that contract pharmacies provide covered entities a "process for accessing 340B pricing for patients."²⁴

Multiple district courts have followed the Eighth Circuit's lead.

Interestingly, though, the one court to date that has sided with manufacturers in a contract pharmacy policy case emphasized its view that the Section 340B program did not translate into a direct benefit to patients in the form of discount sharing at the pharmacy counter.²⁵

In that case, PhRMA v. Morrisey last year, the <u>U.S. District Court for the Southern</u> <u>District of West Virginia</u> began its decision by pointedly observing that, in assessing the benefits of the Section 340B pricing scheme, the "covered entities of the 340B program are not the low-income patients themselves."²⁶

In granting a preliminary injunction against the West Virginia law at issue, the court returned, emphatically, to the same point at the end of its decision. Specifically, it rejected the state's contention that an injunction imposed against the state law would not be in the public interest, concluding that contract pharmacy transactions, "[a]fter all," are "for the benefit of the covered entities."

They, the court asserted, "enjoy the benefits of the 340B Program, not patients themselves, as acknowledged by all parties."²⁸

Although the six pending challenges to HRSA's refusal to permit manufacturers to deploy rebate models are not yet finally resolved, that litigation framed the same issue of patient benefit at the pharmacy counter and in the form of charity care.²⁹

In the complaint for <u>Johnson & Johnson</u> v. <u>U.S. Department of Health and Human Services</u> in the U.S. District Court for the District of Columbia last year, for example, the plaintiff alleged in its very first substantive paragraph, that the Section 340B program, "[i]nstead of supporting uninsured or indigent patients," benefits "sophisticated, well-resourced hospital systems, major for-profit retail pharmacy chains and their affiliated pharmacy benefit managers," all to "the detriment of patients."³⁰

In intervening in these cases or submitting amicus briefs in support of HRSA, Section 340B interests have similarly repeated their themes.

The MDH Report's Findings

Like the HELP report, the MDH report provides a means of assessing the competing claims about whether Section 340B pricing benefits patients through charity care, including at the pharmacy counter.

For the 2023 calendar year, the report indicates that Minnesota Section 340B hospitals and clinics received \$1.5 billion in total Section 340B payments, paid \$734 million in acquisition costs at Section 340B discounted prices, and paid another \$120 million in fees to contract pharmacies and third-party program administrators, yielding a "collective net 340B revenue" or profit after all costs, of "at least \$630 million," or 42% of the total payments.³¹

These findings are set out below in Table 1.

Table 1: Summary of 340B Financial Flows in Minnesota, 2023

Total 340B Payments Received*	\$1,483,842,241
340B Acquisition Costs**	(\$733,549,211)
External Operational Costs***	(\$120,030,677)
Net 340B Revenue (\$)	\$630,262,352
Net 340B Revenue (% of Total Payments)	42%

^{*} Defined as "total payments a Covered Entity received—directly or indirectly—from patients and their insurers for 340B drugs that the entity prescribed to their patients."

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^{**} Defined as "the total dollar amount a Covered Entity paid—directly or indirectly—to purchase 340B drugs from drug manufacturers at 340B discounted prices."

^{***} Defined as "the sum of payments to contract pharmacies and intermediaries for program administration (e.g., fees charged by [third-party administrators])."

Significantly, the MDH report states that "[the data presented] should be considered a significant underestimate." Its incompleteness is attributed to several factors, including the "inability" of some providers to report the required information, "data quality" issues, and, "[m]ost importantly, the failure of most entities to report data for office-administered drugs," also referred to as physician-administered drugs.33

The absence of data on physician-administered drugs, a financially important segment of drugs for providers, from the data generated by a majority of Section 340B hospitals and clinics is a material concern for those interested in bringing transparency to the program.³⁴ The MDH report estimates that if complete data had been reported to the department, statewide Section 340B revenues could have been as high as \$3 billion.³⁵

In addition to incomplete reporting on physician-administered drugs, another limitation of the MDH report is the lack of information on amounts paid out of pocket by patients. While reported total revenues should include these amounts, they are not reported separately from the revenues that covered entities receive from payers.

Visibility into this split would shed further light on the extent to which Section 340B covered entities are sharing (or not sharing) discounts with patients at the pharmacy counter. Ideally, other states considering transparency provisions like Minnesota's will call for reporting of this important split, but, unfortunately, some recent examples indicate that is not occurring.³⁶

Finally, the MDH report stresses the outsized share of 340B revenues, and thus program benefits, that were captured by a small number of hospitals. In particular, the state's largest Section 340B hospitals — representing 13% of all reporting entities — collectively received 80% of the \$630 million in reported statewide profits from the Section 340B program, or approximately \$500 million in Section 340B profits.³⁷

We examined these entities' charity care expenditures, which should be inclusive of any charity care provided to patients in need at the pharmacy counter, to offer perspective on the HELP report's conclusions and the competing claims of Section 340B advocates and critics regarding whether patients benefit from the Section 340B program at the pharmacy counter.

Charity Care

Our analysis of the 23 hospitals with the highest net Section 340B revenues in Minnesota found that these hospitals had an average charity care ratio of 0.91% in 2022, inclusive of any charity care provided to patients at the pharmacy counter.³⁸

Individual hospital ratios ranged from 0.11% to 4.56%. This average exceeded the statewide average among all hospitals, including many that do not participate in the Section 340B program and, therefore, generate no Section 340B profits, by 0.11 percentage points.

Indeed, the 23 Section 340B hospitals' charity care ratios exceeded the statewide average among non-Section 340B hospitals by just 0.3 percentage points. In other words, despite receiving the vast majority of the Section 340B program benefits in Minnesota,

these Section 340B hospitals, on average, provided only marginally more charity care — including at the pharmacy counter — than the average of all hospitals statewide and the subset of non-Section 340B hospitals that realize no Section 340B profits.

Even larger differences emerge when these 23 hospitals are compared to national figures. The 23 hospitals had an average charity care ratio that was 1.56 percentage points below the national all-hospital average, meaning that their average charity care ratio was 63.2% less than the national average, inclusive of hospitals that generated no Section 340B profits. The 23 hospitals' average charity care ratio was also 1.44 percentage points, or 61.3% below the national non-Section 340B hospital charity care ratio.

Table 2: Charity Care Ratios of 23 Minnesota 340B Hospitals

Covered Entity	Cost of Charity Care	Net Patient Revenue	Charity Care Ratio
Essentia Health Duluth	\$593,734	\$519,219,914	0.11%
Olmsted Medical Center	\$757,328	\$217,635,032	0.35%
Stevens Community Medical Center	\$180,540	\$49,834,718	0.36%
Welia Health	\$398,835	\$106,731,108	0.37%
Fairview Range	\$520,669	\$120,962,228	0.43%
St. Mary's Regional Health Center	\$725,036	\$167,834,234	0.43%
Essentia Health Virginia	\$598,322	\$132,004,703	0.45%
Essentia Health-St. Joseph's Medical Center	\$1,319,144	\$283,339,603	0.47%
CentraCare - St. Cloud Hospital	\$4,504,516	\$943,564,397	0.48%
Winona Health Services	\$496,236	\$100,273,055	0.49%
M Health Fairview Univ. of Minnesota Medical Center	\$10,457,279	\$1,842,477,989	0.57%
Hutchinson Health	\$594,645	\$89,500,051	0.66%
Grand Itasca Clinic and Hospital	\$906,368	\$117,700,061	0.77%
Maple Grove Hospital	\$1,932,462	\$249,510,837	0.77%
Abbott Northwestern Hospital	\$9,908,165	\$1,240,356,877	0.80%
Sanford Bemidji Medical Center	\$3,030,903	\$312,585,843	0.97%
M Health Fairview St. John's Hospital	\$3,628,185	\$375,781,182	0.97%
North Memorial Health Hospital	\$5,604,607	\$571,353,325	0.98%
United Hospital	\$7,625,159	\$762,851,203	1.00%
Mercy Hospital	\$7,941,947	\$783,050,851	1.01%
Hennepin Healthcare	\$19,491,348	\$1,194,466,000	1.63%
Regions Hospital	\$16,344,187	\$862,702,310	1.89%
Sanford Thief River Falls Medical Center	\$3,375,549	\$73,966,425	4.56%
All 23 Covered Entities	\$100,935,164	\$11,117,701,946	0.91%

Only one Minnesota Section 340B hospital, Sanford Thief River Falls, had a charity care ratio (4.56%) that exceeded the national all-hospital average (2.47%). However, this hospital was the second smallest in terms of net patient revenues among the top recipients of Section 340B benefits in Minnesota.

The Section 340B hospital with the next-highest charity care ratio was Regions Hospital, with a charity care ratio of 1.89%, 23.5% below the national all-hospital average. Notably, approximately half of the 23 hospitals reported charity care ratios below even the lower Minnesota average for non-Section 340B hospitals (0.61%).

Advocates of the Section 340B program may argue that national charity care ratios are not an appropriate comparator because Minnesota is among those states that expanded their Medicaid program under the Affordable Care Act.

As a result, Minnesota has a lower uninsured rate relative to the U.S. as a whole — 3.8% versus 8.0% — and demand for charity care may be lower.³⁹ However, even when the national all-hospital average is scaled by the ratio of Minnesota's uninsured rate to the national rate, the average charity care ratio of these 23 Minnesota hospitals is still 22% below the adjusted national all-hospital benchmark, at 0.91% versus 1.20%.

Further, this comparison does not consider the needs of underinsured individuals who represent a much higher percentage of the U.S. population than the uninsured individuals (23% vs. 8.0%).⁴⁰

MDH reports that 24.5% of all Minnesotans, both those with and those without insurance, did not access some type of health care in 2023 due to costs.⁴¹ Whatever Minnesota's uninsured rate may be, that additional group of patients would further suggest that state residents' charity care needs, including at the pharmacy counter, are inadequately addressed, based on the low charity care ratios reported by the Minnesota hospitals we reviewed.

Conclusion

The HELP report's conclusions that reform is needed to "ensure that manufacturer discounts actually benefit 340B-eligible patients" seem to be reinforced by the MDH report.⁴²

MDH's first Section 340B transparency report reveals that, while 23 hospitals generate the majority of the Section 340B program's profits in Minnesota, their average charity care ratio — including charity care at the pharmacy counter — was low relative to state-level and national benchmarks.

Their average charity care ratio only marginally exceeds the statewide average for all Minnesota hospitals and compares unfavorably to national averages, even when accounting for Minnesota's lower rate of uninsured patients and without considering the higher rate of the underinsured.

As a result, the MDH report raises questions about Section 340B advocates' claims that the program's discounts are benefiting patients through the provision of charity care, including at the pharmacy counter. Those questions appear to echo the concerns reflected in the HELP report.

With that said, further research is needed to determine, with precision, what percentage of needy Section 340B patients receive financial assistance at the pharmacy counter. Congress or state legislators could increase transparency into Section 340B patient assistance at the pharmacy counter by instituting reporting requirements specifically designed to assess whether and to what extent that assistance is provided to

those patients by covered entities and how much of Section 340B revenues are paid out of pocket by Section 340B eligible patients.

Adoption of the rebate model also would be a source of transparency into the level of patient assistance provided at the pharmacy counter. As the press release accompanying the HELP report states, "there are transparency and oversight concerns" that "prevent 340B discounts from translating to ... lower costs for patients."

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Endnotes

- 1 Majority Staff, U.S. Senate Health, Education, Labor, and Pensions Committee, "Congress Must Act to Bring Needed Reforms to the 340B Drug Discount Program," April 2025, ("HELP Report"), p. 5.
- 2 Id. at 1.
- 3 Id. at 5 and 8.
- 4 Id. at 39.
- 5 See, e.g., Young, Shannon, "Stakeholders React to HELP Committee Chair Cassidy's 340B Probe Findings, Reform Recommendations," 340B Report, April 24, 2025 (CEO of the American Hospital Association criticizing the HELP Report because it was "limited in scope"); Young, Shannon, "National HIV Group Voices Concerns Over Sen. Cassidy's 340B Probe Findings, Recommendations," 340B Report, May 1, 2025, at 1 (quoting a 340B advocate who criticized the Report for its purported "inherent unreliability" in attempting to craft policy solutions "based on a small survey," but acknowledging "direct patient benefit" is an "important aspect[] of the 340B program").
- 6 Minnesota Department of Health, "340B Covered Entity Report," November 25, 2024, ("MDH Report").
- 7 Manufacturer contract pharmacy policies typically limit the number of contract pharmacies or the geographical radius in which contract pharmacies operate. A contract pharmacy is independent of the covered entity, but the covered entity treats the dispensing or administration of a drug by that pharmacy as its own for the purpose of claiming 340B pricing. The Third Circuit and the D.C. Circuit Courts of Appeals have permitted such manufacturer-imposed conditions, provided they do not effectively result in the manufacturer failing to offer the 340B price altogether. See American Hospital Association, "3rd Circuit sides with 340B drugmakers in contract pharmacy case," January 30, 2023; Association of American Medical Colleges, "D.C. Circuit Rules in Favor of Drug Manufacturers in 340B Contract Pharmacy Case," May 24, 2023.

- 8 In a rebate model, the manufacturer provides 340B pricing through a retrospective rebate rather than a prospective discount. The rebate is typically paid within a short time frame usually within seven to ten days. The short delay between the dispensing or administration of the drug and the rebate payment gives the manufacturer a limited opportunity to assess whether the 340B price is owed under the statute. A recent decision by the <u>United States District Court for the District of Columbia</u> held that the government has authority to approve the use of a rebate model and, with respect to several drug makers, has not acted arbitrarily and capriciously in denying its approval, as the government has not yet fully analyzed the model. See, e.g., <u>Bristol-Myers Squibb</u> v. Kennedy, Memorandum Opinion, Case No. 24-CV-3496 (DLF) (May 5, 2025). However, with respect to one manufacturer, the court held that the government had acted arbitrarily and capriciously because it had arrived at a final decision and denied the request to implement a rebate model without considering the manufacturer's diversion and duplicate discount concerns. See id. A different district court judge in the same court has another case pending before him, for which a ruling is still forthcoming. It is expected that appeals will be filed in these cases.
- 9 According to the <u>Health Resources and Services Administration</u> (HRSA), the federal agency that runs the program, the 340B Program reached \$66 billion in discounted purchases in 2023, a 24% increase in its size in just one year. Prior research has demonstrated that the value of those purchased drugs at their list prices, an approximation of their reimbursement value to 340B hospitals and clinics, was \$124 billion. See Health Resources & Services Administration, "2023 340B Covered Entity Purchases," and Martin, Rory and Harish Karne, "The 340B Drug Discount Program Grew to \$124B in 2023," IQVIA, 2024.
- 10 Martin, Rory and Kepler Illich, "Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies?" IQVIA, 2022.
- 11 Fein, Adam "For 2023, Five For-Profit Retailers and PBMs Dominate an Evolving 340B Contract Pharmacy Market," Drug Channels, July 11, 2023.
- 12 See HELP Report, p. 4 and MDH Report, p. 9.
- 13 The charity care ratio is the cost of charity care provided as a share of revenues.
- 14 Charity care ratios were calculated using the cost of charity care (i.e., the cost of care provided to low-income patients who qualify for free or discounted care under the hospital's financial assistance policy) divided by net patient revenue (i.e., the actual payments a hospital receives for services rendered to patients rather than the full billed charges). Charity care ratios are sometimes calculated as a share of hospital operating expenses. Data were obtained from CMS Hospital Provider Cost Report 2022, the latest year for which data are available. See CMS, "Hospital Provider Cost Report," 2022. 340B enrollment is determined using data obtained from the Office of Pharmacy Affairs of the Health Resources & Services Administration. See 340B OPAIS, "Covered Entity Search," 2025.
- 15 U.S. House Report No. 102-384, pt. 2, at 12 (1992).
- 16 American Hospital Association, et al., <u>Amicus Brief</u>, Novartis v. Fitch, Case No. 1:24-cv-164, at 4, 8 (November 15, 2024).
- 17 Ibid.
- 18 Id. at 9.
- 19 Id. at 9.
- 20 Ibid.
- 21 See, e.g., CF United and ADAP Advocacy Amicus Brief, Bristol Myers Squibb v. Fink, Case No. 1:24-cv-03337, February 10, 2025.
- 22 Plaintiff's Response to Defendant's Motion to Dismiss, AstraZeneca Pharm. v. Ellison, Case No. 24-cv-02621, October 9, 2024 (quoting Sanofi-Aventis U.S. LLC v. HHS, 58 F.4th 696, 699, 3rd Circuit 2023).
- 23 Plaintiff's Opposition to Defendant's Motion to Dismiss, AbbVie, Inc. et al v. Ellison, Case No. 24-cv-02605, October 9, 2024 (quoting Plaintiff's Amended Complaint, at ¶70).
- 24 Appeal No. 22-3675, PhRMA v. McClain, Case No. 4:21-cv-00864, March 12, 2024, at 7.
- 25 Memorandum Opinion and Order, PhRMA v. Morrisey, Case No. 2:24-cv-00271, December 17, 2024 (with consolidated cases).
- 26 Id. at 3.
- 27 Id. at 34 (emphasis in original).
- 28 Ibid.

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- 29 See Johnson & Johnson v. HHS, Case No. 1:24-cv-03188, United States District Court for the District of Columbia, November 14, 2024; Eli Lilly v. HHS, Case No. 1:24-cv-03220, United States District Court for the District of Columbia, November 12, 2024; BMS v. HHS, Case No. 1:24-cv-03337, United States District Court for the District of Columbia, November 26, 2024; Kalderos v. HHS, Case No. 1:21-cv-02608-DLF, United States District Court for the District of Columbia, December 9, 2024; Sanofi v. HHS, Case No. 1:24-cv-03496, United States District Court for the District of Columbia, December 16, 2024; Novartis v. HHS, Case No. 1:25-cv-00117-DLF, United States District Court for the District of Columbia, January 15, 2025.
- 30 See Johnson & Johnson v. HHS, Case No. 1:24-cv-03188, United States District Court for the District of Columbia, November 14, 2024, at 2. This is the case, referenced above in note 7, that has not been the subject, as yet, of a district court decision.
- 31 MDH Report, pp. 7-8, 15-16.
- 32 MDH Report, p. 7 (emphasis added).
- 33 Ihid
- 34 Robinson, James C. et al., "Hospital Prices for Physician-Administered Drugs for Patients with Private Insurance," New England Journal of Medicine, Vol. 390, No. 4, 2024, pp. 338-345.
- 35 MDH Report, p. 4 ("Based on national data, MDH believes this [\$1.5 billion] figure may represent as little as half of the actual total 340B revenue for Minnesota providers").
- 36 See, e.g., Indiana Senate Bill No. 118, 2025 (although it would require reporting of charity care, it fails to require that the amounts paid out of pocket by 340B patients be disclosed as a separate line item).
- 37 MDH Report, p. 8.
- 38 The MDH Report identifies 26 covered entities that "generated the top 90% of statewide net 340B revenue in Minnesota" in 2023. Among these 26 covered entities, two are affiliated with a single parent organization which did not report information on costs of charity care, and one does not treat Medicare patients (as such, it is not required to submit a provider cost report to CMS). Thus, the average charity care ratio of 0.91% was estimated among 23 covered entities. See MDH Report, Appendix 5.
- 39 Minnesota Department of Health, "Findings from the 2023 Minnesota Health Access Survey (MNHA)," March 2024; Keisler-Starkey, Katherine and Lisa N. Bunch, "Health Insurance Coverage in the United States: 2023," United States Census Bureau, September 10, 2024.
- 40 The Commonwealth Fund, "The State of Health Insurance Coverage in the U.S.," November 21, 2024; Keisler-Starkey, Katherine and Lisa N. Bunch, "Health Insurance Coverage in the United States: 2023," United States Census Bureau, September 10, 2024.
- 41 Minnesota Department of Health, "Findings from the 2023 Minnesota Health Access Survey (MNHA)," March 2024, p. 3.
- 42 HELP Report, p. 39.
- 43 U.S. Senate HELP Committee, "Chair Cassidy Releases Report on 340B Reform, Calls for Congressional Action", April 24, 2025, p.1.

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