April 18, 2024
Senate Health and Human Services Committee

Chair Wiklund and Committee Members,

As 340B covered entities and members of the Minnesota 340B Coalition, we are writing with comments and recommendations specific to SF4699 which would change current 340B reporting requirements.

The 340B Drug Pricing program which was enacted by Congress in 1992 provides a way for safety- net providers to purchase discounted drugs from participating pharmaceutical companies. To qualify to participate in 340B, covered entities like community health centers, sexually transmitted infection clinics and hospitals must serve a disproportionate share of low-income patients or patients living in isolated rural communities. The program allows providers to offer more comprehensive services by stretching scarce resources as far as possible to give patients access to the healthcare services they need.

The 340B program requires participating entities to meet various program integrity requirements as outlined in the enclosed fact sheet. Legislation enacted in Minnesota in 2023 added to this list a requirement to provide the state with data specific to this program. In compliance with this law and the final Form and Manner for 340B Covered Entity Report that was published on March 1, covered entities worked hard to gather data to meet the current April 1, 2024 deadline.

This bill would add a requirement to report data on clinician administered drugs. Pulling this data is a new, complex and, in some cases, insurmountable process that will require a significant amount of time and resources. Much of the complexity is due to reimbursement processes. When providers submit claims for patient care that include administered drugs these claims are bundled with other services. Unlike for dispensed drugs, claims that include administered drugs do not reference a line item for that drug. Payers then reimburse in a large lump sum that often includes multiple forms of treatment for multiple patients. This is why determining what specifically was reimbursed for an administered drug is a manual process that requires significant staff and external vendor time. For some coalition members, including some critical access hospitals, the challenges related to pulling this data cannot be overcome and it simply cannot be done.

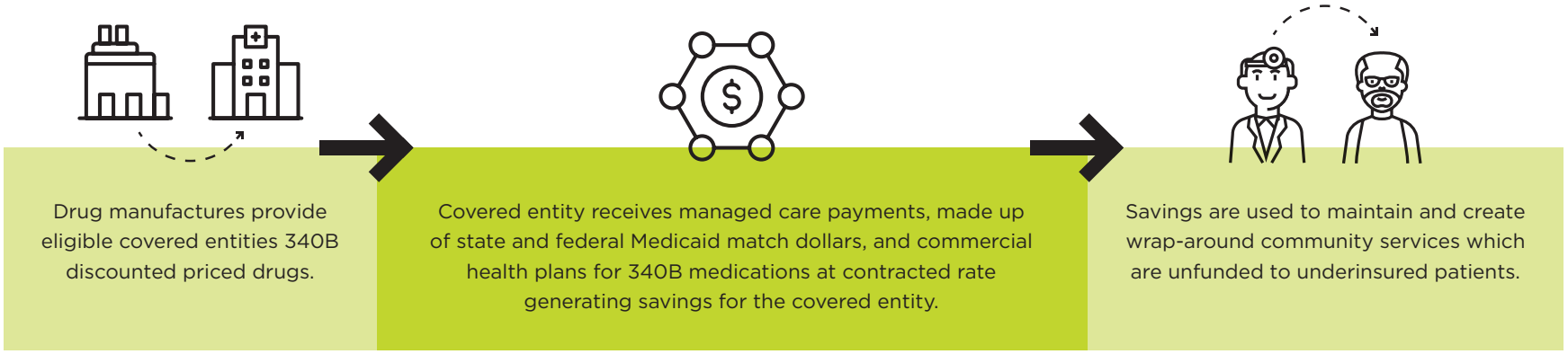
As a coalition, we welcome the opportunity to be as transparent about the 340B program as possible and invite the same transparency with state data related to this program. We appreciate the bill's intent is that this new data would be required as of the 2025 report. **We ask that, if this legislation passes, MDH engage with covered entities early and often to develop specifications that recognize the complexity of this data and the manual processes required to provide it.** This will help create a shared understanding of the data while reducing as much burden to covered entities as possible.

Sincerely,

Coalition partners referenced in the enclosed document
Enclosure: Minnesota 340B Coalition Fact Sheet

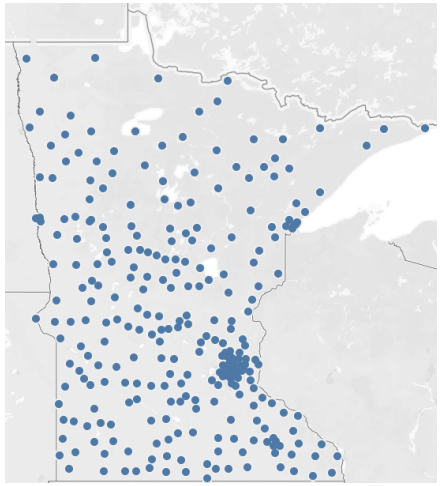
340B DRUG PRICING PROGRAM PROTECTS ACCESS TO CARE IN MINNESOTA

In 1992, in response to rapidly rising drug costs, Congress enacted the 340B Drug Pricing Program which provides a way for safety-net providers to purchase discounted drugs from participating pharmaceutical companies. To qualify to participate in 340B, covered entities like community health centers, sexually transmitted infection clinics and hospitals must serve a disproportionate share of low-income patients or patients living in isolated rural communities. The 340B program does not rely on taxpayer dollars and allows providers to offer more comprehensive services by stretching scarce resources as far as possible to give patients access to the healthcare services they need.



Regulatory Requirements

The 340B program requires participating entities to meet a variety of program integrity requirements. This includes annual eligibility recertification, successful completion of audits conducted by the Health Resources and Services Administration (HRSA) and drug manufacturers and maintaining auditable records and inventories of all 340B and non-340B prescription drugs. In Minnesota, there are also new reporting requirements that will begin in 2024.



340B covered entities in Minnesota

Community Impact

In Minnesota, the 340B program supports children and families in every corner of the state, supporting those navigating complex mental health, social and financial challenges on top of difficult chronic health conditions like a child's cancer diagnosis, a parent's hemophilia disorder or a diagnosis of HIV/AIDS. Because of 340B, providers are able to reduce their drug spending and invest instead in wrap around services that receive little to no reimbursement, reduce health disparities, address social determinants of health, and are essential to meeting the health care needs of underserved patients in our state.

FREQUENTLY ASKED QUESTIONS ABOUT 340B

How does an entity qualify to participate in the 340B program?
To participate, a provider must serve a disproportionate share of low-income patients or patients living in rural communities. Section 340B(a)(4) of the Public Health Service Act specifies which entities are eligible to participate in the 340B Drug Program. These "covered entities" include qualifying hospitals, Federal grantees from Health Resources and Services Administration (HRSA), the Centers for Disease Control and Prevention (CDC), the Department of Health and Human Services' Office of Population Affairs, and the Indian Health Service.

How does 340B support patients?
Every covered entity cares for a unique patient population with a distinct set of needs. This is the primary reason Congress directed covered entities to receive the 340B benefit allowing them to use the program to address their communities' unique needs by increasing access to free or heavily discounted prescription drugs in addition to tailored programs and services like trauma care, care for HIV/AIDS, and treatment for opioid and other substance use disorders.

Are pharmaceutical companies required to participate in 340B?
Pharmaceutical companies choose to participate in the program. By participating in 340B, drug manufacturers are able to participate in Medicaid, which gives them greater access to a larger purchaser base in exchange for offering discounted prices.

Why is it referred to as 340B "savings" and not revenue?
Covered entities generate savings by purchasing eligible outpatient drugs at a discounted price. By spending less on drugs, these savings allow the flexibility of investing in efforts to improve access to care, like reducing the price of outpatient pharmaceuticals for patients and expanding health services to the patients and communities they serve, and continuing to provide services that get little to no reimbursement.

Do covered entities mark up the price of 340B drugs when billing a third-party payer?
No, covered entities do not mark up the cost of drugs. Whenever a drug is billed, it is billed at one usual and customary rate charged for a product regardless of payer and acquisition cost. The rate does not change based on 340B program participation.

Does the state or the federal government pay for the savings?
While the program was an act of Congress, it does not have Congressional or state funding attached to it. The savings are funded by drug company discounts, not separate government spending. All payers, except for Medicaid which reimburses the acquisition cost, reimburse at the same amount whether the drug was purchased with a 340B discount or not.

What impact would the proposed moving of Minnesota's Medicaid pharmacy benefit from managed care to a fee for service model have on 340B covered entities?
Moving Minnesota's Medicaid pharmacy benefit from managed care to fee for service would result in a significant loss for 340B covered entities, impacting their ability to invest savings in the services their communities rely on. Today, for example, $100 of savings in the system are entirely used by providers to deliver services to underserved populations. These savings are about 50-90% federally funded via matching Medicaid dollars. If pharmacy benefits were administered fully by the state, only $10-$50 of that $100 in savings would remain in the system because the state loses the federal share of the rebate they receive. These rebates would be applied to the state's bottom line, and clinical programs and services funded through current 340B savings would be severely at risk.

Does the 340B program contribute to drug shortages?
In the over 30-year history of the program, no evidence links 340B to drug shortages. The majority of drugs on shortage are not purchased under 340B.

Allina Health · Avera · CentraCare · Children's Minnesota The Kid Experts · Fairview · Hennepin Healthcare · HealthPartners · Minnesota Hospital Association · Rainbow Health

Ramsey County · rha reproductive health alliance of minnesota · the Aliveness project · Astera Health · Center Clinic · Minneapolis City of Lakes · Essentia Health · gillette Children's · North Memorial Health