In Opposition to North Dakota HB 1473
340B Mandate

HB 1473 would prohibit biopharmaceutical manufacturers from interfering with the acquisition of a 340B drug by a contract pharmacy on behalf of a covered entity. This type of provision not only raises constitutional concerns but exacerbates existing problems with the 340B program without ensuring that vulnerable patients needing discounted medicines will benefit.

Created in 1992 to help low-income and uninsured patients obtain prescription drugs at discount prices, this little-known, and poorly designed, program has expanded unchecked and strayed far from its purpose.

Today, despite its purpose, hospitals are using the program as a cash cow, racking up profits without passing the savings on to patients, as Congress intended.

And while on paper it has no taxpayer cost, 340B has quietly grown into the second-largest federal prescription drug program, surpassing Medicare Part B and Medicaid in volume.

To understand the program, it helps to understand its history — a history both fascinating and disheartening.

In 1990, Congress enacted the Medicaid Best Price Rule, the goal of which was to save taxpayer money on prescription drugs that are purchased for low-income Americans through state-run Medicaid programs. The rule requires drug manufacturers who want to sell their products to Medicaid to do so at their "best price," meaning the lowest price they sell to anyone.

But the law had a flaw. It included in the definition of "best price" gifts of free and charitably discounted drugs. Traditionally, drug companies make their products available at low or no cost to patients who simply cannot afford them. By treating these acts of charity as sales, the rule caused drug manufacturers to lose money on Medicaid. The companies faced a dilemma: either stop selling to Medicaid altogether or stop providing free and discounted drugs to low income and uninsured patients. They chose the latter.

How did Congress respond? Instead of amending "best price," Congress established the Section 340B Discount Drug Pricing Program, which entitles certain safety-net hospitals and health clinics ("covered entities") to buy drugs from manufacturers at a discount and then resell them

at a profit. (The average discount is around 55%.) This, the authors assumed, would enable safety-net providers to "stretch scarce federal resources" and provide medicines to the needy more affordably. But remarkably, the law did not require entities to pass the discounts on to patients. Instead, the entities can pocket the money.

Well, almost. They *are* supposed to use the money to benefit "qualified patients." But the statute does not define that term. Federal efforts to enforce the law, and curb abuses, have been hampered by this and other ambiguous provisions.

Thirty years on, evidence suggests most covered entities are *not* passing the discounts on to the intended beneficiaries. According to one comprehensive study, discounts reach as few as 1.4% of patients. The study concludes: "It's clear the majority of low income, uninsured, 340B-eligible patients at contract pharmacies are not directly benefiting from 340B discounts."

Meanwhile, some providers illicitly divert their 340B drugs, selling them to patients who do not qualify for the program.

The number of covered entities has boomed, rising from 2,140 in 2014 to 12,700 in 2020 — a 600% increase in six years. Non-safety net providers lobby to get themselves included in the program. Some sneak in through a side door, buying up local safety-net providers and capturing their 340B profits for themselves. This is fueling local hospital market consolidation, which means less competition, higher prices, and higher insurance premiums and out-of-pocket costs for everyone.

Today, 40% of hospitals in the U.S. are classified as a 340B "covered entity."

A 2022 Milliman analysis found the average cost of an outpatient medicine administered at a 340B hospital is more than 150% higher than the average cost of an outpatient drug administered at a non-340B hospital.

- 340B hospitals provide less charity care than the average of all hospitals.
- 340B hospitals tend to be larger entities, located in more affluent areas.

Driving Up Prices

The estimated dollar value of total 340B drug sales has grown from $7 billion in 2012 to $54 billion in 2022. (It jumped 23% in 2021 alone.) Tellingly, from 2018 to 2023, while non-340B sales grew by 41.4%, 340B sales grew by 129.4%, more than three times as fast.

340B sales now represent more than 7% of all drug sales in the United States. And there's evidence the program's explosive growth is driving up Medicare Part B premiums, which, if you think about it, means seniors are subsidizing hospital corporations.

How to Fix It

Clearly, the wayward 340B program cries out for oversight.

Three important principles:

1. Fund patients, not systems.
2. Protect taxpayers.
3. Reduce prices through competition and choice, not mandates and price controls.

The simplest remedy would be to exempt drugmakers' gifts of free and discounted products from the definition of "best price" — in other words, reverse the error that started it all.

1. **Focus on the Vulnerable**. Define "340B patient" in statute to prevent abuse and ensure discounted drugs actually go to low-income and uninsured patients.
2. **Tighten Eligibility**. Narrow the definition of "covered entity" to true safety-net hospitals only.
3. **Maximize Transparency**. Require hospitals to report exactly how they use their 340B profits.

Ultimately, we need to reform *health care* to be more affordable and accessible. Let's remove barriers and empower consumers to unleash the world-class innovation — and generous safety nets for the vulnerable — that only free markets can deliver.

In conclusion,

This legislation does not address patient access or help patients better afford their medicines. The 340B program is a comprehensive federal program that is governed exclusively by federal law. State governments do not have authority to place these requirements on how manufacturers engage in the 340B program, let alone create new requirements that are not in the federal statute to begin with or that conflict with requirements in the statute.