Testimony in Support of HB 276

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Chair Lampton, Vice Chair Craig, Ranking Member Hall, and members of the Insurance Committee,

Thank you for allowing me to testify today in support of HB 276. The bill is incredibly important to the sustainability and survival of Ohio's safety-net health care providers, including community health centers, HIV/AIDS and STD clinics, and hemophilia treatment centers. These providers rely heavily on being able to acquire significantly discounted drugs that they have a right to purchase under the federal 340B drug discount program. Federal law, however, is silent regarding delivery of those drugs. Drug manufacturers have exploited that silence and refused to ship the discounted drugs to the pharmacies that Ohio safety-net providers rely on to dispense the drugs to their patients in their communities.

I am an attorney at the law firm Powers, Pyles, Sutter & Verville PC. I have focused solely on the 340B drug discount program for the past 13 years and have worked closely with the Ohio Association of Community Health Centers and numerous community health centers and Ryan White HIV/AIDS Program participants during that time. I have also worked with similar providers and associations across the country to support legislation like HB 276, leading to 20 states passing 340B drug delivery protection bills just since 2021.

Community health centers and other safety net grantees are facing a wave of financial difficulties. They rely on federal grant funding, but that funding will not increase and is often insufficient to cover the cost of caring for uninsured and underinsured Ohioans that often have complex health care and social needs that cannot be met by the traditional health care system. Cuts to Medicaid coupled with the potential expiration of the Premium Tax Credits for the Health Insurance Marketplace will further pressure these providers, which often are the only source of accessible primary care in rural areas.

The 340B drug pricing program is a federal program established in 1992 through bipartisan legislation signed into law by President George H.W. Bush. The law enables certain types of safety-net providers that receive federal support – called "covered entities" – to purchase outpatient drugs at significantly discounted prices from drug manufacturers. The manufacturers <u>choose</u> to participate in the 340B program if they want their drugs covered by Medicaid and Medicare. Essentially, the manufacturers gain access to one of the best markets in the world but they have to agree to support the American health care safety net in exchange for that privilege.

The program benefits covered entities in two ways. First, they can acquire outpatient drugs at substantially reduced prices, which limits the burden they shoulder when dispensing or administering those drugs to uninsured patients or patients with high co-pays or deductibles. Under an Executive Order issued by President Trump this year, community health centers for example are required to provide injectable epinephrine and insulin to uninsured patients and those with high co-pays or unmet deductibles. Covered entities, however, leverage 340B discounts to lower out-of-pocket costs for uninsured and underinsured patients every day. The discounted drugs also offset losses when the reimbursement paid is insufficient to cover the cost of care, including drugs used during in-clinic procedures.

The program also benefits covered entities when they dispense the discounted drugs to insured patients. Covered entities are able to bill patients' insurance for 340B drugs, resulting in better margins than if they had to purchase the drugs at full price. Congress intended for the 340B program to work in this way, "stretching scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1] These additional resources allow covered entities to do things for patients they would not be able to do without the additional financial support. Ohio has already passed legislation that requires payers to reimburse covered entities fairly for 340B drugs.

The federal Health Resources and Services Administration (HRSA) allows covered entities to contract with a third party pharmacy to dispense their discounted drugs to their patients. Covered entities contract with a range of pharmacies, including independent pharmacies, chain pharmacies, specialty pharmacies, and mail order pharmacies. Covered entities will contract with pharmacies that their patients choose to use or in many cases must use due to insurance restrictions. The vast majority of these pharmacies are located in Ohio, but payer restrictions or drug manufacturer limited distribution networks sometimes require them to use out-of-state pharmacies as well to serve their in-state patients.

All covered entities are subject to two primary restrictions. First, they can only provide the discounted drugs to their patients. Second, they cannot bill fee-for-service Medicaid for reimbursement for the drugs if the state will seek a Medicaid rebate on the drug. HRSA audits covered entities to ensure that they comply with these requirements. Manufacturers also may audit covered entities if they suspect one of the requirements is being violated. In addition, grantee covered entities fully report to the federal government on all of their income and expenditures, and Ohio Revised Code Section 3701.88 requires them to report on other metrics relating to how they use 340B program savings to benefit patient care.

[1] H.R. Rep. 102-384, Pt. 2, at 12 (1992).

In 2020, in the heart of the COVID epidemic, drug manufacturers began to refuse to ship 340B drugs purchased by covered entities to their contracted pharmacy partners despite doing so for the preceding 24 years. The 340B statute addresses purchasing and pricing, not delivery, and the manufacturers decided they could impose onerous conditions on shipments. What begin with one manufacturer imposing restrictions has evolved into 40 manufacturers imposing restrictions on the delivery of 340B drugs to covered entities, with approximately 20 of those policies impairing the ability of grantee covered entities to ship 340B drugs to their pharmacy partners.

Those restrictions have devastating financial impacts on already struggling grantees. Many of the restrictions limit the covered entities to a single contract pharmacy and impose burdensome and constantly changing reporting rules to allow them even that limited access. As a result, covered entities are unable to extend the 340B discount to their patients at most of their contract pharmacy partners, and are unable to obtain the enhanced reimbursement margins that Congress intended when insured patients use contracted pharmacies.

HB 276 prohibits those limitations and requires drug manufacturers to ship 340B drugs to covered entities' contracted pharmacies as they did for more than two decades. The law returns Ohio safety-net providers to the status quo. Most importantly, it keeps dollars for patient care in the State of Ohio instead of further padding the bottom lines of highly profitable drugmakers.

Twenty states have already recognized the importance of these protections. Those states are diverse, rural and urban, red and blue, but they all want to protect their health care safety net and ensure that vulnerable patients have a place to go when they cannot access the more traditional health care system.

Please join those states and support HB 276. Without it, safety net providers will have to reduce or eliminate services. Some will be forced to close their doors, especially in light of other mounting financial pressures.

Thank you again for this opportunity to discuss the importance of the 340B program to Ohio safety net providers, and the important role the Legislature can play in ensuring that they can regain the right to receive those discounted drugs through their pharmacy partners.