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Chair Huffman, Vice Chair Johnson, Ranking Member Liston, and members of the Health Committee, thank you for allowing me to testify today on SB 198. 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 on legislation like SB 198, leading to 20 states passing 340B drug delivery protection bills just since 2021.

SB 198 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, in many cases, 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.

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 choose 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 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.

Grantees, such as Community Health Centers, that participate in the 340B program are subject to many other restrictions and requirements as well. For example, each health center award document contains provisions that ensure that health center funds are not spent on activities that conflict with federal priorities. Grantees may only provide 340B drugs to patients who have received a health care service consistent with the scope of their grant award. Health centers must be fully transparent with respect to their revenues and expenditures, completing extremely detailed "Uniform Data System" reports that are available to the general public and submitting annual financial reports to the federal government.

[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 – or no contract pharmacies if the grantee has even one in-house 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. Patients also are limited in their ability to use the pharmacy of their choice, since 340B discounts might only be available at certain pharmacies.

SB 198 prohibits those limitations on grantees, such as community health centers, and requires drug manufacturers to ship 340B drugs to covered entities' contracted pharmacies as they did for more than two decades. It is important to note, the bill is limited to grantees, such as Community Health Centers and returns the law for 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-one 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.

The primary objections to SB 198 and the bills that came before it in other states are also misguided. Manufacturers complain that they lack transparency into how 340B drugs are used when dispensed by contracted pharmacies. First, manufacturers argue that they are subjected to duplicate discounts when they pay a rebate on a drug purchased at 340B pricing. Covered entities support the establishment of a claims clearinghouse to ensure that manufacturers are not subjected to Medicaid rebates on 340B claims. Manufacturers are not entitled to protection for other types of privately negotiated rebates – like those that manufacturers pay to pharmacy benefit managers (PBMs) and insurers in exchange for preferential formulary placement or hitting market share targets. Those rebates have been roundly criticized for increasing patient costs by resulting in higher drug list prices.[2] The federal Department of Health and Human Services has finalized a rule to criminalize them by revoking a safe harbor under the federal antikickback statute, but enforcement is currently delayed to 2032.[3]

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[2] See, for example, House Committee on Oversight and Reform Minority Staff, A View from Congress: Role of Pharmacy Benefit Managers in Pharmaceutical Markets (Dec. 10, 2021), at https://oversight.house.gov/wp-content/uploads/2021/12/PBM-Report-12102021.pdf. Rep. Comer has conducted additional hearings exploring the role of rebates in increased drug costs.

[3] *See* Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and

Second, manufacturers claim that they should have full transparency into how every 340B drug is used. Drug manufacturers already have the authority to audit covered entities under the federal 340B statute.[4] HRSA requires covered entities to respond to any good faith inquiry that a drug manufacturer sends to a covered entity. HRSA itself audits approximately 200 covered entities a year and posts the results of those audits on its website. The manufacturer audit tool is designed to provide a form of self-help to manufacturers that are concerned about how a particular covered entity is using the 340B program. Congress did not intend for the over 800 manufacturers participating in the 340B program to receive claims-level data from every covered entity and constantly pepper health centers and other safety net providers with a deluge of inquiries. The federal government is still the primary enforcement authority for the 340B program.

Please join the 21 states that have chosen to protect their health centers and support SB 198. 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. Health centers already have had to pare back services, and some have closed locations, due to these restrictions.

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.

Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees, 85 Fed. Reg. 76666 (Nov. 30, 2020).

[4] 42 U.S.C. § 256b(a)(5)(C).