OCHIN

A driving force for health equity

Transmitted via electronic mail

April 1, 2024

Honorable John Thune
511 Dirksen Senate Office Building
Washington, DC 20510

Honorable Debbie Stabenow
731 Hart Senate Office Building
Washington, DC 20510

Honorable Shelley Moore Capito
172 Russell Senate Office Building
Washington, DC 20510

Honorable Tammy Baldwin
709 Hart Senate Office Building
Washington, DC 20510

Honorable Jerry Moran
521 Dirksen Senate Office Building
Washington, DC 20510

Honorable Benjamin L. Cardin
509 Hart Senate Office Building
Washington, DC 20510

Re: Bipartisan 340B Senate Working Group SUSTAIN 340B Act Discussion Draft and Supplemental Request for Information (RFI)

Dear Senators Thune, Stabenow, Capito, Baldwin, Moran, and Cardin,

On behalf of OCHIN, I appreciate the opportunity to provide comments on the *Discussion Draft of the Supporting Underserved and Strengthening Transparency, Accountability, and Integrity Now and for the Future of 340B Act or the "SUSTAIN 340B Act"* and accompanying *Request for Information on the 340B Drug Discount Program*. OCHIN is a national nonprofit health information technology and research network that serves nearly 2,000 community health as well as Critical Access Hospital (CAHs) sites with 32,000 providers in 43 states, reaching more than 5.9 million patients in rural and other underserved communities. We support legislation that will protect patients' access to affordable medication and health care services through the 340B affordable prescription drug program (340B program) in underserved and rural communities. Despite record profits both pharmaceutical companies and pharmaceutical benefit managers continue to whittle away the essential 340B savings needed to maintain access to life-saving medication and keep the doors open of many community provider and critical access hospitals. We applaud your efforts to clarify and strengthen two critical components of the 340B affordable prescription drug program concerning contract pharmacies and the patient definition.

Since its inception over 22 years ago, the OCHIN collaborative of community providers has focused on expanding access in underserved and rural communities to quality health care services through technology solutions, technical assistance, operational support, informatics, evidence-based research, workforce development and training, and policy. Today, the OCHIN network includes federally qualified health centers (FQHC) (the largest network of them in the

nation), FQHC look-alikes, CAHs, rural health clinics, tribal health organizations, and other community health providers and local public health agencies. The 340B affordable prescription drug program plays a vital role for many of our members' ability to ensure their patients can access medically necessary treatments, but also provides these providers a financial lifeline. The urgency of legislative action continues to mount as patients in rural communities face worsening health outcomes and their community providers including CAHs face extreme financial crisis further undermining patient access to health care and affordable treatment. Similarly, community-based clinics, including FQHCs, look alikes, and other providers serving patient populations facing significant structural barriers, are at the confluence of increasing needs due to long COVID health effects, the opioid use disorder public health emergency and deepening mental health crisis. Our members are on the frontlines of these challenges just as pharmaceutical companies and insurers further reduce resources needed to maintain and expand access to care at a time both industries have experienced record financial windfalls during COVID-19 that persist.

OCHIN - RURAL AND COMMUNITY HEALTH PROVIDERS

Left unchecked, the actions by pharmaceutical companies and pharmaceutical benefit managers to reduce 340B savings for patients and their providers among community health clinics, CAHs, and other rural providers will further de-stabilize the safety net of front-line providers. OCHIN examined available accounting data for 26 OCHIN network community health clinic members and found that most of them depend on the 340B affordable prescription drug program to provide access to essential medication for their patients *and to keep the doors open (stay financially solvent)*. These OCHIN members serve everyone, regardless of their ability to pay. Our members' patients are some of the most medically and socially complex individuals in the country and without the 340B affordable prescription drug program, many members would not be able to cover their costs of providing patient care. Further, we found the scale of potential revenue shortfall without the 340B affordable prescription drug program to be considerable, accounting for three times the margin of revenue over expenses on average needed to keep doors open and provide affordable medication. In the OCHIN network, the 340B affordable prescription drug program is used more by providers in rural communities. Given the health care crisis in Rural America, attacks on the 340B program by pharmaceutical and health insurance companies create disparate negative impact on the patients and providers in rural areas and CAHs are already feeling the strain of this program.

KEY RECOMMENDATIONS AND COMMENTS

We have offered recommendations below that are responsive to several of the requests for information related to the efficiency of the program, transparency, program integrity, and provisions that ensure the benefit of the program accrues to the congressionally intended recipients.

- Contract Pharmacies are Essential for Patients of Community Health Clinics, CAHs, and other Rural Providers Which Rely on Such Arrangements to Support Patient Access. Many

community health clinics, CAHs and other rural providers do not have the economies of scale, infrastructure, or resources to support an in-house pharmacy. Further, they are not able to rely on one contract pharmacy alone to meet all their patient's needs due to distance, specialty medication needs, or federal requirements to secure appropriate reimbursement which entails contracting with multiple pharmacies, for example. Over 40% of health centers do not have the financial means to open and maintain an in-house pharmacy and nearly 90% of health centers use contract pharmacies to expand the reach of their 340B program and meet their communities' needs. Patients in rural and underserved communities would face insurmountable barriers to accessing a single contract pharmacy in a geographically delineated service area due to transportation and geographic mismatches *and varied insurer specialty medication coverage policies*. The contract pharmacy limitations advanced by pharmaceutical companies on the number and location are unambiguously intended to reduce the savings meant for qualifying patients and their providers for specialty medication as more than half of the savings for federally qualified health centers is derived from these prescriptions. CAHs also rely more on contract pharmacies than their urban counterparts. Further, FQHCs are required by law to accept all forms of public and private insurance. Currently, almost all insurers require their beneficiaries to use specific pharmacies for specialty and mail-order drugs (and these pharmacies are almost never located within the FQHC's service area). While insurers generally have a single mail order site for regular drugs, most have multiple separate pharmacies for specialty drugs. In the OCHIN network, our members' patients are among the most socially and clinically complex, particularly among our rural and frontier providers. OCHIN also strongly supports ensuring that community health clinics, CAHs, and other rural providers have the option of utilizing mail order pharmacies, in particular. Limitations on contracted pharmacies fall heaviest on them and will further exacerbate structural barriers to care. In addition, efforts to limit contract pharmacies by pharmaceutical companies are not supported by the 340B program's authorizing statute. Section 330 of the statute provides that health centers are entities that provide staff and supporting resources including "through contracts or cooperative arrangements." The statutory language clearly contemplates multiple contracts.

- Clarifying the "Patient Definition" to Ensure that 340B Prescription Drug Discount Program Benefits the Intended Patients and Covers Qualifying Prescription. OCHIN strongly supports stakeholder efforts to clarify the existing statutory definition of "patient." We support Congress establishing a "patient test" followed by a "prescription test." The patient test must ensure that the individual has had an encounter with a provider within the past 24 months who is employed or under contract with the covered entity (which should include locum tenens). It is essential, particularly for patients in rural communities and those facing housing and transportation insecurity, that the encounter may occur via telehealth including via audio-only (which is more common in rural and underserved communities). In the OCHIN network, we conducted a regional analysis and found that patients facing housing and transportation insecurity were significantly more likely to use telehealth generally and audio-only in particular. In addition to the foregoing, OCHIN strongly supports a specific carve out for FQHCs, CAHs as well as other providers that permits them to qualify prescriptions written for their qualifying patients with 340B covered medication written by a prescriber that does

not meet the above criteria. If FQHCs are not authorized to apply the 340B discounts to fill prescriptions written by non-FQHC providers (often specialists who are not employed or contracted by FQHCs but have been referred patients by the FQHCs), the FQHC will absorb the costs which is not part of the original congressional intent and will further destabilize the safety net. Further, CAHs and other rural providers are facing unprecedented financial sustainability challenges and all 340B savings should be optimized which means that this carve-out should extend to them and include prescriptions written by specialists of rural covered entities' patients. Lacking this carve out particularly harms FQHCs, CAHs, other rural providers, and their patients since other covered entities such as hospitals in urban areas are much larger and have specialists on staff and therefore would not be impacted by a policy that prohibits filling prescriptions from a specialist that is not employed or contracted by the covered entity.

- Prohibit Pickpocketing Practices by Pharmaceutical Benefit Managers (PBM) and Other Third Parties (including State Medicaid Programs) that Divert Savings Intended for Patients and their Providers in Rural and Underserved Communities. We strongly support the inclusion of the PROTECT 340B Act into the SUSTAIN 340B Act. In addition, we support policies that ensure PBM-owned pharmacies and other for-profit third parties limit fees and other 340B-related administrative costs that divert savings from the intended patients and covered entities. We specifically call out that PBMs should be prohibited from imposing specified discriminatory contract terms (e.g., fees or chargebacks) due to a covered entity's or pharmacy's participation in 340B. PBMs should not be permitted to prevent community clinics, CAHs and other rural providers and their contract pharmacies from providing 340B claims data to third parties or from reducing copays for low-income insured patients who receive 340B drugs. We also ask that you clarify that federal law does not preempt action by states that have passed legislation that afford covered entities and their patients a higher level of protection than federal law. This remains an important safety valve for the least resourced providers in underserved and rural communities and is a mechanism needed to generate momentum to drive reform when needed. Finally, a growing number of states are limiting community health clinics, CAHs, and rural providers' ability to generate 340B savings in Medicaid Managed Care. States have the authority to determine 340B reimbursement for Medicaid, but state policies increasingly are negatively impacting safety-net providers' ability to maintain access to affordable medications and health care services.

- Increase Accuracy and Efficiency While Maintaining Rigorous Oversight of the 340B Prescription Drug Program. OCHIN supports requiring covered entities to work with pharmaceutical manufacturers to identify the source of any duplicate discounts on Medicaid drugs. We also support that covered entities should be required to repay manufacturers for these duplicate discounts if they are responsible for them. The current language, however, in the draft bill creates ambiguity and could be read to compel a covered entity to repay manufacturers for duplicate discounts even if the covered entity was not at fault. Finally, we strongly support leveraging technology to improve oversight and review of documentation submitted by covered entities. Currently, HRSA is required to review all contracts and voluminous documentation for each covered entity. This diverts vital agency resources away

from other aspects of the program that require oversight. We urge Congress to permit statistical sampling methods that are widely accepted in other federal programs and throughout most industries.

Thank you for your leadership and inclusive approach to gathering stakeholder feedback on the 340B program. Please contact me at stollj@ochin.org if we can provide any additional information or be of further assistance.

Sincerely,

Jennifer Stoll
Chief External Affairs Officer
OCHIN