ADVOCATES FOR COMMUNITY HEALTH

April 1, 2024

The Honorable John Thune
511 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Debbie Stabenow
731 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Shelley Moore Capito
172 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Tammy Baldwin
702 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Jerry Moran
521 Dirksen Senate Office Building
Washington, D.C. 20510

The Benjamin L. Cardin
509 Hart Senate Office Building
Washington, D.C. 20510

RE: Bipartisan 340B Senate Working Group Draft, SUSTAIN 340B Act

Submitted electronically *Bipartisan340BRFI@email.senate.gov*

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

Thank you for your work on the Supporting Underserved and Strengthening Transparency, Accountability, and Integrity Now and for the Future of 340B Act (SUSTAIN Act), and the collaborative process you are undertaking to finalize it. Advocates for Community Health (ACH) is a national membership organization comprised of leading federally qualified community health centers (CHCs) focused on health equity and innovation to drive health care systems, policies, and health programs. Our members provide high-quality, comprehensive primary health care, mental health services, preventive care, and social services to over two million people living in under-resourced communities. **The 340B program enables us to meet our mission every day, and without it, the nation's strongest primary care network would falter.**

To achieve long term stability for CHCs and other covered entities, we agree with the Working Group that the 340B program needs clarity, transparency, and accountability. As we will discuss in our response, in 2022, ACH released a legislative proposal to offer covered entities the ability to "opt in" to a higher level of transparency and accountability in exchange for certain codified protections. **We are pleased to see elements of our proposal included in the SUSTAIN Act, and strongly support the comprehensive reform effort you are leading.** We offer the following comments in the hopes that it helps your working group move toward introduction, consideration and final passage this year.

Section 2: Sense of Congress

We are grateful for the inclusion of this Sense of Congress, as there has been significant debate in the field over Congressional intent. We support Section 2 and urge inclusion in the final draft. As required by Section 330 of the Public Health Service Act, CHCs are committed to serving all individuals regardless of their insurance status or availability to pay. As opposed to other covered entity types, CHCs have no other funding streams to support our mission to serve everyone in our communities. Other covered entities are able to supplement their work through facility fees, support from 1115 waiver dollars, or other mechanisms to recoup lost revenue. **340B remains one of precious few sources of support for the care we provide – and it doesn't use a dime of taxpayer dollars to do it.**

The 340B program helps CHCs serve as health care lifelines for millions of Americans. By allowing the purchase of drugs at a discounted price, the 340B program enables CHCs to serve a patient population with disproportionately complex health and social needs.[1] As required by law and regulation, and as core to our mission, CHCs reinvest every dollar of program income back into patient care and support. We are proud to re-invest 340B savings into initiatives like medication adherence programs, outreach workers for hard-to-reach populations, enrollment assisters and navigators to ensure insurance access, and population health projects that improve individual and community health. Health center participation in the 340B program exemplifies the intent that the SUSTAIN Act would codify – to maximize federal investment and expand care to underserved communities as effectively as possible.

Section 3: Contract Pharmacy

Under current federal guidance, 340B covered entities are permitted to dispense 340B drugs to patients through contracting with external pharmacies. These arrangements are particularly helpful in rural communities, where health centers may be farther apart, and access to a local pharmacy is a better way to facilitate patient access to care. It is also essential for health centers that do not have an in-house pharmacy, which are expensive to establish and resource-intensive to maintain.

Unfortunately, this networked, access-oriented approach – that has worked well for CHCs and their patients for over a decade – is under threat. Drug manufacturers are unlawfully limiting access to contract pharmacy services through burdensome restrictions, which prohibit access to care for vulnerable populations. The contract pharmacy arrangements that do remain are often set up to overcompensate pharmacies, and do not allow for maximum accrual of savings to the benefit of patient care. We support the protections offered in the draft SUSTAIN Act that address some of these issues occurring in the market.

[1] https://www.nachc.org/wp-content/uploads/2023/07/Community-Health-Center-Chartbook-2023-2021UDS.pdf

RFI Questions

Health centers rely on contract pharmacies to ensure access to low-cost medications to all patients, no matter where they live and regardless of insurance status. We strongly oppose any restrictions or limitations on contract pharmacy arrangements.

Specialty Pharmacy Access

We also strongly oppose any restrictions to access to specialty pharmacy either through contract arrangement, or specialty drugs through on-site dispensing. Patients who rely on medications that are only available through specialty pharmacies face unique access challenges. These are often not located near a covered entity, and medications must be dispensed to patients from pharmacies in alternative locations or through mail order. Restrictions on contract pharmacies without special protections for specialty pharmacies would endanger access to specialty medicines with the support of a clinical pharmacist. While we believe that SUSTAIN meant to include specialty pharmacy in its protections for contract pharmacy arrangements, we want to clarify this point.

To deliver the highest quality patient care, it is critical that CHC pharmacists are able to deliver specialty medications to patients in order to ensure effective patient education, timely monitoring through lab work, quick resolution of issues related to insurance/prior authorization, and continuous patient care. CHC handling of the specialty pharmacy also avoids medication delivery mishaps and can ensure cultural and linguistic competence which is so critical with a complex medication regimen.

The final draft of SUSTAIN should ensure that:

a) **Manufacturers are prohibited from placing any restrictions on access to specialty pharmacies for CHCs and their patients; and**
b) **For covered entities with clinical pharmacy support, CHCs should be able to purchase and dispense the specialty medication with no geographic restriction.**

Section 3, sections (a)(11)(A)

We strongly support the protections included in the draft bill to prohibit restrictions on contract pharmacies, and support the requirements that protect patients seeking 340B drugs at a contract pharmacy.

Section 3, Sections (a)(11)(B)-(D)

We also strongly support transparency efforts to ensure that the Department of Health and Human Services (HHS) has a line of sight into these arrangements. We support attestation of

compliance for CHCs to these requirements, as well as the requirement that contract pharmacies and covered entities undergo regular audits.

We suggest the following revisions to ensure that, in the implementation of this law, there are no gaps in access to care for patients currently receiving their medicines at a contract pharmacy:

> (ii) register each contract pharmacy arrangement with the Secretary, in relation to both the parent and child or associated sites, as applicable, ~~prior to~~ within six months of implementing the contract pharmacy arrangement, with allowances provided for arrangements already in place at the time of enactment of this subsection.

Section 3(a)(11)(D)(ii)

In order to protect health centers' ability to retain and use 340B savings in line with the intent outlined in Section 2, we recommend Congress give HHS the authority to cap the percentage of 340B savings that contract pharmacies can receive, in order to ensure that benefits accrue to covered entities for the benefit of patients. Suggested redline in Section 3(a)(11)(D)(ii), add:

> (XI) in the case of a federally qualified health center, a cap on the percentage of 340B savings shared with the contract pharmacy.

Section 3(a)(11)(D)(v)

We suggest a record retention period of three years, rather than 10, to align with the standard auditing protocol of the Health Resources and Services Administration (HRSA).

Section 3(a)(11)(D)

We recommend HHS issue template agreements that outline these requirements and other limitations on contract restrictions that negatively impact CHCs and our patients. Such templates will help bolster the leverage of small and under-resourced CHCs negotiating with large chain pharmacies. Suggested addition in Section 3(a)(11)(D):

> (vi) Provide template contract agreements for the use of covered entities and contract pharmacies that meet the requirements of this subsection.

Section 4: Patient Definition

The 340B statute does not include a definition of patient. In 1996, HRSA proposed a patient definition and then proposed a revised definition in 2015 which they then withdrew. Since the program has evolved since the original statute was written, how should these changes be reflected in how a patient is defined?

Since 1996, health centers have been abiding by the guidance given by the Health Resources and Services Administration (HRSA), which requires (1) an established relationship with the patient, including maintenance of records; (2) ongoing responsibility for care of the patient, no matter where the prescribing health care provider works; and (3) that the patient receives health care services consistent with the scope of the grant that qualifies the entity for the 340B program. We still support the spirit and intent of this guidance which has governed the program for almost 30 years, especially the way in which health centers take responsibility for a patient's care. However, we acknowledge that some of the vagaries in the definition cause confusion and uncertainty in the marketplace. We also acknowledge that since 1996, health centers have become the largest network of primary care providers in the country, and a central source of care in an increasingly siloed health care marketplace. Unnecessary restrictions on who is a "patient" of a health center fail to recognize the role that health centers play in the care of their patients, and underestimate the administrative burden placed on under-resourced providers. Similarly, defining a patient by each of his or her prescriptions does not acknowledge the complexity of the health care system today, and the role that CHCs play in the management of patient care.

What factors should inform whether the covered entity has a meaningful relationship with a patient? Should the type of patient encounter or specific level of services provided be considered in determining whether a relationship exists between a covered entity and a patient? If so, how would these improve or provide additional program integrity?

Advocates for Community Health supports three factors to inform a meaningful relationship should be a) recency of service by the covered entity; b) type of service, and c) record maintenance. These factors ensure that the patients accessing drugs under the 340B program are patients of the health center as required under the law.

Yes, the type of patient encounter should be considered. The service provided should be consistent with the scope of the grant through which the entity is eligible for the 340B program.

Should the length of time a relationship exists between a covered entity and a patient be a factor in how a patient is defined? If so, what is an appropriate time frame? Should there be a time limit on how recently an individual must have qualified as a patient in order to continue to be eligible for 340B?

100% of ACH's member health centers are designated primary care medical homes, meaning that they have been found by accreditors to be accountable for meeting the large majority of each patient's physical and mental health care needs, including prevention and wellness, acute care, and chronic care. Health centers are responsible for coordinating and ensuring access to care consistently. However, health centers also care for patients in their communities who have difficulty maintaining consistent access to care, such as migrant farmworkers who change location seasonally, the unstably housed who drop out of care, and patients struggling with behavioral health issues. Therefore, we recommend a "look back" period of three years.

Should the patient definition include a requirement to determine when the patient is first identified as a patient? Should there be an ability to retroactively recoup payments?

Yes. Permitting a retrospective eligibility and recoupment process will permit CHCs to prioritize health care first without sacrificing potential savings for the entity.

When a patient is served by multiple covered entities, what elements should be considered when determining which covered entity claims a discount for a given patient?

This issue arises most frequently in the context of contract pharmacies, and we recommend assessing patient assignment based on the higher number of visits ("preponderance of visits") within the last three years at the primary care provider.

What tools should be provided to HRSA to ensure it can implement a patient definition that accommodates diversity in covered entity types while promoting consistency, clarity and integrity in the program?

ACH offers the following legislative language that allows the Secretary of Health and Human Services the opportunity to issue regulations to provide clarity in this space, but establishes a ceiling for any regulatory definition such that health centers can still run comprehensive, successful 340B programs. The definition outlined below is the most restrictive that ACH can support and still provide the patient-centered, comprehensive care that is our mission.

(D) DEFINITION OF PATIENT –

(i) The Secretary of Health and Human Services may issue regulations to define a patient as an individual under medical care and treatment for the purposes of this section if such regulation does not include provisions that are more limiting than--

(a) Patients are eligible if they have received a health care service, provided in person or via telehealth, as defined under 42 USC 1395m(m)(4)(F)(i), from a covered entity within the last three years;

(b) The service described in (a) is consistent with the scope of services supported by the federal grant that qualifies the entity for 340B; and

(c) The covered entity maintains records of the care provided to the patient directly by the covered entity.

(ii) In issuing regulations under this subsection, the Secretary may not consider the source of an individual's prescription as a consideration for their eligibility as a patient of the covered entity.

Section 5: Child Sites – N/A

Section 6: Transparency

ACH is an ardent supporter of increased transparency and accountability in the 340B program; we believe that the lack of transparent, reliable information around this program and its impact

on covered entities has contributed to its instability. For this reason, in 2022, ACH developed a proposal to ensure that participating entities can access the benefits of the program, while ensuring greater accountability and transparency. This proposal creates a new opt-in program for 340B covered entities called "340C." Entities can opt-in to 340C, through which they receive protections from the actions that are reducing their savings, and in return are required to reinvest all savings into the populations they serve, submit annual reports on such savings, and undergo regular compliance audits with meaningful sanctions. 340C is completely voluntary – anyone who participates in 340B may choose to participate in 340C. The proposal maintains key provisions of the original 340B program, including the prime vendor, certification processes, and a prohibition on resale of drugs.

If entities opt to participate in 340C, they are subject to detailed accountability and transparency standards, including the following:

- Any funds generated shall be reinvested into program operations, patient care, and other community benefits, as determined by the covered entity leadership and governing board, to the populations served.
- Entities shall submit annual reports attesting to these requirements.
- Participants are subject to risk-based audits of records that establish their compliance.

In return for agreeing to these standards, entities will have access to:

- Reimbursement at wholesale acquisition cost (WAC) for all Medicaid drugs,
- Protection against discriminatory network and reimbursement actions by health insurers and PBMs, which undermine the intent of the 340B program, and
- Unlimited use of contract pharmacies as necessary.

Under our 340C proposal, we recommend entities submit annual reports to HRSA that include community benefit as reported on the health center's IRS form 990, and evidence of tangible benefit to patients, which could include critical staffing, service expansion, infrastructure investments and/or access to medications, among other initiatives.

We support the elements of the SUSTAIN Act that reflect ACH's 340C proposal, including annual reporting on the use of the 340B program savings. We offer two technical edits that reflect our desire to give health centers the opportunity to report savings in a way that balances transparency and administrative burden.

<u>Section (6)(5)(A)(i)(II)</u>

> ''(II) in the case of a covered entity that is not required to submit a Medicare cost report that indicates charity care levels, or in the case of a federally qualified health center that elects this option, a qualitative description of the charity care provided by such entity, in the aggregate, in such manner that is not overly burdensome to covered entities, as the Secretary may require.

We anticipate that in the early phases of the implementation of these new reporting requirements, there will be significant challenges in coordination with contract pharmacies. As larger health centers use many different contract pharmacies with different third party administrators, health center staff may need to compile and quality-check this information manually until the systems improve. Therefore, for the first few years of implementation of this section, we recommend that Congress permit HRSA to accept estimates and/or submissions with a stated margin of error for the data requests that require coordination with contract pharmacies, including (5)(A)(i),(ii), and (v). This change could be made by adding on page 28, line 17:

> (F) SECRETARY DISCRETION – In the case of federally qualified health centers that have contract pharmacy arrangements, the Secretary may provide alternative mechanisms for submitting the information required in this subsection, including good faith estimates for up to three years following the date of enactment.

Section 7: Enhancing Program Integrity

As noted above, ACH strongly supports 340B program integrity and supports the provisions of the SUSTAIN Act that authorize HHS to conduct audits. In addition to the audits authorized in the bill, we strongly recommend the addition of HHS authority to conduct interim desktop audits (sometimes called a "tabletop exercise"), with smaller sample sizes to help entities identify problems or misunderstandings before they escalate. Including these audits can identify problems quickly before they escalate, and more effectively preserve federal resources. To that end, we suggest the following edit on page 31, line 3:

> (B) describes ~~how~~ the risk-based mechanisms for the auditors ~~will~~ to review eligibility for being a covered entity…"

We also recommend a strong commitment to phased compliance, whereby entities are given the opportunity to engage in corrective action, but should they fail to come into compliance, be excluded from 340B purchases for a set period of time. We also recommend that entities demonstrating gross negligence and/or failure to follow policies and procedures should also be excluded from the program for a set period of time. For precedent, you can look to the Health Center program, in which health centers struggling with compliance lose eligibility for Federal Tort Claims Act status for up to one year.

Therefore, we recommend adding, on page 34, line 5:

> (VI) Establishing policies for re-entry into the program.

Finally, we strongly recommend that the SUSTAIN Act include dedicated funding for HRSA to fully staff its audit teams. We believe that achieving adequate oversight of the 340B program is contingent on providing HRSA with adequate resources to conduct comprehensive oversight. Resources should also allow for technical assistance from HRSA staff to assist health centers

struggling to establish policies and procedures to comply with a significant increase in reporting and record-keeping requirements.

Section 8: Duplicate Discounts

ACH members share in the desire, and hold responsibility, to abide by the 340B statute and prevent duplicate discounts from occurring. Many are able to do so through claims modifiers, and through mandatory carve-out programs instituted by states. We appreciate the layers of privacy protections included in the bill and the prohibition against profiting from the sale of the data. Based on our experience with other clearinghouses meant to protect against similar issues, we support the addition of protections for covered entities in the case of disputed claims, such as the inclusion of an appeals and/or mediation process when conflicts arise.

Section 9: Ensuring Equitable Treatment of Covered Entities and Participating Pharmacies

Pharmacy benefit managers (PBMs) and insurance companies impose policies that dramatically reduce health center savings from the 340B program. For example, they may treat 340B providers differently than other providers in terms of reimbursement, participation in standard or preferred networks or inventory management systems, or they may interfere in a patient's choice to receive drugs from a 340B pharmacy. This behavior reduces health centers' savings from the program and impacts the provision of patient care. We strongly support the provisions in Section 9 and appreciate the Working Group including them.

Additional Comment: Prohibition on Rebates

Recent activity in the marketplace has increased ACH's concern about the pharmaceutical industry attempting to transition the 340B program to a rebate model. We urge the Working Group to include an explicit prohibition of manufacturers from providing 340B pricing via rebates -- instead of upfront discounts -- for all CEs except AIDS Drug Assistance Programs (ADAPs). Small CEs such as FQHCs could not sustain their 340B programs if discounts were converted to rebates. FQHCs would face challenges in purchasing drugs at full price, and then wait months to receive the rebate. Such a model would also add significant administrative burden to request and track rebate payments on each unit of drug dispensed, and give a private, for-profit entity control over if and when the FQHC receives the rebate.

Recommended edits:

"(a) REQUIREMENTS FOR AGREEMENT WITH SECRETARY."

IN GENERAL.—The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any specified rebate or discount, as ~~provided by the Secretary~~ defined in subsection(b)(3)) to the manufacturer for covered outpatient drugs…"

b. Add the following after (b)(2)(B) (Other Definitions):

(3) SPECIFIED REBATE OR DISCOUNT. For purposes of subsection (a)(1), the term 'specified rebate or discount' means, with respect to a drug purchased by a covered entity, any rebate or discount, as provided by the Secretary. In the case of a covered entity that is not an entity described in subsection (a)(4)(E)*, all discounts anticipated by this statute shall be realized by such covered entities at the time they purchase 340B eligible drugs from drug wholesalers or drug manufacturers, at the ceiling prices described herein.

We appreciate the opportunity to provide comments. For more information, please contact me at apearskelly@advocatesforcommunityhealth.org and Stephanie Krenrich, our Senior Vice President Policy and Government Affairs, at skrenrich@advocatesforcommunityhealth.org.

Sincerely,

Amanda Pears Kelly
Chief Executive Officer
Advocates for Community Health