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Chairman Bill Cassidy
United States Senate
Committee On Health, Education, Labor, And Pensions
455 Dirksen Senate Office Building,
Washington, DC 20510
Via Electronic Mail

RE: Senate HELP Committee Request for Information — 340B Drug Pricing Integrity and Affordability for Patients Act Discussion Draft

Dear Chairman Cassidy:
The Community Access National Network (CANN) appreciates the opportunity to provide comments on the discussion draft of the 340B Drug Pricing Integrity and Affordability for Patients Act.

ABOUT CANN: The Community Access National Network (CANN) is a 501(c)(3) national nonprofit organization (formerly incorporated under the "Ryan White CARE Act Title II Community AIDS National Network") focusing on public policy issues relating to HIV/AIDS and viral hepatitis. CANN's mission is to define, promote, and improve access to healthcare services and supports for people living with HIV/AIDS and/or viral hepatitis through advocacy, education, and networking. CANN's coalition-based work is done on behalf of the patient advocacy groups, pharmaceutical partners, and government agencies.

We believe strongly in the purpose of 340B. Congress created the program to enable certain safety-net providers to stretch scarce federal resources and expand access to care for vulnerable patients. The program can and does support important services in communities across the country.

At the same time, supporting 340B does not require accepting the program's current lack of transparency and accountability.

CANN believes Congress should reform 340B so that the public can clearly see who benefits from the program, how much value is generated, where that value goes, and whether patients actually experience lower costs, improved access, or expanded services as a result.

For that reason, CANN welcomes the Committee's willingness to pursue comprehensive statutory reform.

Senator Cassidy's discussion draft represents an important opportunity to move 340B from a program largely dependent on trust and self-reporting toward a system grounded in transparency, measurable patient benefit, and meaningful federal oversight.

The Committee has appropriately identified transparency and oversight as central problems. The discussion draft itself recognizes concerns regarding whether the substantial growth of 340B has consistently translated into better access, lower costs for vulnerable patients, and better health outcomes for patients. The Committee reports that 340B purchases reached approximately $81 billion in 2024. The Health Resources and Services Administration further reported that 340B purchases in 2025 exceeded $100 billion and yet another year of more than 20% growth in the program. Disproportionate Share Hospitals represent about 80% of the program.

CANN supports the direction of reform but believes the legislation should be strengthened in several important areas.

Reform Should Begin with a Simple Principle: 340B Must Produce a Demonstrable Patient Benefit

The most important question Congress should ask is not simply whether an entity is legally eligible to participate in 340B.

The question should be:

What measurable benefit does the program produce for patients and communities?

Today, the financial benefit generated by a 340B transaction can flow through multiple entities before ultimately reaching a patient—or it can remain within an organization's broader operating or financial structure. Without standardized reporting, it is difficult for policymakers, patients, or taxpayers to determine how much of the value created by 340B is actually reaching patients.

CANN therefore strongly supports the discussion draft's transparency provisions.

However, reporting should not be treated as the end goal. Transparency is the mechanism; patient benefit is the objective. Congress should establish a statutory expectation that covered entities demonstrate how 340B-generated value improves:

- Patient affordability;
- Access to prescription medicines;
- Charity care;
- Preventive care;
- Primary and specialty care;
- Mental and behavioral health services;
- Transportation and other access barriers;
- Medication adherence;

- Case management;
- Community health worker services;
- HIV prevention and treatment;
- Services for uninsured and underinsured patients; and other documented services targeted to vulnerable populations.

The discussion draft appropriately identifies many of these expenditure categories, including medical care, mental health, pharmaceuticals, sliding-fee discounts, case management, transportation, patient education, community health workers, outreach, and eligibility assistance.

CANN recommends that Congress go one step further by requiring covered entities to demonstrate outcomes, rather than simply reporting expenditures.

For example, an entity reporting $10 million in 340B-generated margin should be able to identify how that investment affected patients—not merely categorize the $10 million as an expenditure.

Subgrantee Limitations Must be Considered Carefully to Ensure Board Access and Prevent Abuse

Section 3 of the draft notes a bracketed subsection and paragraph 318 subgrantees. In this area, since the publication of the draft, noted Judicial activities have brought to light concerns and subsequent rulings have narrowed a specific area of exploitive behavior ("sub-sub-grantee" designs which function as an "affiliate" qualification for unrelated and potentially unqualified clinic entities).

Similarly, after reviewing certain OPAIS entity qualification under 318 sub-grantee status, CANN highlights further concerns, which may be occurring within the currently permissible structure. For example, it is unclear what, if any, sexually transmitted infection services or care the Mary Bird Perkins Cancer Center are or have provided. Indeed, the very nature of the entity is not directed toward sexual or reproductive health outreach or services, but oncology.

CANN would encourage Senator Cassidy and/or the Committee to specifically seek sworn answers to inquiry as to the following:

- Did the mentioned entity or any other 318 qualified entity hire a consultant to guide their qualification as a sub-grantee?
- Were any administrators or contractors specifically compensated for qualifying the entity for the 340B program?
- We suggest requesting all written communications from the Louisiana Department of Health regarding certification of the entity and any similarly situated entity to be provided to the Committee.

While CANN remains concerned how 340B may be leveraged inappropriately by way of 318 sub-grantee status, we also recognize that many legitimate entities also qualify under the designation. For example, a significant segment of the nation's pre-exposure prophylaxis for the prevent of HIV infection (PrEP) access is provided by way of the in-kind 318 qualification. Furthermore, no-cost-to-patient access to curative syphilis

treatments are provided by way of discounted, purchase only (no insurance claims) across improvised communities, especially in the South. These programs should be protected and the current language threatens this access.

A more targeted approach, requiring validation of qualifying activities as a 318 sub-grantee entity by way of in-kind only contributions, would better serve to prevent abuses while maintaining access for legitimate offerings of these critical public health activities.

CANN emphasizes the need for the Secretary and the Committee to more fully investigate the mechanisms and process by which 318 sub-grantees are being qualified in order to more appropriately tailor legislative language.

Pharmacy Contract Sufficiency

Section 5 offers appropriate guardrails for transparency in contract pharmacy arrangements, with some qualifications. Most notably, CANN is aware some contract pharmacy arrangements include extraordinary and increasing fee schedules. We would encourage the Senator and Committee to consider limiting fee schedules and increases in order to discourage exploitive contracting and to better protect covered entity investment into patient services.

Several states have moved to prohibit manufacturer-imposed efforts to limit the use of contract pharmacies. While CANN has historically opposed these efforts, we do so specifically because the historical notion of contract pharmacies where to fill a need where a covered entity did not operate an in-house pharmacy. What this means functionally is a contract pharmacy would, in the ideal, operate as a substitute point of access for an in-house pharmacy. If a contract pharmacy is miles or states away, it is simply not doing that. Contract pharmacy arrangements and limitations therein should seek to revitalize pharmacy deserts, provide ready, geographical access to the entities they serve and the patients within those communities.

On the principle alone, states speaking into the silence of federal clarity of a federal program poses a problem the Committee should not allow to stand. Patchwork statutory and regulatory design serves only to make health care access more cumbersome, complicated, and expensive for patients.

340B Transparency—but Requirements Should Apply More Broadly

We strongly support Section 6 of the discussion draft.

The proposed requirements would require certain covered entities to report information concerning the number and types of patients receiving 340B drugs, costs, charity care, and margins. The legislation would also require HHS to make significant portions of this information publicly available in searchable electronic form.
This is a significant improvement over the current system.

However, CANN is concerned that the draft's revenue thresholds could unnecessarily limit the usefulness of the transparency provisions. The draft establishes reporting requirements at thresholds including $200 million and $1 billion in net patient revenues. CANN recommends that Congress establish graduated reporting requirements

for all covered entities, rather than creating a system in which smaller entities have no meaningful transparency obligation:

- Basic standardized reporting for every covered entity;
- More detailed reporting for larger covered entities;
- Comprehensive financial and patient-impact reporting for the largest covered entities; and
- Additional reporting for entities with substantial 340B margins or extensive contract-pharmacy operations.
- This would preserve proportionality while ensuring that no segment of the program remains effectively invisible.

On Hospital Child Sites, the Draft does not Consider Adverse Action – Should be Revised

As with other proposals regarding hospital child site designations, the draft here does not consider how hospitals might leverage geographic requirements to the detriment of patient access. Court records across several states show hospital acquisition by way of Certification of Public Advantage / Certification of Need laws are used to mask harmful consolidation of geographic access points and closure of low-margin services line. Instead, in these situations, we see high revenue 340B entities doing the exact opposite of the statutory intent to "…offer more comprehensive services…."

Herein, the Committee should consider functions like requiring extended patient assistance at child sites, served community evaluation, and other similarly situated metrics as a mechanism for identifying appropriate child site activities. In essence, if a child site is not operating within a qualifying service area or providing services which otherwise would not be available, the parent entity should not be able to funnel 340B revenues to that child site.

Transparency will help address these noted loopholes. Given noted consolidation, acquisition, and increased prices associated with same, hospital entities and large 330 systems should be made to be more accountable to multi-billion dollar revenue streams in order to prove their charitable mission.

Congress Should Require Reporting of the Actual Patient Savings Generated by 340B

Section 7 rightly seeks to improve patient access and affordability. To that end, the section should be more expansive in alignment with already existing federal health care programs. Consideration of sliding fee scales should be expanded to reach to 400% of the federal poverty level. In order to ensure patients in need are receiving these benefits, reporting should be required as described below.

We believe the most important missing metric is patient savings.

The program's name and statutory purpose are centered on drug pricing. Yet a covered entity can purchase a medicine at a substantially discounted price while a patient or insurer may be charged a substantially higher amount.

Congress should therefore require reporting of:

- The 340B acquisition price;
- The amount paid by the patient;
- The amount paid by the insurer or other third-party payer;
- The entity's gross margin;
- Contract-pharmacy and third-party administrator fees;
- The amount of the 340B benefit retained by the covered entity;
- The amount directly passed through to the patient; and
- The amount used for documented patient-benefit activities.

Without this information, policymakers cannot determine whether 340B is functioning as a patient affordability program, a provider revenue program, or some combination of the two.

To be clear, CANN supports a strong 340B program. When the program operates as it was intended, the delicate healthcare safety-net thrives, and families, individuals, and communities have access to the care and services they otherwise may not have.

Should anyone within the Senator's office or among Committee members and their staff have further questions regarding CANN's feedback, or any other matter of public health, I can be reached by phone at 913.954.8816, or email kalvin@tiicann.org.

Warmly in service,

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On behalf of
Jen Laws
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