HIV+HEP
POLICY INSTITUTE

July 28, 2023

Submitted via email: Bipartisan340BRFI@mail.senate.gov

Re: Response to Request for Information on Improving Integrity & Stability of the 340B Program

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

The **HIV+Hepatitis Policy Institute** is a leading national HIV and hepatitis policy organization promoting quality and affordable healthcare for people living with or at risk of HIV, hepatitis, and other serious and chronic health conditions. Given the importance of the 340B program to both HIV treatment and prevention in the United States, we are pleased that you are taking steps to improve the integrity and stability of the program. While the program has grown in recent years, we believe Congress should take steps now to ensure the 340B program works as intended and any abuses are addressed in order to ensure that the 340B program will be on solid ground and available in the future.

340B Program Essential to HIV Treatment & Prevention

Before responding to your specific questions, we would like to emphasize the centrality of the 340B program to both HIV prevention and treatment in the United States. The Ryan White HIV/AIDS Program currently provides care, treatment, and support services to over 560,000 low-income people living with HIV. While federal funding has remained rather stagnant over the years at approximately $2.6 billion, as people are living longer and there are new diagnoses, the income generated by the 340B program has been and will continue to be absolutely necessary for expanding HIV care and treatment. In addition to approximately $800 million in ADAP rebates, Ryan White Program clinics, according to HRSA, benefited from the purchase of $2.2 billion of medications at 340B discounted prices in 2021. It is not unusual for HIV clinics to receive over half of their revenue from the 340B program. These revenues augment federal resources and other payers, such as Medicaid, Medicare, and private insurance, and help pay for salaries, uncompensated medical care, and other health care services which are in accord with the Ryan White Program grant for the care and treatment of low-income people living with HIV.

The 340B program is also critical to HIV prevention, particularly for the provision of pre-exposure prophylaxis (PrEP). In the absence of a federally funded national PrEP program, 340B program is one of main ways providers, community health centers, and STD clinics throughout the county are able to provide PrEP to people who need it today. Through the income

generated by 340B, these entities are able to hire providers, outreach workers, and adherence counselors, and pay for PrEP and associated lab services for the uninsured. According to HRSA, STD clinics benefited from the purchase of $871 million in 340B discounted prices. Since the volume of 340B purchasing by STD clinics grew by 54 percent in one year and most STD drugs are low-cost generics, one can assume that the bulk of this growth was for PrEP. One important aspect of the *Ending the HIV Epidemic* initiative is that it provides grants to community health centers to conduct PrEP work, including outreach, education, and adherence services. Currently funded at $167 million, 302 community health centers were able to leverage the 340B program and in just the first two years provided PrEP to over 52,000 people. Almost 200,000 people in the U.S are receiving their PrEP through telemedicine, which leverages the 340B program and helps pay for providers and community outreach and PrEP and the labs for the uninsured. Since only 30 percent of the people eligible for PrEP are taking it today, there is a great need to expand PrEP uptake in the country, especially among Black people and Latinos. The 340B program is and will remain critical to ensuring greater use of PrEP.

In order to end HIV in the US a stable and reliable 340B program is and will be absolutely necessary to sustain HIV treatment and prevention systems.

<u>Current State of the 340B Program</u>

While there are some areas in which we recommend improvements for the covered entities that use the 340B program (see below), the **HIV+Hepatitis Policy Institute** believes that the program is working rather well and as intended. Where we see that there are questionable practices and abuses, in our view, are in the Disproportionate Share Hospitals, which account for $34 billion, or 78 percent of all 340B drug purchases. (This compares to Ryan White clinics that represent 5 percent and STD clinics that represent only 2 percent of total 340B drug purchases.) These hospitals not only comprise the largest part of the 340B program by far, but also are account for most of the growth in the program. According to HRSA, in 2015, total DSH hospital discounted 340B drug purchases were $6.3 billion, which means the growth over 6 years was 444 percent.

Unlike those covered entities named in the 340B statute that qualify for 340B discounts and receive federal grants, hospitals do not report on how they utilize their 340B discounts nor do they have to use them in any particular fashion. **Therefore, we believe that much of your attention should focus on tightening up 340B program use by the DSH hospitals.** We believe that lack of reporting and criteria on how 340B revenue can be spent has led to unintended growth in the program and outright abuse. **In order to protect the integrity and stability of the overall 340B program, which is so vital to HIV treatment and prevention, necessary steps must be taken to address these actions by the hospitals.**

See below for responses to your specific questions.

1. What specific policies should be considered to ensure HRSA can oversee the 340B program with adequate resources? What policies should be considered to ensure HRSA has the

appropriate authority to enforce the statutory requirements and regulations of the 340B program?

In order to oversee and regulate the entire 340B program, which includes both manufacturers and covered entities, HRSA's Office of Pharmacy Affairs is allocated only $12.2 million for the entire country. In order for HRSA to properly ensure better oversight, including the conduct of audits, the office desperately needs additional funding. Further, we are supportive of the proposal contained in the FY2024 Budget Request that provides HRSA the authority "to require covered entities to annually report to HRSA how the savings achieved through the Program benefits the communities they serve." We also support the HRSA proposal to "explicit regulatory authority to define necessary terms" and "strengthen compliance and transparency related to the utilization of contract pharmacies."

2. What specific policies should be considered to establish consistency and certainty in contract pharmacy arrangements for covered entities?

We believe that current practices for those covered entities that utilize the 340B program for HIV treatment and prevention are working well, and we would not want to limit the use of subgrantees or telemedicine, as they are critical to HIV treatment and prevention. If there is not adequate reporting by any of these entities, including the reporting and use of their 340B discounts, then that should be an added requirement.

Where there needs to be greater control over contract pharmacies is for those associated with hospitals. For example, DSH hospital contract pharmacies should be required to be located in a medically underserved area or serving a medically underserved population. All contract pharmacies should be required to take steps to prevent diversion and duplicate discounts.

3. What specific policies should be considered to ensure that the benefits of the 340B program accrue to covered entities for the benefit of patients they serve, not other parties?

We support, at a minimum, HRSA's proposal in its FY2024 budget request to increase 340B Program integrity "by requiring covered entities to annually report to HRSA how the savings achieved through the Program benefits the communities they serve."

While an annual report on how 340B revenues are used should be mandatory for all covered entities and hospitals, the level of detail included in the reports must be addressed. It would seem that the appropriate level should include the categories included in grant reports (eg salaries, administrative, medical, outreach, uncompensated care and treatment, facilities, transportation, etc).

Covered entities must use 340B program revenues in accordance with their federal grant. For example, HRSA's Ryan White HIV/AIDS Program requires its grantees only to allocate money to help people who are living with HIV/AIDS and grantees must submit data to the HIV/AIDS Bureau. It is essential that other grantees, including CDC grantees that qualify for 340B through

Section 318 grants, also submit reports on how they are using their 340B revenues to ensure it is benefiting those that they serve.

While there are parameters on what covered entities can use their 340B program generated revenue, there are no such provisions for hospitals. Hospitals, including child sites, must be required to use their 340B revenues to assist needy patients, and must ensure that these patients benefit from these discounts by receiving the drugs and medical care at no or very low cost. Congress should require DSH hospitals to report on how their 340B revenue is being used to help uninsured and underinsured patients, as well as to report on their payer mix, charity care, gross and net acquisition cost of drugs purchased through the 340B program, and total reimbursement received for 340B drugs.

It is important to allow covered entities to use revenue on administrative expenses to set up, run, and oversee their 340B program with its complex requirements. Not all grantees have this expertise in-house and often turn to outside entities with the expertise and staff to administer their 340B program.

4. What specific policies should be considered to ensure that accurate and appropriate claims information is available to ensure duplicate discounts do not occur?

We support the establishment of a neutral, independent clearinghouse that can receive all claims data while protecting patient confidentiality.

5. What specific policies should be considered to implement common sense, targeted program integrity measures that will improve the accountability of the 340B program and give healthcare stakeholders greater confidence in its oversight?

We have proposed a number of policy proposals above that we believe, taken together, will improve program integrity: additional resources and regulatory authority for HRSA, greater reporting requirements, a claims clearinghouse, and tighter controls for hospitals on how they qualify contract pharmacies, how they can use their program revenue, and ensure the program truly benefits low-income patients.

6. What specific policies should be considered to ensure transparency to show how 340B health care providers' savings are used to support services that benefit patients' health?

We support public reporting by all entities of certain information that is specific to their 340B program involvement, including total acquisition cost and reimbursement of their 340B drugs, along with the total amount used to reduce patient costs of 340B drugs.

Thank you for this opportunity to provide comments in response to your request for information. Should you have any questions or need any additional information, please do not hesitate to reach out via phone at (202) 462-3042 or email at cschmid@hivhep.org.

Sincerely,

Carl E. Schmid II
Executive Director