April 1, 2024

Submitted via email to Bipartisan340BRFI@email.senate.gov[1]

Bipartisan 340B Senate Working Group
ATTN: Senators Thune, Stabenow, Capito, Baldwin, Moran, and Cardin
United States Senate
Washington, D.C. 20510

Re: Request for Information (RFI) for the SUSTAIN 340B Act [Discussion Draft from the Bipartisan 340B Senate Working Group]

We are writing on behalf of Equitas Health, which is headquartered in Columbus, Ohio, to express comments regarding the Bipartisan 340B Senate Working Group's recent discussion draft and request for information on the SUSTAIN 340B Act. As noted throughout this comment, Equitas Health is in favor of improving the integrity and stability of the 340B Drug Pricing Program, while also protecting and enhancing access to care for patients, and we appreciate the opportunity to provide these comments.

As you may be aware, Equitas Health is a non-profit community health center and one of the largest LGBTQ+ and HIV/AIDS serving healthcare organizations in the country. Each year, we serve tens of thousands of patients in Ohio, Texas, Kentucky, and West Virginia, and since 1984, we have been working to advance "care for all." Our mission is to be the gateway to good health for those at risk of or affected by HIV; for the lesbian, gay, bisexual, transgender, and queer/questioning (LGBTQ+) community; and for those seeking a welcoming healthcare home. In doing so, we offer primary and specialized medical care, pharmacy services, dentistry, mental health and recovery services, HIV/STI prevention and treatment services, Ryan White HIV case management, overall care navigation, and a number of community health initiatives.[2] And in 2023, Equitas Health filled more than 250,000 prescriptions for nearly 14,000 unique patients across the state of Ohio.

<u>Contract Pharmacy [i.e. Section 3 of the Discussion Draft]</u>
Importance of Contract Pharmacy Use: As noted in the comment from the National Association of Community Health Centers (NACHC), community health centers are the largest primary care network in the country, and these community health centers serve as an important safety net for millions of patients in medically underserved communities.[3] As you are likely aware, many community health centers are not able to operate an in-house pharmacy, and these community health centers rely on the use of contract pharmacies to fill prescriptions for their patients. While Equitas Health does have multiple in-house pharmacies, our agency still relies on nearly 50 contract pharmacies for a number of

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[1] Document prepared by Rhea Debussy, Ph.D. (she/her), Director of External Affairs and Nick Saltsman, Pharm.D. (he/him), Chief Pharmacy Officer. Document reviewed by Sam Brinker (he/him), General Counsel and Dante Fuscardo (he/him), Associate General Counsel.
[2] https://equitashealth.com/about-us/
[3] https://www.nachc.org/wp-content/uploads/2023/08/Americas-Health-Centers-2023.pdf

reasons. For instance, most of these contract pharmacies are classified as ‘specialty pharmacies,’ which our patients are *required* to use because of their health insurance plan. As the largest LGBTQ+ and HIV/AIDS service-provider in the state of Ohio, we have patients across the state, and many of our patients – particularly those in rural areas – access services via telehealth and our mobile clinics, while others come to our community health centers in Akron, Cincinnati, Columbus, or Dayton. Our use of contract pharmacies is essential for our patients in rural areas, because it enables them to access life-saving medication in their geographic area. Regarding the request for information, we have a number of comments and recommendations in relation to Section 3: Contract Pharmacy of the discussion draft.

Number of Contract Pharmacies: Recalling that many patients’ health insurance plans require the use of a specialty pharmacy, we would recommend that covered entities are allowed to use an unlimited number of contract pharmacies. As noted by Ryan White Clinics for 340B Access, “the ability to access 340B drugs through contract pharmacies is especially important for persons living with HIV/AIDS. The preparation, dispensing and management of antiretroviral medications and other HIV-related drugs often requires special expertise and support that Ryan White clinics can only offer through contract pharmacy arrangements. By partnering with contract pharmacies, Ryan White clinics can augment important social work and linkage services that ensure that people living with HIV are able to access and stay in care.”[4]

Ensuring Access to Care: In addition to the importance of contract pharmacies for patients living with chronic health conditions, we would also like to call attention to the rising rates of pharmacy deserts, which underscore the importance of allowing community health centers to use an unlimited number of contract pharmacies. As noted by *Becker’s Hospital Review*, 1 in 3 independent pharmacies are at serious risk of closing in 2024.[5] Additionally, 1 in 4 neighborhoods across the country – as noted by the National Community Pharmacists Association – already exist in pharmacy shortage areas, which highlights the seriousness of this problem.[6] And finally, this problem is exacerbated in large urban areas; specifically, one-third of all neighborhoods in the largest cities across the country are already pharmacy deserts.[7] Given this grave reality, Equitas Health strongly recommends 1) to allow covered entities to use an unlimited number of contract pharmacies and 2) to disallow manufacturers from restricting the shipment or distribution of 340B medications to a contract pharmacy.

Patient Definition [i.e. Section 4 of the Discussion Draft]

Recommended Definition: As noted in the request for information, we agree that setting an appropriate definition of a “patient” for a covered entity is important for helping to maintain the integrity of the 340B Drug Pricing Program. As noted by guidance from the Health Resources and Services Administration (HRSA) in 1996, “all covered entities must establish a relationship with their patients such that the entity will maintain records of the individual’s health care…and will document in the record the care provided and, when appropriate, the prescriptions written.”[8] Equitas Health agrees with this long-standing definition of “patient.” Regarding the frequency of medical visits, we – alongside our

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[4] https://rwc340b.org/wp-content/uploads/2023/10/RWC-340B-Contract-Pharmacy-Arrangements-Are-Critical-to-the-340B-Safety-Net-Get-the-Facts.pdf

[5] https://www.beckershospitalreview.com/pharmacy/1-in-3-independent-pharmacies-to-close-this-year-survey.html

[6] https://ncpa.org/newsroom/news-releases/2022/10/24/ncpa-collaborates-usc-groundbreaking-pharmacy-mapping-project

[7] https://today.usc.edu/pharmacy-deserts-american-cities-health-disparities-usc-research/

[8] https://www.hrsa.gov/sites/default/files/hrsa/opa/patient-entity-eligibility-10-24-96.pdf

partners at the National Association of Community Health Centers (NACHC) – strongly recommend that patients of grantees should be seen at least every 24 months or 2 years.

Covered Entity Hierarchy: In the course of providing care, smaller covered entities, such as community health centers, often refer patients to specialists to ensure that they receive appropriate medical care. As such, patients may have relationships with multiple providers at different facilities. Regarding the question of which covered entity should be able to claim the 340B discount, we recommend the covered entity, who is responsible for the patient's overall case management and/or care coordination, should be able to claim said 340B discount, so those savings can be re-invested into that patient's whole-person care needs. As noted by the Alliance to Save America's 340B Program (ASAP 340B), such "eligibility for a 340B discount should reflect a direct connection between the patient's medical condition and the services being provided or managed…by the covered entity."[9] However, we also recommend that the Bipartisan 340B Senate Working Group considers certain exemptions to this, and we recommend that such exemptions are considered for Ryan White clinics, who manage specialty care needs related to HIV treatment and prevention services. As noted by the Health Resources and Services Administration (HRSA), data from 2023 indicates that roughly 90% of patients receiving HIV-related care were virally suppressed, which means that they can live longer and healthier lives that are free from the fear of transmitting HIV.[10] As noted by Ryan White Clinics for 340B Access, "clinics' higher rate of success [in achieving such rates of viral suppression for their patients] is directly attributable to their participation in the 340B program."[11] As such, we strongly recommend that such an exemption for Ryan White clinics are considered in the final draft of the SUSTAIN 340B Act.

Child Sites [i.e. Section 5 of the Discussion Draft]

Eligibility and Guidelines for Child Sites: Along with the Bipartisan 340B Senate Working Group, we agree that child sites should be wholly-owned by, clinically integrated with, and financially tied to the covered entity that is receiving the 340B discount. Like the Alliance to Save America's 340B Program (ASAP 340B), we agree that child site eligibility – along with grantee eligibility more generally – be limited to non-profit facilities, and this will prohibit "for-profit companies, like pharmacy benefit managers" and for-profit clinics "from siphoning off 340B savings intended to help patients" and the non-profit facilities where they receive care.[12]

Transparency [i.e. Section 6 of the Discussion Draft]

Reporting from Covered Entities: Along with other organizations like the National Coalition of Community Health Centers (NACHC), AIDS United's 340B Work Group, and others, we welcome transparency in the 340B Drug Pricing Program. However, it is important to note that both community health centers and Ryan White clinics – which are both federal grantee organizations – already exhibit such transparency, because of federal grantee status. As such covered entities already submit data to the Health Resources and Services Administration (HRSA), we recommend that no additional reporting measures be imposed upon such covered entities. As noted by Ryan White Clinics for 340B Access, "federal regulators already have the data they need to validate proper use of 340B savings by Ryan

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[9] https://www.asap340b.org/_files/ugd/b11210_318c9f05aca84d17abef9296659a86b8.pdf?index=true

[10] https://www.hhs.gov/about/news/2023/12/01/latest-data-hrsa-ryan-white-hiv-aids-program-highlight-nine-out-ten-clients-hiv-virally-suppressed.html

[11] https://rwc340b.org/wp-content/uploads/2023/10/RWC-340B-%E2%80%93-Who-We-Are-and-Our-Patient-Centric-Mission-Get-the-Facts.pdf

[12] Ibid *supra* note 9.

White clinics," and "most of that information is [already] publicly available."[13] However, we understand that 3 of the 14 categories of covered entities, who are currently eligible to participate in the program, are not; for covered entities, who are not federal grantees but who are currently eligible to participate in the program, we strongly recommend that such reporting requirements be placed upon them. This will help to 1) ensure transparency among the covered entities, who are not currently reporting how their 340B savings are used for their patients, and 2) limit any additional undue burdens on federal grantees, who are already legally required to report this data to federal regulators.[14]

Program Integrity [i.e. Section 7 of the Discussion Draft]

Financial Assistance at Contract Pharmacies: While we do not have specific comments on the bulk of this section, we would like to offer some comments in relation to the questions about financial assistance at contract pharmacies. As noted above, community health centers across the nation rely on contract pharmacies to ensure that their patients have access to affordable, life-saving medications. Offering financial assistance at all contract pharmacies is essentially impossible from a logistical standpoint. For instance, the five largest contract pharmacy participants (i.e. Cigna, CVS, Optum, Walgreens, and Walmart) currently account for roughly 75% of total contract pharmacy agreements in the country.[15] For many community health centers, such for-profit contract pharmacies use systems that do not allow for patient financial assistance programs to be applied or implemented. While we wish that such for-profit contract pharmacies would use our sliding-scale fee structure and/or other financial assistance programs to make medication more accessible, the reality is that many of these for-profit contract pharmacies are ill-equipped and disincentivized from doing so. In terms of a solution, we offer a sliding-scale fee structure and multiple financial assistance programs for eligible patients who utilize one of our in-house pharmacies, but we cannot currently identify a solution that will fit every scenario with every contract pharmacy.

Preventing Duplicate Discounts [i.e. Section 8 of the Discussion Draft]

Establishing a 340B Clearinghouse: We – alongside other organizations like the National Association for Community Health Centers (NACHC), Ryan White Clinics for 340B Access, and others –also recommend establishing a neutral, independent 340B Clearinghouse that is capable of receiving Medicare, Medicaid, commercial claims data. This 340B Clearinghouse could then be used to identify potential duplicate discounts, which are already prohibited in the 340B Drug Pricing Program. As such, we strongly recommend the inclusion of such language in the final draft of the SUSTAIN 340B Act.

Ensuring Equitable Treatment of Covered Entities and Participating Pharmacies [i.e. Section 9 of the Discussion Draft]

Prohibiting Discrimination from Pharmacy Benefit Managers (PBMs): As noted by Ryan White Clinics for 340B Access, "increasingly, pharmacy benefit managers (PBMs) and other third-party payers are usurping the benefit of the 340B drug discount program. They do so by offering Ryan White clinics and other 340B covered entities lower reimbursement rates on drugs than those offered to non-340B entities or forcing health care providers to use only selected (and sometimes financially tied) pharmacies. These discriminatory practices are a direct attack on the 340B program because they take the benefit of the 340B program from covered entities for the financial benefit of PBMs and private

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[13] https://rwc340b.org/wp-content/uploads/2023/10/RWC-340B-340B-Reporting-Requirements-Are-Unwarranted-Get-the-Facts.pdf

[14] See ibid.

[15] Fein, Adam. 2023. *The 2023-24 Economic Report on Pharmaceutical Wholesalers and Specialty Distributors.* Drug Channels Institute.

insurers."[16] As such, Ryan White clinics and other community health centers face this discriminatory practice, and "ultimately, discriminatory reimbursement harms the low-income and medically vulnerable patients that 340B providers serve."[17] Our agency, which is based in Ohio, is already protected from such practices, because of state law; however, we strongly recommend the creation of statutory language that will prohibit these discriminatory practices from PBMs nationwide.

Concluding Remarks

Equitas Health would like to thank you for this opportunity to present comments regarding the Bipartisan 340B Senate Working Group's recent discussion draft and request for information on the SUSTAIN 340B Act. As noted previously, Equitas Health is in favor of improving the integrity and stability of the 340B Drug Pricing Program, while also protecting and enhancing access to care for patients. We appreciate the opportunity to provide these comments, should you have any questions about these comments, please feel free to contact Rhea Debussy, PhD (she/her), Director of External Affairs at Equitas Health or Nick Saltsman, PharmD, RPh, AAHIVP (he/him), Chief Pharmacy Officer at Equitas Health.

[16] https://rwc340b.org/wp-content/uploads/2023/10/RWC-340B-Discriminatory-Practices-Undermine-the-Healthcare-Safety-Net-Get-the-Facts.pdf
[17] Ibid.