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April 1, 2024

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

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

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

Senator Tammy Baldwin
141 Hart Senate Office Building
Washington, D.C. 20510

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

Senator Benjamin Cardin
509 Hart Senate Office
Washington, D.C. 20510

Re: NASTAD's response to Senate RFI

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

On behalf of the National Alliance of State and Territorial AIDS Directors (NASTAD), a leading non-partisan non-profit association that represents public health officials who administer HIV and hepatitis programs in the U.S., we appreciate the opportunity to submit comments on the bipartisan request for information (RFI) on the 340B Drug Pricing Program and the SUSTAIN 340B Act. NASTAD primarily supports state, county, and municipal health departments receiving federal HIV care, STI and HIV prevention, and viral hepatitis grants authorized under Title XXVI and Section 318 of the Public Health Service Act.

Contract Pharmacy

NASTAD commends Congress's attempt to balance competing interests in the proposed contract pharmacy guidance and applauds Congress's recognition of the geographic barriers that some covered entities and patients face. NASTAD encourages Congress not to impose geographic or other restrictions on contract pharmacy arrangements. Grantees serve patients with unique, often complex pharmacologic needs, including culturally competent

pharmacy services in their own communities, and therefore encourage Congress not to impose additional barriers. In particular, AIDS Drug Assistance Programs (ADAPs) would be unduly burdened by restrictions on the number or geographic locations of 340B contract pharmacies because they are statewide programs originating from a single location (usually the state or territorial health department) serving clients residing throughout the jurisdiction.

ADAPs' primary function is to ensure that low-income, typically uninsured or underinsured people with HIV can secure and maintain access to essential HIV drugs, medications to prevent and treat AIDS-related opportunistic diseases, and other medicines to prevent and treat HIV-associated health complications. Eighty-four percent of ADAP clients served had undetectable viral loads – a key indicator of health and goal of a federal initiative to end the HIV epidemic in the U.S. – as of December 31, 2022.[1] This is significantly more than the estimated 66% of all people living with diagnosed HIV infection nationally who were virally suppressed, based on most recent viral load test during 2021. Geographic and other restrictions on ADAPs' use of contract pharmacies threaten this critical mission success and risk reducing the number of people living with HIV that ADAPs can effectively serve. As such, it is essential that ADAPs maintain unrestricted access to 340B contract pharmacies of their choosing, both in number and geographic locations, to ensure that patients across their jurisdiction have access to lifesaving treatment.

Additionally, many people requiring HIV prevention (including PrEP) and viral hepatitis treatment must contend with long travel times to access centers of excellence providing comprehensive, specialized, and culturally competent medical care and support services.[2,3,4,5] Many of these HIV prevention and viral hepatitis programs are subgrantees of federal funds authorized under Section 318 of the PHSA, thereby qualifying them for the 340B Drug Pricing Program. Ensuring these programs can maintain networks of 340B contract pharmacies to meet the medication access needs of geographically distributed clients is key to addressing structural barriers of care facing people living with, and vulnerable to, HIV and viral hepatitis. NASTAD urges Congress to preserve grantees' ability to select the contract pharmacy that best serves them and their patients without geographic restrictions.

Likewise, NASTAD urges Congress not to restrict access to specialty pharmacies. As Congress recognizes, specialty medications can often be obtained only at a few specialty pharmacy locations

[1] Centers for Dease Control and Prevention. *Ending the HIV Epidemic (EHE).* https://www.cdc.gov/endhiv/index.html
[2] Siegler AJ, Bratcher A, Weiss KM. Geographic Access to Preexposure Prophylaxis Clinics Among Men Who Have Sex with Men in the United States. Am J Public Health. 2019 Sep;109(9):1216-1223. doi: 10.2105/AJPH.2019.305172.
[3] Sharpe JD, Sanchez TH, Siegler AJ, Guest JL, Sullivan PS. Association between the geographic accessibility of PrEP and PrEP use among MSM in nonurban areas. J Rural Health. 2022 Sep;38(4):948-959. doi: 10.1111/jrh.12645. Epub 2022 Jan 7.
[4] Njei B, Esserman D, Krishnan S, Ohl M, Tate JP, Hauser RG, Taddei T, Lim J, Justice AC. Regional and Rural-Urban Differences in the Use of Direct-acting Antiviral Agents for Hepatitis C Virus: The Veteran Birth Cohort. Med Care. 2019 Apr;57(4):279-285. doi: 10.1097/MLR.0000000000001071.
[5] Du P, Wang X, Kong L, Jung J. Can Telementoring Reduce Urban-Rural Disparities in Utilization of Direct-Acting Antiviral Agents? Telemed J E Health. 2021 May;27(5):488-494. doi: 10.1089/tmj.2020.0090.

throughout the country, significantly limiting access to vital medications. Many HIV prevention and treatment drugs, along with medicines for viral hepatitis and sexually transmitted infections, are only available through limited distribution systems and not at community pharmacies. Therefore, there needs to be an option for all covered entities to maintain contracts with specialty pharmacies outside of their regular community-based pharmacy networks. NASTAD recommends that Congress ensure that patients have access to specialty medications by not restricting a covered entity's ability to contract with specialty pharmacies.

NASTAD appreciates stakeholder concerns about the number of contract pharmacies used by covered entities. Again, NASTAD urges Congress not to limit the number of contract pharmacies that may be associated with a covered entity, particularly in the case of ADAPs or other programs administered by governmental public health. ADAPs must serve an entire state or jurisdiction as a single covered entity, thus it is often necessary for ADAPs to have multiple contract pharmacies spread across the region. Therefore, any restrictions on the number of contract pharmacies a covered entity may have or how far those contract pharmacies may be from a covered entity would disproportionately and uniquely harm governmental public health programs, including ADAPs and contribute to the geographic barriers and health disparities already faced by ADAPs and their patients.

Patient Definition

While NASTAD appreciates Congress's desire to clarify the 340B statute by providing an explicit patient definition, we want to ensure that Congress evaluates the impact of that definition on each of the 340B program's diverse grantees, especially ADAPs. Currently, ADAP clients are categorically eligible for the 340B Program because of the unique way that ADAPs participate in the 340B Program. NASTAD urges Congress to maintain the categorical inclusion of ADAP clients under the current patient eligibility criteria.[6] Participation in the 340B program is critical for ADAPs to meet the needs of low-income uninsured and underinsured persons living with HIV/AIDS, and if the categorical eligibility changed, ADAPs would be forced to severely limit client enrollment, institute waitlists for access, and many people would lose access to medication impacting their health and the nation's public health. Additionally, NASTAD cautions Congress against using a "one-size-fits-all" approach to the patient definition and instead encourages Congress to promulgate a definition that reflects all grantees' unique structures and purposes and explicitly continues categorical eligibility for ADAP clients.

[6] An individual registered in a State operated or funded AIDS drug purchasing assistance program receiving financial assistance under title XXVI of the PHS Act will be considered a ''patient'' of the covered entity for purposes of this definition if so registered as eligible by the State program. 61 Fed. Reg. 55158 (1996).

While NASTAD recognizes Congress's hesitation to enact an expansive patient definition, we encourage Congress to consider the impact that a narrow patient definition would have on patients seeking HIV and/or viral hepatitis prevention or care. Specifically, NASTAD recommends that the patient definition explicitly state that a "meaningful relationship" between a covered entity and a patient starts on the first visit. The rapid initiation of HIV treatment – typically defined as antiretroviral therapy started on the day of diagnosis or the first clinic visit for HIV care – is supported by randomized controlled trials that were performed in resource-limited settings outside of the United States and observational trials in the United States that included both immediate initiation of HIV treatment (on the day of diagnosis) and rapid antiretroviral treatment initiation (within days or weeks of diagnosis).[7,8,9,10,11,12,13] Rapid initiation of antiretroviral drugs for HIV prevention, known as pre-exposure prophylaxis (PrEP), is also emerging as a best practice,[14,15,16,17] and is gaining considerable traction as a strategy to maximize treatment utilization and cure rates among people with chronic hepatitis C.[18,19,20,21] Therefore, requiring patients to visit a covered entity more than once before they are eligible for 340B-discounted medicines would hinder prompt and effective treatment, would be contrary to promoting public health, and would disproportionately impact low-income and geographically isolated people living,

[7] Rosen S, Maskew M, Fox MP, et al. Initiating antiretroviral therapy for HIV at a patient's first clinic visit: The RapIT randomized controlled trial. *PLoS Med*. 2016;13(5):e1002015.
[8] Koenig SP, Dorvil N, Devieux JG, et al. Same-day HIV testing with initiation of antiretroviral therapy versus standard care for persons living with HIV: A randomized unblinded trial. *PLoS Med*. 2017;14(7):e1002357.
[9] Labhardt ND, Ringera I, Lejone TI, et al. Effect of offering same-day ART vs usual health facility referral during home-based HIV testing on linkage to care and viral suppression among adults with HIV in Lesotho: The CASCADE Randomized Clinical Trial. *JAMA*. 2018;319(11):1103-1112.
[10] Pilcher CD, Ospina-Norvell C, Dasgupta A, et al. The effect of same-day observed initiation of antiretroviral therapy on HIV viral load and treatment outcomes in a U.S. public health setting. *J Acquir Immune Defic Syndr*. 2017;74(1):44-51.
[11] Coffey S, Bacchetti P, Sachdev D, et al. RAPID antiretroviral therapy: high virologic suppression rates with immediate antiretroviral therapy initiation in a vulnerable urban clinic population. *AIDS*. 2019;33(5):825-832.
[12] Colasanti J, Sumitani J, Mehta CC, et al. Implementation of a rapid entry program decreases time to viral suppression among vulnerable persons living with HIV in the Southern United States. *Open Forum Infect Dis*. 2018;5(6):ofy104.
[13] Hoenigl M, Chaillon A, Moore DJ, et al. Rapid HIV viral load suppression in those initiating antiretroviral therapy at first visit after HIV diagnosis. *Sci Rep*. 2016;6:32947.
[14] Wagner GA, Wu KS, Anderson C, Burgi A, Little SJ. Predictors of Human Immunodeficiency Virus Pre-Exposure Prophylaxis (PrEP) Uptake in a Sexual Health Clinic With Rapid PrEP Initiation. Open Forum Infect Dis. 2023 Feb 8;10(3):ofad060.
[15] Schaffer DH, Sawczuk LM, Zheng H, Macias-Konstantopoulos WL. Community-Based, Rapid HIV Screening and Pre-Exposure Prophylaxis Initiation: Findings From a Pilot Program. Cureus. 2022 Jan 2;14(1):e20877. doi: 10.7759/cureus.20877.
[16] Estcourt CS, MacDonald J, Saunders J, Nandwani R, Young I, Frankis J, Clutterbuck D, Steedman N, McDaid L, Dalrymple J, Flowers P. Improving HIV pre-exposure prophylaxis (PrEP) uptake and initiation: process evaluation and recommendation development from a national PrEP program. Sex Health. 2023 Aug;20(4):282-295. doi: 10.1071/SH22170.
[17] Higgins DM, Riba A, Alderton L, Wendel KA, Scanlon J, Weise J, Gibson N, Obafemi O. Evaluation of the Impact and Outcomes of a Rapid Transition to Telehealth PrEP Delivery at a Sexual Health Clinic During the COVID-19 Pandemic. Sex Transm Dis. 2023 Dec 1;50(12):816-820. doi: 10.1097/OLQ.0000000000001872. Epub 2023 Oct 9.
[18] Eckhardt B, Kapadia SN, Mateu-Gelabert P, Pai M, Fong C, Aponte-Melendez Y, Marks KM. Rapid Treatment Initiation for Hepatitis C in Young People Who Inject Drugs: The Seek, Test, and Rapid Treatment Randomized Trial. Open Forum Infect Dis. 2022 May 7;9(7):ofac225.
[19] Finbråten AK, Eckhardt BJ, Kapadia SN, Marks KM. Rapid Treatment Initiation for Hepatitis C Virus Infection: Potential Benefits, Current Limitations, and Real-World Examples. Gastroenterol Hepatol (N Y). 2022 Nov;18(11):628-638.
[20] Lettner B, Mason K, Greenwald ZR, Broad J, Mandel E, Feld JJ, Powis J. Rapid hepatitis C virus point-of-care RNA testing and treatment at an integrated supervised consumption service in Toronto, Canada: a prospective, observational cohort study. Lancet Reg Health Am. 2023 May 17;22:100490. doi: 10.1016/j.lana.2023.100490.
[21] Lichtenstein GR. Rapid Initiation of Hepatitis C Virus Treatment. Gastroenterol Hepatol (N Y). 2022 Nov;18(11):615. PMID: 36866027; PMCID: PMC9972669.

or vulnerable to, HIV and/or chronic hepatitis C infection. Accordingly, NASTAD encourages Congress to adopt a patient definition stating that a relationship between a patient and a covered entity begins on the first visit.

Further, NASTAD acknowledges that a patient should have a measurable ongoing relationship with a covered entity to maintain their 340B patient definition. In determining how often a patient should visit a covered entity to maintain this status, NASTAD strongly believes that this is a decision that must be made solely by patients in close collaboration with their providers, in association with clinical practice guidelines. NASTAD also encourages Congress to consider economic, age-related, and geographic barriers that patients might need to navigate with their clinical care providers, which may require follow-up frequencies that may not align with proposed 340B Drug Pricing Program requirements. As such, NASTAD recommends that Congress allow patients to maintain their 340B eligibility with a requirement of no more than one in-person visit to a covered entity per year.

Finally, NASTAD encourages Congress to consider the evidence-based utility of telehealth in HIV and viral hepatitis care, and include specific language allowing telemedicine, telepharmacy, and other remote health service arrangements between patients and covered entities. Telehealth is an evidence-based and widely accepted mode of clinical care that effectively meets clients where they are.[22,23,24,25,26,27,28] Consequently, many HIV prevention, HIV care, and Section 318 viral hepatitis grantees and subgrantees frequently use telehealth to connect patients with providers outside their geographic area, allowing patients more opportunities to find culturally and linguistically appropriate providers. Ultimately, telehealth is an essential part of comprehensive patient care that is both a cornerstone of health equity and consistent with the existing HRSA patient definition. Therefore, NASTAD urges Congress to explicitly include telehealth as a type of visit that makes a patient eligible for 340B and to include telehealth as an allowable way for a patient to maintain an ongoing relationship with their provider.

[22] Labisi T, Regan N, Davis P, Fadul N. HIV Care Meets Telehealth: a Review of Successes, Disparities, and Unresolved Challenges. Curr HIV/AIDS Rep. 2022 Oct;19(5):446-453. doi: 10.1007/s11904-022-00623-z.
[23] Touger R, Wood BR. A Review of Telehealth Innovations for HIV Pre-Exposure Prophylaxis (PrEP). Curr HIV/AIDS Rep. 2019 Feb;16(1):113-119. doi: 10.1007/s11904-019-00430-z.
[24] Dandachi D, Lee C, Morgan RO, Tavakoli-Tabasi S, Giordano TP, Rodriguez-Barradas MC. Integration of telehealth services in the healthcare system: with emphasis on the experience of patients living with HIV. J Investig Med. 2019 Jun;67(5):815-820. doi: 10.1136/jim-2018-000872.
[25] Salgado S, Felzien G, Brumbeloe J. Georgia Leverages Telehealth to Expand HIV Care Management in Underserved Areas. Am J Prev Med. 2021 Nov;61(5 Suppl 1):S55-S59. doi: 10.1016/j.amepre.2021.07.001.
[26] Fomiatti R, Shaw F, Fraser S. 'It's a different way to do medicine': Exploring the affordances of telehealth for hepatitis C healthcare. Int J Drug Policy. 2022 Dec;110:103875. doi: 10.1016/j.drugpo.2022.103875.
[27] Schulz TR, Kanhutu K, Sasadeusz J, Watkinson S, Biggs BA. Using telehealth to improve access to hepatitis C treatment in the direct-acting antiviral therapy era. J Telemed Telecare. 2020 Apr;26(3):180-185. doi: 10.1177/1357633X18806651.
[28] Halder A, Li VG, Sebastian M, Nazareth S, Tuma R, Cheng W, Doyle A. Use of telehealth to increase treatment access for prisoners with chronic hepatitis C. Intern Med J. 2021 Aug;51(8):1344-1347.

ADAPs are categorically eligible for the 340B Drug Pricing Program. This means that all clients eligible for and enrolled in an individual ADAP meet the 340B patient definition.[29] In addition to purchasing medications directly for clients, leveraging either up-front 340B discounts or back-end 340B rebates paid directly by manufacturers, ADAPs are eligible for rebates on partial-pay claims, whereby the ADAP pays either the medication deductible, co-payment, or co-insurance – either with or without ADAP payments toward the client's health insurance premium – in accordance with the Health Resources and Services Administration (HRSA) HIV/AIDS Bureau program guidance issued in 2005 and voluntary agreement terms executed with manufacturers.[30] This may generate additive revenue for the ADAP, specifically when rebate payments received from manufacturers exceed the program expenditures associated with insurance premium and cost-sharing payments associated with prescription drug coverage.

An individual may receive services from, and thus be considered a patient of, both an ADAP and another covered entity – an ADAP-funded insurance program client receiving HIV care and support services from a disproportionate share hospital (DSH) clinic, for example – and thus both covered entities would be eligible for the 340B discount. However, only one covered entity is permitted to receive the statutorily defined 340B price, by rebate or discount, for a patient's prescription. The ADAP may receive the 340B price through an up-front discount (direct purchase) or through a manufacturer rebate. Even when the other covered entity receives the up-front 340B discount, the ADAP is still eligible for any voluntary supplemental rebates (i.e., the difference between the 340B ceiling price and the voluntary sub-340B price, where applicable), assuming the requirements of the 2005 HRSA HAB program guidance and the voluntary manufacturer agreements are met.

ADAPs are expected to develop clear expectations, policies, and processes for coordinating 340B discounts, program income, and rebates on prescription drug fills for individuals who are 340B eligible patients of multiple 340B CEs, including the state or territorial ADAP, as to avoid duplicate discounts.

Child Sites

NASTAD wants to ensure that Congress differentiates between actual child sites and sub-recipients (or sub-grantees) and clarifies their differences in the statute. The relationship between HRSAand/or U.S. Centers for Disease Control and Prevention (CDC) federal grant recipients and their sub-recipients is wholly different from the parent-child relationship between hospitals and their outpatient clinics. Unlike outpatient clinics that are part of the hospital, sub-recipients are distinct entities from grant recipients and are not generally clinically or financially integrated.

[29] 61 Fed. Reg. 55158 (1996).
[30] HRSA HIV/AIDS Bureau, Guidance Letter to Title II ADAP Colleagues (Apr. 29, 2005).

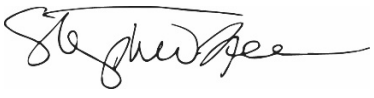
Further, direct grantees have no legal authority to direct subrecipient activities outside the grant program, and there is no legal ownership, affiliation, or organizational relationship between a direct grantee and its sub-recipient. As such, grantees are not "parents" of their sub-recipients. However, NASTAD wants to ensure that sub-recipients maintain full access to the rights and privileges of the 340B program. Therefore, NASTAD encourages Congress to clarify that sub-recipients are not child sites but nonetheless maintain their 340B eligibility as non-hospital covered entities.

Transparency

NASTAD appreciates stakeholder concerns about a lack of transparency from covered entities and believes that annual reporting requirements may be reasonable. However, NASTAD is concerned that new transparency guidance could be unnecessary for some covered entities and urges Congress to consider the potential burden that these requirements may have. Specifically, many federal grantees, including Ryan White HIV/AIDS Program recipients and subrecipients and ADAPs, are already subject to 340B program income and rebate expenditure and reporting requirements in accordance with their HRSA HIV/AIDS Bureau notices of award (NOA), and additional reporting requirements risk repetition or being administratively burdensome. NASTAD wants to ensure that grantees can use their limited capacity and resources to serve their communities and are not impeded by duplicative requirements. Therefore, NASTAD encourages Congress to ensure that new reporting requirements are compatible with grantees' and subgrantees' existing oversight procedures or to promulgate separate guidance appropriate for federal grantees.

We appreciate your attention and consideration of these recommendations. Please do not hesitate to contact me at (202) 434-8090 or by email at slee@NASTAD.org if you have questions related to these comments.

Sincerely,



Stephen Lee, MD, MBA, DHSM
Executive Director