July 28, 2023

The Honorable John Thune
511 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Debbie Stabenow
731 Hart Senate Office Building
Washington, DC 20510

The Honorable Shelley Moore Capito
172 Russell Senate Office Building
Washington, DC 20510

The Honorable Tammy Baldwin
709 Hart Senate Office Building
Washington, DC 20510

The Honorable Jerry Moran
521 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Benjamin Cardin
509 Hart Senate Office Building
Washington, DC 20510

Re: Senate Request for Information on the 340B Drug Pricing Program

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

On behalf of the National Association of Community Health Centers (NACHC), we thank the Senators for the opportunity to provide feedback on your efforts to create bipartisan solutions to improve the integrity and stability of the 340B program. NACHC is the preeminent national membership organization for Federally Qualified Health Centers (also known as FQHCs or Community Health Centers). FQHCs are federally funded or federally supported nonprofit, community-directed provider clinics serving as a health home.

Since its establishment in 1992, the 340B program has been a critically important program for Community Health Centers. It allows Community Health Centers to purchase outpatient medications at significantly reduced costs, enabling them to provide affordable discounted, or free medications to uninsured and underinsured patients. By law and statute, health centers are required to reinvest every penny of 340B savings into activities that expand access for their patients. These savings are used to meet the unique needs of their communities, such as dental care, behavioral health, specialty care, translation services, food banks, housing support, and copay assistance programs. When health centers lose 340B savings, our 30 million patients suffer irreversible consequences.

As health centers’ concerns have grown about the viability of the 340B program, the National Association of Community Health Centers (NACHC) has taken a proactive approach to finding common ground with all stakeholders in the program. Specifically, the Alliance to Save America’s 340B Program (ASAP 340B)\(^1\) was formed to support comprehensive legislative reforms that work to ensure the 340B Drug Pricing Program is put on a sustainable path for the future and to benefit patients and true safety-net providers. Our coalition has developed principles for 340B reform that would require changes applicable to all stakeholders in the program. We

\(^1\) [https://www.asap340b.org/](https://www.asap340b.org/)
thank you for your interest in the 340B program and in developing “bipartisan policy solutions that would ensure the program has stability and oversight to continue to achieve its original intention of serving eligible patients.”

ASAP 340B members are a partnership of Community Health Centers, patient, provider, and consumer advocates, and leaders from the biopharmaceutical industry. We are all working to ensure the 340B program supports true safety-net providers and the communities they serve. Our members have not always seen eye-to-eye on how to improve the 340B program, but we have come together now because of the urgent need for action to ensure the program’s long-term viability. As we continue to grow the alliance, it will reflect the voices of a broad range of safety-net providers who support strengthening the 340B program. ASAP 340B has an open door to all 340B stakeholders who are ready to discuss how to improve and modernize the 340B program for all stakeholders.

NACHC’s responses to your specific questions are below. In general, like our coalition, we support an approach consistent with ASAP’s principles, which includes reforms across a range of policy areas to increase program integrity, with statutory changes that codify critical provisions necessary to better tailor the program to benefit rural and safety-net providers and their patients and curb abuse. We urge you to recognize that a broad set of reforms are needed to realign the 340B program, and we stand ready to provide ideas and technical feedback to support a legislative process.

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?

NACHC understands that HRSA will need adequate resources to implement robust and comprehensive oversight for the 340B program, and we are open to ideas for feasible and non-burdensome policies that would provide these resources. Over the last 30 years, the reach of the 340B program has expanded to more than 50,000 covered entity sites. And while the program has grown substantially, requirements and resources to protect program integrity have not kept pace. Covered entities, like health centers, rely on the Health Resources and Services Administration’s (HRSA) Office of Pharmacy Affairs (OPA) to provide up-to-date guidance and technical assistance in running a successful 340B program. NACHC supports policies that will provide HRSA with adequate resources to meet current programmatic needs and future demands related to current efforts to modernize and reform the 340B program. Resources can include additional funding to ensure OPA has adequate staffing to support increased oversight and program integrity-related activities.

NACHC supports Congress in strengthening the 340B statute by providing clarity on essential components of the program to support HRSA’s programmatic oversight. HRSA will need targeted rulemaking authority to implement specific legislative provisions, but only as part of other

holistic reforms to the program. We believe there is an appropriate balance between Congress’ role in updating the 340B program and HRSA’s role in enforcing new requirements. As we have seen over the last three years with the contract pharmacy restrictions, we believe it’s essential for Congress to continue its role in establishing the bounds of the 340B program, and at the same time, it’s also critical for HRSA to have the authority to enforce and interpret the 340B statute as new challenges arise.

Additionally, health centers in the 340B program encounter several unique operational challenges as the programmatic requirements intersect with the federal health center Program. NACHC recommends Congress consider policies that provide resources to HRSA to facilitate more technical assistance on operational and program integrity requirements that impact 340B federal grantees and their respective federal grant programs. We encourage more internal coordination between federal grant programs to minimize administrative burdens while pursuing the goal of serving safety-net patients.

Lastly, NACHC supports additional and improved program integrity measures to help enforce needed program reforms and recently enacted Inflation Reduction Act (IRA) changes. For instance, we believe HRSA should conduct any rulemaking jointly with the Centers for Medicare & Medicaid Services (CMS), as appropriate, to ensure that any new rulemaking (if needed) complements CMS’s efforts to operationalize the IRA’s provisions related to 340B and the existing statutory prohibition on 340B/Medicaid duplicate discounts.

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

First, NACHC appreciates this request for information (RFI) and taking steps to ensure the 340B program has the stability and oversight to achieve its original intent of serving eligible patients. NACHC supports comprehensive legislation that includes changes that provide certainty in contract pharmacy arrangements and ensure continued access to affordable medications for underserved and vulnerable patients. Specifically, we recommend amending the 340B statute to explicitly include contract pharmacy arrangements and establish the appropriate program integrity measures. Taking from lessons learned over the last three years, NACHC supports a balanced approach to creating clear and concise contract pharmacy arrangement policies that address all 340B stakeholders’ concerns. After years of litigation, health centers support amending the 340B statute to create maximum clarity in the 340B program.

Since 1992, safety-net providers, like health centers, have relied on the 340B program to expand access to pharmaceutical services. Today, over 40% of health centers do not have the financial means to open and maintain an in-house pharmacy.³ Additionally, nearly 90% of health centers use contract pharmacies to expand the reach of their 340B program and meet their communities’ needs. With over 90% of health center patients at 200% or below the Federal Poverty Level⁴, it is important that health center patients can access affordable medications without any additional barriers related to transportation, child care, or work obligations. Health centers prioritize addressing social drivers of health that impact our patients’ ability to access affordable


health care services and medications. NACHC recommends legislation that addresses the ambiguity in the treatment of drugs dispensed through contract pharmacies that protects patient choice and creates dependable access to the medications they need.

To date, health centers have nine manufacturers restricting shipments of 340B-priced drugs to contract pharmacies. The current restrictions have impacted the most vulnerable patients and have left some uninsured patients without access to discounted or free medications. Health centers rely on the 340B price to provide these discounted medications, and without it, they do not have the resources to absorb full-price medication costs. Furthermore, the loss of 340B savings impacts the health centers’ ability to provide affordable services that improve and maintain health outcomes for underserved patients. NACHC strongly urges Congress to implement comprehensive 340B policies that ensure health centers maintain the flexibility to establish contract pharmacy arrangements that meet the needs of their communities. These policies can include patient affordability requirements for eligible patients’ access to medications, particularly for those living in underserved areas and rural communities.

In partnership with key 340B stakeholders as part of ASAP 340B, we encourage Congress to consider how contract pharmacy arrangements could be permitted in specific circumstances and as part of the broader 340B program reforms listed below. In general, and consistent with our coalition principles, contract pharmacies should be permitted for:

1. Covered entities, including both hospitals and grantees, that serve medically underserved area and/or medically underserved populations; and

2. Grantees providing care to a specific population, such as patients with HIV or chronic illness, for qualified prescriptions provided within the scope of the grantee’s 340B-qualifying HHS grant.

Contract pharmacies should also be located near the covered entity’s service area and be required to honor any applicable sliding fee scale or other affordability benefits for patients. It’s also critical for all covered entities and contract pharmacies to maintain comprehensive policies and procedures that prevent diversion and duplicate discounts. The other areas of broader 340B reform that should be included with a contract pharmacy policy include:

- **Patient affordability**: NACHC supports policies that require covered entities to meet basic standards to increase access to affordable medications for patients needing financial assistance. Additionally, new requirements should extend to prescriptions filled at contract pharmacies to ensure for-profit entities, like retail pharmacies, comply with the intent of the 340B program.

- **Patient definition**: HRSA’s 1996 patient definition is overly broad and needs to be updated to safeguard the integrity of the program and to better serve vulnerable populations. A statutory definition of “patient” should create more objective and auditable standards to assess whether a prescription qualifies for a 340B discount. We recommend strengthening and modernizing the patient definition to resolve the

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confusion over patient eligibility. We support legislation that requires all covered entities to maintain consistent responsibility for the care of eligible patients, as demonstrated through improved and auditable record-keeping requirements. In general, auditable records should be able to establish a connection between the patient’s eligible prescriptions and the medical condition for which an individual sought care from the covered entity or from the covered entity managed on behalf of the patient in the context of permitted referrals.

- **Updated entity eligibility rules:** While some covered entities are focused on care for safety net and rural populations, evidence suggests that others do not share that commitment. Any Congressional efforts to modernize the 340B program should be made in a way that helps put the program on a more sustainable path for underserved and vulnerable patients, safety net providers and rural hospitals, such as critical access hospitals (CAHs) and sole community hospitals (SCHs).

- **Claims data requirements and role of a clearinghouse:** To facilitate verification of 340B claim eligibility, the 340B program needs a neutral, independent clearinghouse capable of receiving Medicare, Medicaid, and commercial claims and 340B utilization data. We discuss this in greater detail below in Question 4.

- **Insurers and For-Profit Stakeholders’ Involvement in 340B:** Congress should include safeguards to ensure that 340B discounts support safety-net providers and their vulnerable patients. These savings should not be diverted for private benefit or other purposes not closely tied to a covered entity’s safety net mission. Congress should prevent pharmacy benefit managers (PBMs) and insurers from siphoning off 340B savings by lowering reimbursement for prescriptions with 340B discounts. Additionally, pharmacies and other for-profit third parties should have limits placed on the fees they can charge for 340B-related services to ensure covered entities and their patients receive most of the savings associated with the program.

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?**

NACHC supports Congress’ current work to address PBMs and other for-profit companies’ role in the health care system. For years, PBMs have taken advantage of the lack of clarity in the 340B program by implementing discriminatory business practices that harm true safety-net providers. Vertically integrated health care companies use their role as PBMs and contract pharmacies to siphon 340B savings intended to benefit safety-net providers and their patients. NACHC strongly encourages Congress to pass the PROTECT 340B Act (H.R. 2534), which addresses PBMs’ participation in and discriminatory treatment of 340B covered entities.

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Health centers believe the savings generated from the 340B program are intended to support safety-net providers and vulnerable patients and should not be diverted for private benefit or other purposes not closely tied to a covered entity’s safety-net mission. Several policies should be considered to better direct safety-net funding to providers dependent on the 340B program to stretch scarce federal resources. Today, more than half of the top 20 companies on the Fortune 500 generate profit from the 340B program— and 340B represents a significant source of profit for these large conglomerates. In fact, in their official filings with the U.S. Securities and Exchange Commission (SEC), two of the largest 340B contract pharmacies, CVS and Walgreens, both reported that changes in 340B contract pharmacy arrangements and utilization could impact their profits so significantly that it would result in a material change to their financial statements and affect their ability to exceed their earnings projections.

Until Congress creates statutory requirements for PBMs and vertically integrated health care companies that interact with the 340B program, covered entities will continue losing critical savings that should be flowing back into patient care and underserved communities. NACHC supports policies that ensure PBM-owned pharmacies and other for-profit third parties limit fees and other 340B-related administrative costs that siphon covered entities’ savings. Additionally, PBMs and insurers should be prevented from dipping into 340B revenue intended for safety-net providers by lowering reimbursement for 340B-discounted medicines. Furthermore, PBMs and insurers should not be permitted to prevent covered entities and their contract pharmacies from providing 340B claims data to third parties or from reducing copays for low-income insured patients who receive 340B drugs.

Additionally, considering that approximately half of health center patients are Medicaid beneficiaries, NACHC encourages Congress to monitor how current Medicaid policy changes impact the 340B program. Specifically, we are concerned with the growing number of states limiting covered entities’ ability to generate 340B savings in Medicaid Managed Care. While we recognize states have the existing authority to determine 340B reimbursement for Medicaid, it is important policy changes do not impact safety-net providers’ ability to maintain access to affordable medications and health care services. As states make changes to their Medicaid programs, it is critical for Congress to understand the impact on 340B covered entities and their ability to stretch scarce federal resources to serve vulnerable patients.

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

NACHC supports Congress’ and HRSA’s goals to increase accountability in the 340B program. To facilitate verification of 340B claims eligibility, the 340B program needs a neutral, independent clearinghouse capable of receiving Medicare, Medicaid, and commercial claims data. Establishing a national clearinghouse run by a neutral third party will also strengthen program integrity and create transparency. It is important that the clearinghouse is run by a neutral party to foster trust from all 340B stakeholders. This neutral clearinghouse is a step toward building

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accountability and coordination for covered entities without increasing administrative burdens for safety-net providers. Data provided to a clearinghouse would be deidentified and subject to safeguards that prohibit use for marketing or other unauthorized purposes.

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 health care stakeholders greater confidence in its oversight?**

NACHC believes an existing challenge in the 340B program is the lack of requirements that ensures all covered entities are participating in the program in the same manner by providing access to affordable medications and services to underserved and vulnerable patients. Health centers serve as model stewards of the 340B program. Due to the lack of standards for how covered entities use the program, there are stark differences among covered entities, and not all use the program to expand access to care for underserved patients. To create more accountability in the 340B program, NACHC recommends Congress adopt policies that create baseline standards for all safety-net providers in the 340B program. These standards should ensure all covered entities have programs and policies that support access to affordable and accessible health care services and medications for underserved and vulnerable patients.

Much of the variability between covered entities is rooted in the different federal grant program requirements grantees face compared to the lack of similarly strict requirements for hospital covered entities. For instance, typically, federal grantees are required to reinvest program income back into services to support the purpose of their federal grant. Based on this separate statutory requirement, federal grantees reinvest 340B savings back into patient care, including affordable medications, medical services, and community-based services. Additionally, all federal grantees are required to complete scope of projects or reporting in relation to their grant funding. Federal grantees also have transparency requirements that provide insight into patient characteristics, services offered, use of program funds, and other essential programmatic functions. Hospital-covered entities do not have any such requirements. As such, NACHC encourages Congress to set stricter standards for 340B hospitals and their child sites to ensure that 340B serves the goals of a safety net program.

Increasing confidence in the 340B program starts with requiring all covered entities to have patient affordability programs that are accessible to patients in need of affordable medication and health care services. Building off existing federal grant requirements, all covered entities should provide support to ensure that low-income and vulnerable patients they serve can afford their medicines. This requirement under the 340B program should be consistent with other federal grant program requirements and could include having a sliding fee program. Similarly, 340B hospitals should have a sliding fee scale for medicines that, at a minimum, applies to uninsured patients and patients under 200% of the federal poverty level with private insurance. This sliding fee scale policy should have auditable records, policies, and procedures and be accessible to all eligible patients regardless of how they fill their prescriptions. To this end, covered entities should also be required to offer prescription discount programs through their contract pharmacy arrangements.

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10 § 1470.25 Program income
NACHC recommends Congress evaluate and amend covered entity eligibility to ensure that only true safety providers are participating in the 340B program. As the health care system has changed, access to affordable and comprehensive health care services and medications has remained challenging for underserved and vulnerable communities. It is important that all covered entities execute the mission of the 340B program to improve access to affordable medications and services for the most disadvantaged and vulnerable 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?**

Public reporting of basic information is critical to maintain the long-term integrity of the program and facilitate appropriate oversight. This will allow HRSA to oversee the 340B program more effectively and efficiently. It is key that all covered entities are held to the same transparency standards to improve program oversight and program integrity.

We believe all covered entities should be required to report basic information to HHS about their involvement in the 340B program, including the total acquisition cost and reimbursement for 340B discounted medicines, payer mix, and the total amount spent subsidizing out-of-pocket costs for patients receiving 340B discounted medicines. NACHC supports transparency and reporting requirements that do not infringe on a covered entity’s discretion to use their 340B savings in ways that benefit their communities’ unique needs. Health centers can stretch their scarce federal resources because of the flexibility of 340B savings. NACHC encourages Congress to adopt policies that preserve health centers’ ability to choose how to use 340B savings ranging from operational costs to medical services and/or medications.

NACHC appreciates your interest in the 340B program. We hope that the ideas we presented above help in your efforts to identify meaningful bipartisan policy solutions. We look forward to working with you on efforts to modernize the 340B program and stand ready to provide further assistance. If you have any questions, please contact me at jdunn@nachc.org, or (703) 244-3799.

Sincerely,

Joe Dunn
Senior Vice President, Public Policy and Research
National Association of Community Health Centers
Supportive Organizations

Primary Care Associations

- California Primary Care Association
- Colorado Community Health Network
- Health Center Association of Nebraska
- Health Center Partners of Southern California (HCP)
- Illinois Primary Health Care Association
- Indiana Primary Health Care Association
- Iowa Primary Care Association
- Maine Primary Care Association
- Michigan Primary Care Association
- Minnesota Association of Community Health Centers
- Community Health Center Association of Mississippi
- Montana Primary Care Association
- New Jersey Primary Care Association
- Oklahoma Primary Care Association
- Oregon Primary Care Association
- Pennsylvania Association of Community Health Centers
- Puerto Rico Primary Care Association
- South Carolina Primary Health Care Association
- Tennessee Primary Care Association
- Texas Association of Community Health Centers
- Washington Association for Community Health

Community Health Centers

ACACIA Network/ JCAP
Access Community Health Network
Access Health
Adelante Healthcare
Ajo Community Health Center dba Desert Senita Community Health Center
Alcona Citizens for Health, Inc.
Alluvion Health
Ammonoosuc Community Health Services
APLA Health
Appalachian Mountain Community Health Centers
Asian Human Services Family Health Center, Inc.
Aspire Indiana Health
Athens Neighborhood Health Center

Infant Welfare Society Family Health
Jane Pauley Community Health Center
Jessie Trice Community Health System, Inc.
Keystone Rural Health Center
Kiamichi Family Medical Center
Kinston Community Health Center
Klamath Health Partnership, Inc.
Knox Winamac Community Health Centers, Inc.
Kokua Kalihi Valley Comprehensive Family Services
Ko'olaua Health Center
Lake Superior Community Health Center
LifeSpring, Inc.
Little River Medical Center
Baltimore Medical System, Inc.
Bay Area Community Health
Beaufort Jasper Hampton Comprehensive Health Services, Inc.

Betances Health Center
Bighorn Valley Health Center, Inc.
Blue Ridge Community Health Services
Bluestem Health
Bond Community Health Center, Inc.
Borrego Health
Boston Health Care for the Homeless Program
Brockton Neighborhood Health Center
Brownsville Community Health Center
Careteam Plus, Inc.
Carevide
Caring Hands Healthcare Centers, Inc.
Carolina Health Centers, Inc.
Center for Family Health
Centerpoint Health
Centerville Clinics, Inc.
Central Counties Health Centers, Inc.
Central Florida Health Care, Inc.
Central Oklahoma Family Medical Center
Central Texas Community Health Centers dba CommUnityCare
Centro De Servicios Primarios De Salud, Inc.
Centro San Vicente
Charles B. Wang Community Health Center
Chase Brexton Health Care
Community Health Center
Center for Health Care Strategies

Lynn Community Health Center
Manet Community Health
Maple City Health Care Center

Marana Health Center
Marias Healthcare Services, Inc.
Mariposa Community Health Center
Maryland Community Health System
Metro Community Health Centers
Miami Beach Community Health Center
Monongahela Valley Association of Health Centers, Inc.
Morovis Community Health Center, Inc.
Morton Comprehensive Health Services, Inc.
Mosaic Health, Inc.
Mount Vernon Neighborhood Health Center
Mountain Family Health Centers
Mountain People's Health
Mountain Valleys Health Centers
Multi-Cultural Health Evaluation Delivery System, Inc.
MVA Health Centers, Inc.
My Care Health Center
Neighborhood Health
Neighborhood Health Center
Neighborhood Health Center of WNY

Neighborhood Healthcare
Neighborhood Improvement project, Inc.
DBA Medical Associates Plus
Neighborhood Medical Center, Inc.
Neighborhood Outreach Access to Health (NOAH)
New Hanover Community Health Center
DBA MedNorth Health Center
New River Health Association
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Denver Community Health Services
Desert Senita Community Health Center
East Arkansas Family Health Center
East Central Oklahoma Family Health Center, Inc.
Eisner Health
El Rio Health
Elica Health Centers
Empower U Community Health Center
Esperanza Health Centers
EXCELth. Inc.
Fair Haven Community Health Clinic
Fairfax Medical Facilities, Inc.
Family and Medical Counseling Service, Inc.
Family Christian Health Center
Family Health Care Centers of Greater Los Angeles
Family Health Center of Marshfield, Inc.
Family Health Center of Southern Oklahoma
Family Health Center of Worcester
Family Health Centers
Family Health Centers of San Diego
Family Health La Clinica
Family Health Network of Central New York, Inc.
Family Health Services of Darke County, Inc.
Family Health Services of Darke Community, Health, Inc.
Finger Lakes Community Health
First Choice Primary Care
Florida's Community Health Center’s Inc.
Friend Family Health Center
Georgia Highlands Medical Services
Redwood Coast Medical Services
Regional Health Care Affiliates DBA Health First Community Health Center
Resources for Human Development/Family Practice & Counseling Network
Roanoke Chowan community Health Center
Rocking Horse Community Health Center
Rogue Community Health
Sadler Health Center
Salud Family Health
Salud Integral en la Montaña, Inc.
Sandhills Medical Foundation, Inc.
Scenic Rivers Health Services
Scranton Primary Health Care Center, Inc.
Sea Mar Community Health Center
Shasta Community Health Center
Shawnee Christian Healthcare Center
Shortgrass Community Health Center
SIHF Healthcare
Siouxland Community Health Center
Solo Pharmacy Consulting
South Central Primary Care Center, Inc.
Southeast Alabama Rural Health Associates
Southeast Community Health Sys’ tems
Southern Tier Community Health Center Network/Universal Primary Care
Spring Branch Community Health Center
St. James Health & Wellness
Stedman-Wade Health Services, Inc.
Stigler Health & Wellness Center, Inc.
Stony Creek Community Health Center/Stony Creek Pharmacy
Su Clinica
Sunset Community Health Center
Sunset Park Family Health Center at NYU Langone
Tandem Health South Carolina
Whatley Health Services, Inc.
Whiteside County Community Health Clinic
Winding Waters Medical Clinic
Windrose Health Network, Inc.
WomenCare, Inc. DBA FamilyCare Health Centers
Yakima Neighborhood Health Services
Zufall Health Center, Inc.