NATIONAL ASSOCIATION OF Community Health Centers

June 13, 2022

340B: A Critical Program for Health Centers

According to congressional report language from 30 years ago, the 340B Drug Pricing Program was created to assist safety-net providers "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Since then, this program has become critically important to 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 invest *every penny* of 340B savings into activities that expand access for their patients. The 340B program generates savings that are reinvested in the health center to meet the unique needs of their communities like dental care, behavioral health, specialty care, translation services, food banks, housing support, and co-pay assistance programs.

For years, pharmacy benefit managers (PBMs) have taken advantage of the lack of federal oversight on their participation in the 340B program. PBMs determine which pharmacies will be included in a prescription drug plan's network and how much said pharmacies will be paid for their services. The 340B statute does not protect health centers from PBMs' discriminatory contracting practices, which transfers 340B savings away from the health center through unpredictable fees, restrictive contracting terms, and aggressive auditing tactics to lower reimbursement. Unfortunately, PBMs are not the only entity successfully blocking health centers from retaining 340B savings.

In August 2020, pharmaceutical manufacturers launched an aggressive attack against 340B covered entities by refusing to ship 340B-priced medications to local pharmacies that expand the reach of health centers, known as contract pharmacies, unless they turned over claims data. While fighting on the front lines of the COVID-19 pandemic, pharmaceutical manufacturers decided to attack safety-net providers serving the most vulnerable and at-risk communities. Across the country, health centers serve 17.5 million people living in poverty, 2.9 million people 65 and older, 18.5 million people of minority background, and 1.3 million people experiencing homelessness. In 2020, more than 90% of health center patients were at or below 200% of the Federal Poverty Level (FPL). 340B savings create the ability for health centers to keep their doors open when they need flexible funding to meet the unique needs of their communities.

All health centers should be able to participate in the 340B program. Congressional intent behind the statute makes it clear that the 340B program was created to include safety net providers that needed additional resources to provide pharmacy services. Many health centers do not have the financial resources to support an in-house pharmacy. Contract pharmacies serve as an extension of health centers, increasing access for patients and ensuring they can receive discounted medications without creating additional barriers. When health centers lose 340B savings, 29 million patients suffer irreversible consequences. Congress must act to protect the 340B program for health centers and their patients.

This report dives into 340B issues impacting Community Health Centers and their patients. It details a recent NACHC survey focused on 340B and contract pharmacy usage and how community health centers and their patients benefit immensely from the savings. The report also outlines recommended political and administrative actions that NACHC and health centers will take to protect the 340B program that is currently in jeopardy due to drug manufacturers and PBMs.

Key Findings:

- Over half (56%) of respondents have an in-house pharmacy, and **86% utilize contract pharmacies**, allowing individual health centers to serve hundreds of zip codes.
- 32% of respondents estimate that **more than half** of their patients would go without needed medications if they did not have access to 340B discounts.
    - 88% of respondents believe that **at least 10%** of their patients would go without needed medications if they did not have access to 340B discounts.
        - Nationally, this could translate to 3 million or more patients losing access to prescription drugs due to 340B program restrictions.
- Health center patients with diabetes, heart disease, and behavioral health needs rely on medications purchased through the 340B program more than any other patient population.
- **92% of respondents utilize 340B savings to increase access** for low-income and/or rural patients by maintaining or expanding services in underserved communities.
- Access to medication and services supported by the 340B program **positively impacts quality outcomes:** almost 90% of respondents report that their 340B program has led to improved medication adherence, clinical outcomes, and access to care.

Need for Action:

Health centers are caught in the middle of corporate greed between pharmaceutical manufacturers and PBMs, both of whom want a larger piece of health centers' 340B savings. Pharmaceutical manufacturers want contract pharmacy claims data to decrease millions of dollars of rebates paid to PBMs for preferential formulary placements. PBMs have a significant incentive to place expensive medications on their formularies to increase manufacturer rebates instead of considering the out-of-pocket costs for patients. Given the uncertain future of the 340B program threatens health centers' financial viability, Congress and the Administration need to implement solutions to address current issues and bolster protections to create a sustainable 340B program.

Legislative Fixes

- ***Passage of The PROTECT 340B Act:*** Health centers have long battled to retain their rightful 340B savings from PBMs, manufacturers, and health insurers. The PROTECT 340B Act, sponsored by Reps. David McKinley (R-WV) and Abigail Spanberger (D-VA), was introduced in July 2021 to create statutory accountability for PBMs and health insurers participating in the 340B program. This legislation creates much needed protections against PBMs' business practices, like pickpocketing health center 340B savings to make up for their lost revenue, and from health insurers in the commercial market, Medicare Part D, and managed care. The PROTECT 340B Act will prohibit health insurers and PBMs from redirecting health center 340B savings to their pocket, a practice that has increased

significantly over the last few years due to lack of regulation. Currently, there is no recourse when PBMs and insurers treat 340B pharmacies differently or lower their reimbursement for specific medications because of the pharmacy's 340B status. Therefore, it is crucial for Congress to pass this legislation, as it is currently the only 340B legislative vehicle to protect covered entities. The PROTECT 340B Act also addresses manufacturers' need for more transparency by utilizing a third-party neutral clearinghouse to review claims data to prevent Medicaid duplicate discounts. A clearinghouse will create the necessary guardrails to guarantee that covered entities can rightfully keep their 340B savings while making a good-faith effort to maintain transparency.

- ***Legislation Safeguarding 340B Contract Pharmacies:*** After a year of litigation and a series of appeals, covered entities need Congressional action to hold pharmaceutical manufacturers accountable for violating the 340B statute. Health centers need federal legislation requiring manufacturers to ship 340B price drugs to contract pharmacies, without any conditions or requirements. Even though Courts have recognized Congressional intent to include contract pharmacies in the 340B statute, it is critical for Congress to amend the 340B statute to expressly include contract pharmacies in the program. Contract pharmacies play an essential role for health center patients by meeting patients where they are in their community. Around 86% of health centers are impacted by manufacturer restrictions on contract pharmacies, and we need a permanent solution to stabilize the program.

- ***State Protections Against PBMs***: Legislation prohibiting PBMs from discriminating against 340B pharmacies has been successful in nearly two-dozen thus far. These laws are an essential step for health centers but have limited reach. Additional states should pursue action to protect health centers while awaiting consideration of a federal solution. This will ensure health centers receive the 340B savings they are entitled to, given the 340B statute, and protect the contract pharmacies they use to dispense discounted medications to their patients.

<u>Administrative actions</u>

- ***Continuation of the Administrative Dispute Resolution (ADR) Process:*** After waiting almost 10 years for the Department of Health and Human Services (HHS) to issue the Administrative Dispute Resolution rule, NACHC filed a lawsuit in December 2020 to push the agency to promulgate regulations and put forth a process to adjudicate 340B violations. Under the law, covered entities are prohibited from filing lawsuits against manufacturers for violating the 340B statute and can only use the ADR process. Once the ADR regulation was finalized, NACHC filed an ADR petition on behalf of the nation's Community Health Centers against drug manufacturers Elli Lilly, AstraZeneca, and Sanofi in January 2021 (the manufacturers restricting shipments to health center contract pharmacies at that time). To date, manufacturers have done everything in their power to impede the progress of our ADR petition and delay any relief for health centers. If this ADR panel finds that manufacturers "overcharged" health centers by refusing to ship 340B price medications to their contract pharmacies, this judgement will set important precedent for future 340B ADR petitions. As we anticipate the ADR panel to refer the manufacturers for civil monetary penalties, this will still not provide the financial relief Community Health Centers need.

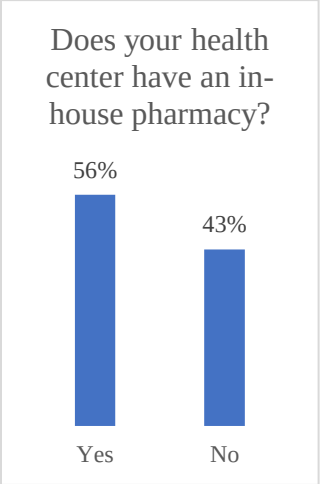
- ***Administrative Enforcement:*** Currently, HRSA has referred seven pharmaceutical manufacturers to the Office of Inspector General (OIG), to impose civil monetary penalties for violating the 340B statute by refusing to ship 340B priced medications to contract pharmacies. Under the previous administrations and the Biden Administration, HHS has expressed continued support to protect the 340B program. NACHC encourages the Biden Administration to explore all possible enforcement actions against manufacturers, which includes the pharmaceutical pricing agreement between HHS and each pharmaceutical manufacturer participating in Medicaid. Over the last few years, Community Health Centers and patients have experienced substantial losses while manufacturers continue to pad their bottom line by flouting 340B statute requirements. While we wait for endless litigation to resolve, the Biden Administration should utilize all their enforcement authority against manufacturers that continue to violate the 340B statute.

NACHC Survey Results

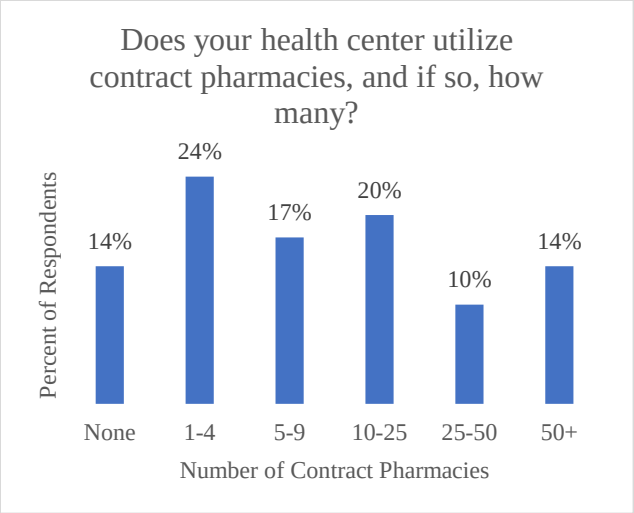
NACHC surveyed Federally Qualified Health Centers (FQHC) and Look-alike (LAL) organizations from April 11 to May 13, 2022. Survey respondents accurately represent the general health center patient population based on number of patients served, geographic location, and patient demographics (race/ethnicity and income level)[1]. The results from 302 health centers (297 FQHCs and 5 LALs) in 48 states are included.

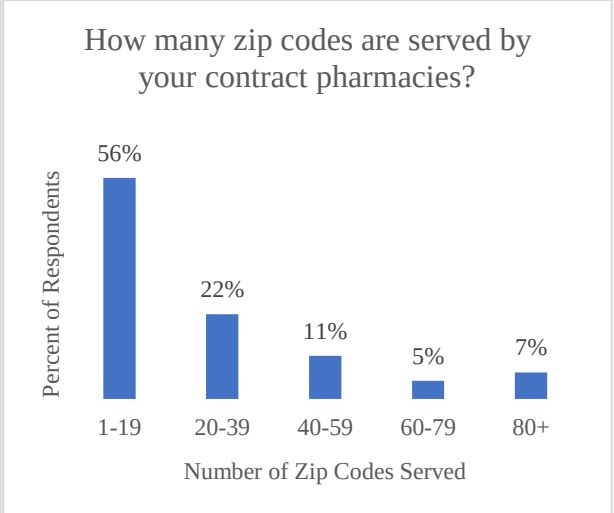
Health Center Patients Depend on Access to 340B Medications

Health centers provide access to affordable medication to millions of uninsured and underinsured patients through pharmacy services. Over half (56%) of survey respondents report having an in-house pharmacy, while **86% of respondents utilize contract pharmacies**. Contract pharmacies play a crucial role in increasing access for health center patients by easing transportation challenges or other barriers that prevent patients from picking up vital medications. Survey respondents reported being able to serve dozens of zip codes through their contract pharmacies, with some reporting services to one hundred or more zip codes. Health centers strategically utilize contract pharmacies to reach their patients, partnering with local independent pharmacies and nationally recognized pharmacy groups.



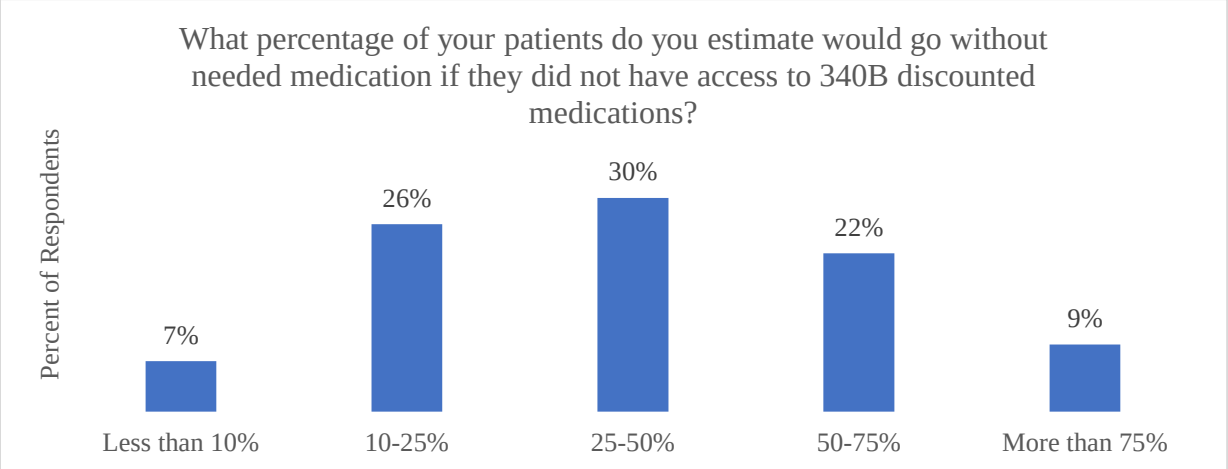
[1] To request survey respondent demographic data, please contact research@nachc.org





Ninety percent of health center patients are below 200% of the Federal Poverty Level, so the cost of care is often a barrier. These patients rely on 340B program discounts to afford their medications. Community Health Centers estimate that without access to affordable discounted or free medications, many of their patients would go without needed treatment:

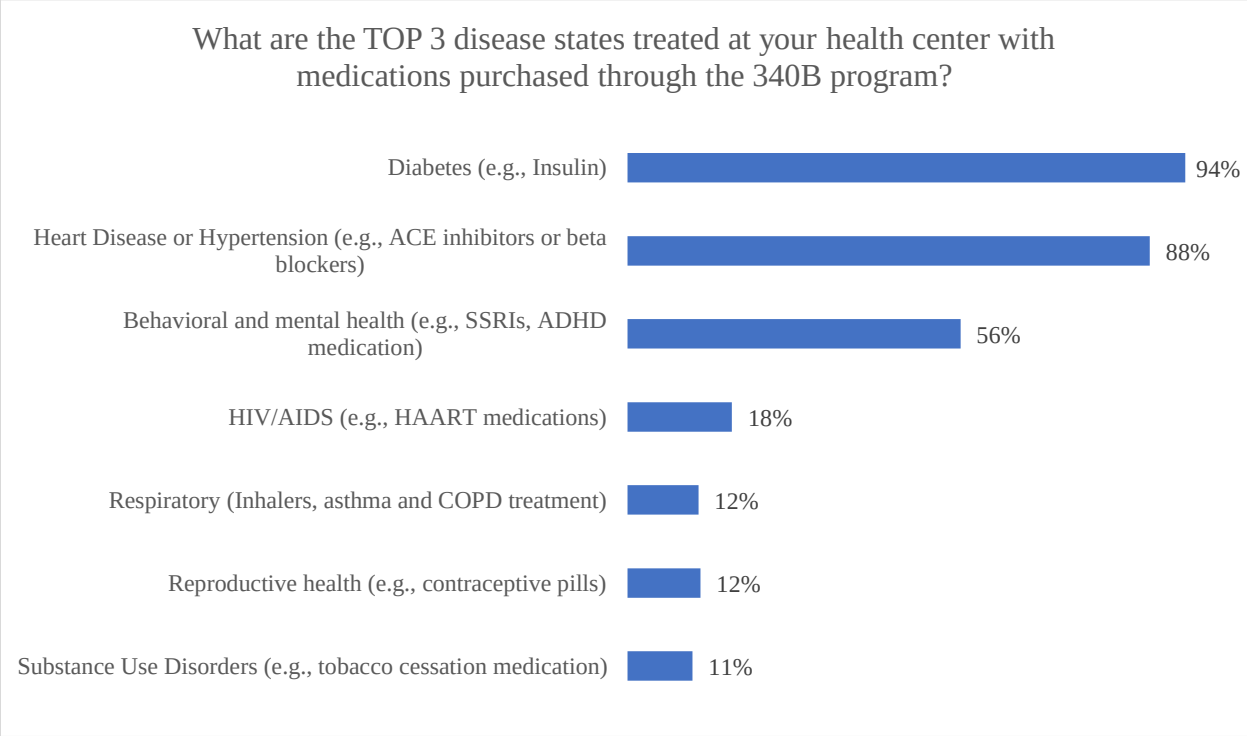
- 32% of respondents estimate that **more than half** of their patients would go without needed medications if they did not have access to 340B discounts.
- 88% of respondents believe that **at least 10%** of their patients would go without needed medications if they did not have access to 340B discounts.
    - Nationally, this could translate to 3 million or more patients losing access.



Patients with diabetes, heart disease, and behavioral health needs rely on medications purchased through the 340B program more than patients with other conditions. These were the top three disease states treated at health centers with medications purchased through 340B, followed by HIV/AIDS and respiratory illness. For many patients with diabetes, the price of insulin and diabetes care is unaffordable, even with insurance. As Congress debates a legislative solution to cap the price of insulin for privately insured patients, 340B enables health centers to keep insulin

affordable for uninsured and underinsured patients. The 340B program also allows health centers to provide psychotropic medications to many patients who otherwise would be likely to go without mental health treatment. With ever-rising rates of diabetes and heart disease, and the spike in mental illness tied to the COVID-19 pandemic, patients need treatment for these conditions now more than ever.

Many health centers explained that the top disease state treated with medications purchased through the 340B program were respiratory conditions such as asthma and COPD. Respondents described the importance of access to affordable inhalers, especially for children with asthma. Research shows that children with uncontrolled asthma have difficulty performing well in school and beyond.[2] Millions of people with asthma relied on health centers for treatment in 2020 alone.[3]



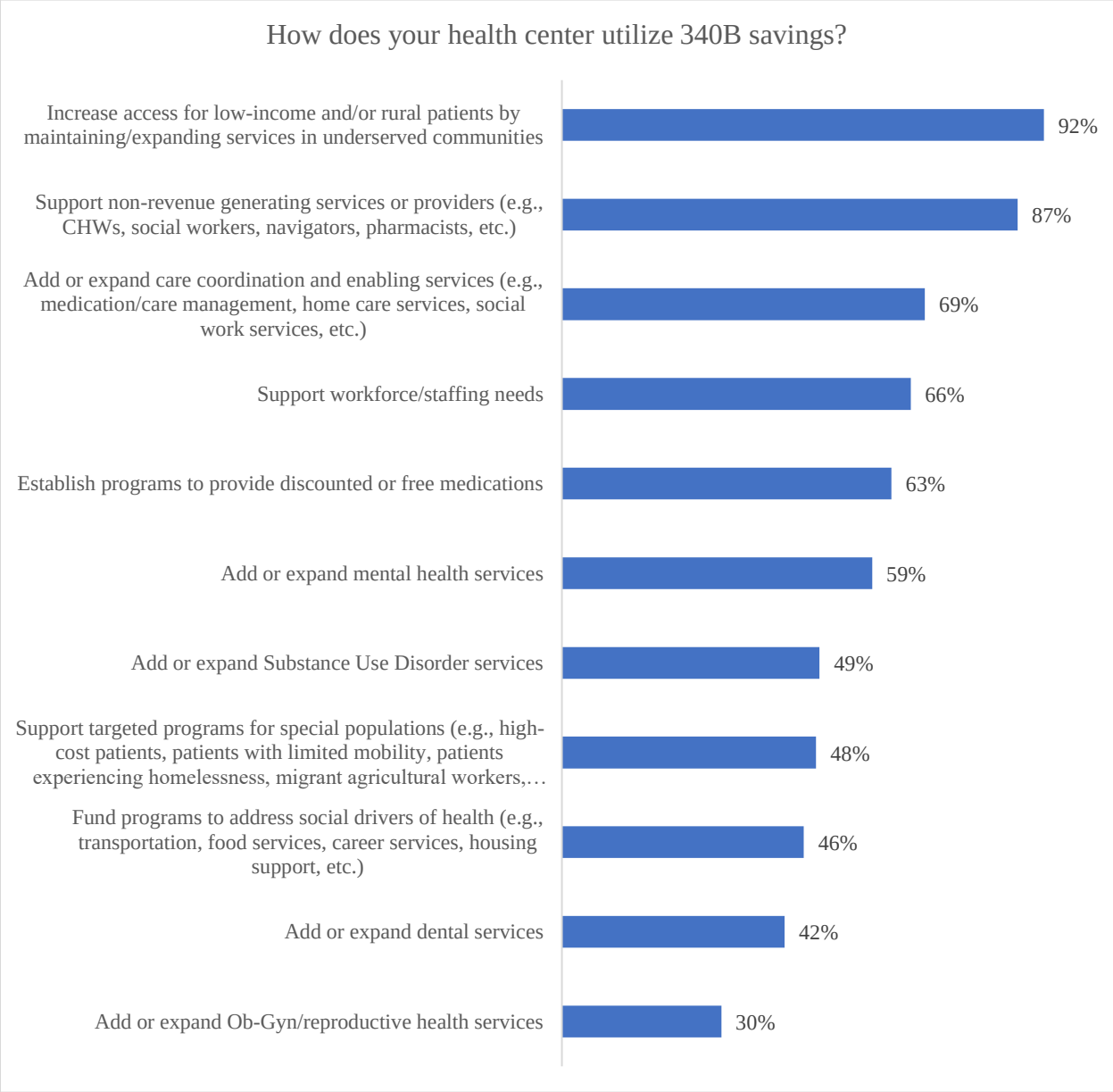
Community Health Centers Use 340B Savings to Expand Services and Improve Quality of Care

An overwhelming **92% of respondents utilized 340B savings to increase access for low-income and/or rural patients** by maintaining or expanding services in underserved communities. Health centers also use savings to expand comprehensive clinical and enabling services they otherwise may be unable to support, such as non-billable services and providers (87%) and care coordination or enabling services (69%). Many essential health services are not billable through public or private insurance, and health centers must find creative ways to maintain them while operating on razor-thin margins. An integrated care team that includes non-

[2] Koinis-Mitchell D, Kopel SJ, Farrow ML, McQuaid EL, Nassau JH. Asthma and academic performance in urban children. Ann Allergy Asthma Immunol. 122 (2019) 471-477. DOI: https://doi.org/10.1016/j.anai.2019.02.030

[3] 2020 Uniform Data System. Bureau of Primary Health Care, HRSA, DHHS

billable providers (such as clinical pharmacists, Community Health Workers, and Licensed Clinical Social Workers) has been shown to improve health outcomes and reduce overall costs.[4]

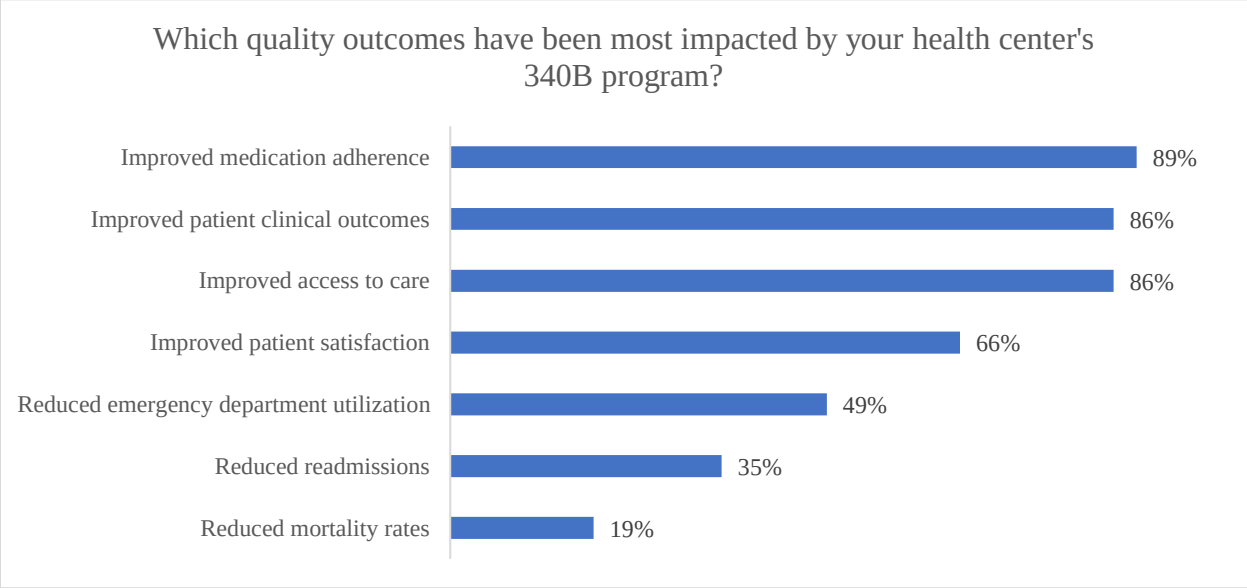


Access to medication and services supported by the 340B program has a positive impact on patient health outcomes. 89% of survey respondents report that their 340B program has led to improved medication adherence, and 86% report both improved clinical outcomes and improved access to care. Nearly half (49%) of respondents said their 340B program led to reduced emergency department utilization.

These improved patient health outcomes result from health centers using 340B savings to meet the unique needs of their patient populations through affordable medications and comprehensive services. A health center patient with diabetes who has access to 340B program discounts may benefit from affordable access to insulin and other needed medication, and also benefits from

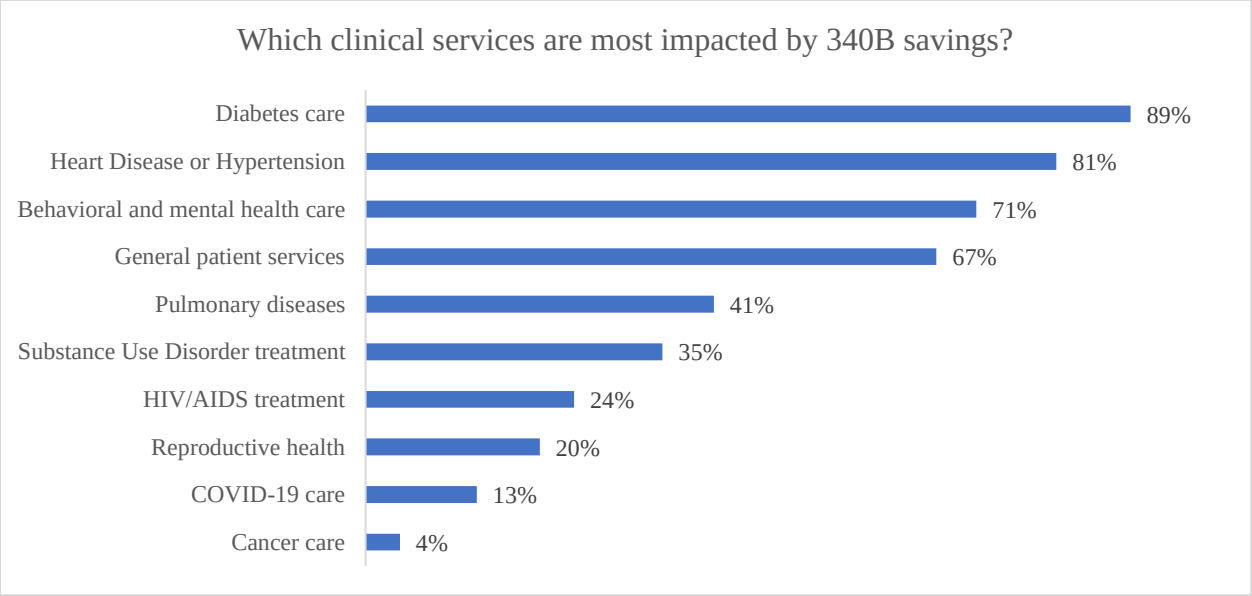
[4] Bodenheimer T. Building Teams in Primary Care: Lessons from 15 Case Studies. California HealthCare Foundation Report (2007)

access to regular primary care, a clinical pharmacist to aid with medication management, a nutrition program to optimize their diet, and education to help the patient manage their diabetes. Combining these services leads to improved patient health and, by doing so, reduces the long-term cost and burden of disease progression on the health system. 340B program discounts represent a small fraction of pharmaceutical company finances, in contrast to the immense cost savings of reduced emergency department utilization[5] and reduced readmissions that result from health centers leveraging 340B savings.

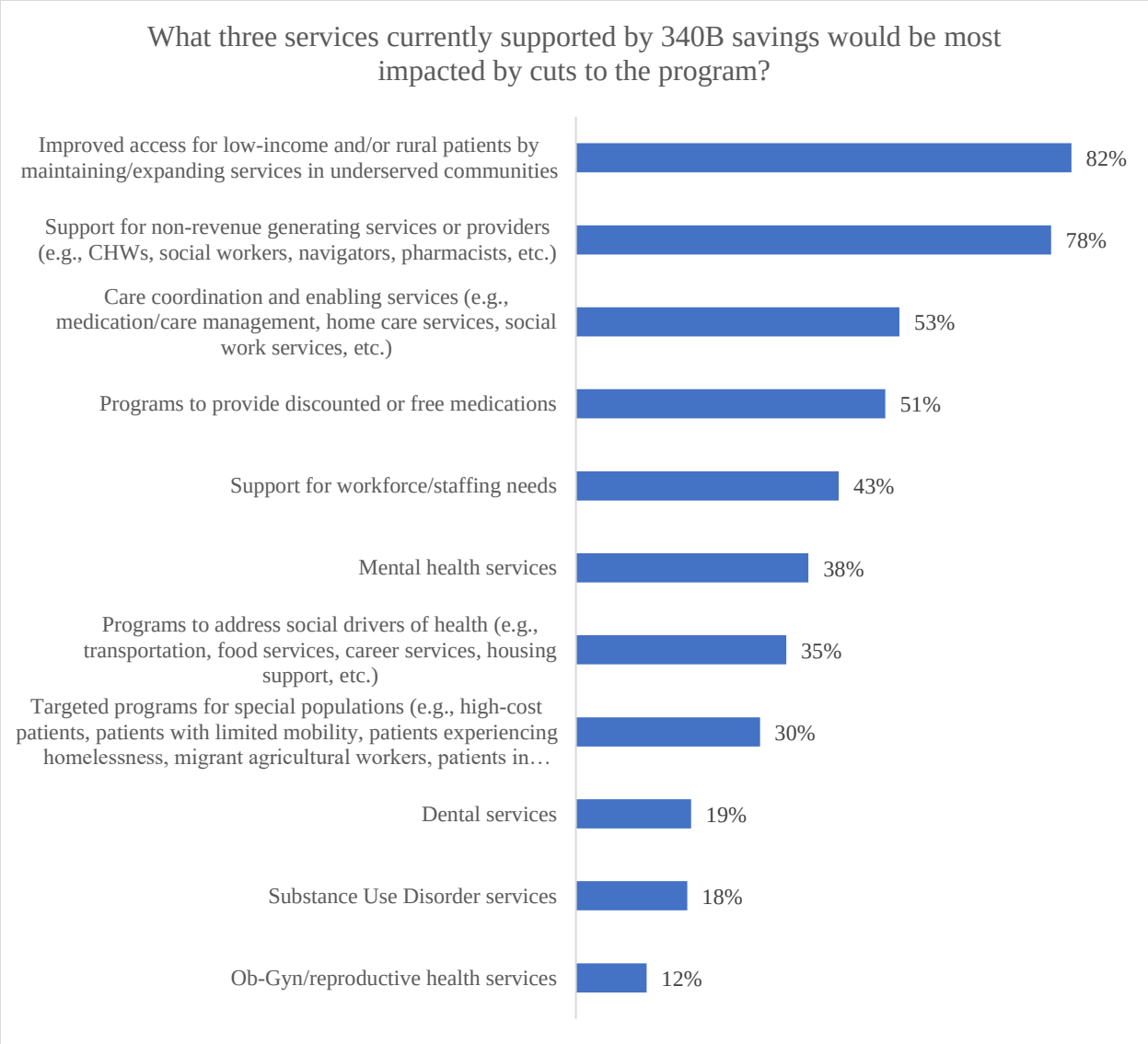


Health centers also rely on 340B program savings to maintain core clinical services. The clinical services most impacted by 340B savings are diabetes care, heart disease or hypertension treatment, behavioral and mental health care, and general patient services. Health centers operating on thin margins require these savings to maintain essential clinical functions, hire sufficient staff, and support operations.

[5] Weinick RM, Burns RM, Mehrotra A. Many emergency department visits could be managed at urgent care centers and retail clinics. Health Aff (Millwood). 2010;29(9):1630-1636. doi:10.1377/hlthaff.2009.



Many critical health center services are at risk because of manufacturers' failure to comply with 340B guidelines. 82% of respondents said that access for low-income and/or rural patients would be negatively impacted, as 340B savings currently support the maintenance of services in medically underserved communities. Non-billable providers and enabling services were reported to be vulnerable to cutbacks according to 78% and 53% of respondents, respectively. Finally, many health centers anticipate cuts to mental health, dental, and substance use disorder services.



Conclusion

The 340B program creates savings that enable health centers to provide high-quality and affordable care to the most vulnerable and underserved communities. **Health centers are the largest primary care network across the country and the safety-net for millions of vulnerable patients in underserved communities. Yet, their mission goes beyond health care and extends to services that improve overall quality of life. Central to that mission is the 340B program.** It promotes health equity by expanding access to patients in underserved communities by creating savings to address social determinants of health like transportation, food insecurity, life skills training, and social support services. 340B savings fill in the gaps to better meet community and patient needs. **Restrictions placed on the 340B program are chipping away at health centers' financial stability.**

By siphoning off 340B savings, private for-profit entities, such as drug companies and PBMs, impacts care for millions of health center patients. For example, a patient managing diabetes is impacted by contract pharmacy restrictions because they could lose access to the

sliding fee program discount available at the contract pharmacy near their home, and the health center could be forced to reduce access to education and care management. This **could lead to increased co-morbidities, increased emergency department utilization, and increased lifetime costs for health care.** The contract pharmacy restrictions combined with PBMs' discriminatory contracting practices jeopardize patients' health and wellbeing and the health centers that serve them.

These reasons make it more important now more than ever to take deliberate actions, both legislatively and administratively, to protect the 340B program from PBMs and pharmaceutical manufacturers.

Methodology

The National Association of Community Health Centers (NACHC) surveyed Federally Qualified Health Centers and Look-alike organizations from April 11 to May 13, 2022, and garnered responses from 302 health centers. The respondents accurately represent the general health center population based on patient demographics, size and geographic location. To request survey respondent demographic info, please contact research@nachc.org.

The survey tool is available here.

About the National Association of Community Health Centers

The National Association of Community Health Centers (NACHC) is the national membership organization for Federally Qualified Health Centers (also known as FQHCs or health centers). Health centers are federally-funded or federally-supported nonprofit, community-directed provider clinics that serve as the health home for over 30 million people, including 1 in 5 Medicaid beneficiaries and 1 in 3 people living in poverty nationwide. It is the collective mission and mandate of over 1,400 health centers around the country to provide access to high-quality, cost-effective primary and preventative medical care as well as dental, behavioral health, and pharmacy services and other "enabling" or support services that facilitate access to care to individuals and families located in medically underserved areas, regardless of insurance status or ability to pay.