2021 340B Health Annual Survey: 340B Continues to Support Essential Programs and Services in the Face of Significant Financial Stress on Hospitals

Overview

In November and December 2021, 340B Health conducted its annual survey of hospital members to learn about how 340B hospitals are using their 340B savings to support care for patients with low incomes and/or living in rural areas and other features of program operations and finances, including the impact of manufacturer restrictions on community and specialty contract pharmacies. This report separately presents findings from the survey for disproportionate share (DSH) hospitals, rural referral centers (RRCs), and sole community hospitals (SCHs), which are larger and more likely to be urban, and critical access hospitals (CAHs), which are predominantly rural and defined as having 25 beds or fewer and located more than 35 miles from another hospital.

Despite the enormous financial pressures of responding to the COVID-19 pandemic and restrictions on 340B discounts imposed by a growing group of drug companies, all 340B hospitals continued to use savings from the program to pay for expanded access to vital services including free and low-cost drugs, uncompensated care, and programs to improve health outcomes. The results include:

- 88% of DSH/RRC/SCH hospitals used 340B savings to offset the cost of uncompensated and unreimbursed care and 89% reported savings helped support medication adherence to help patients get well and stay well.
- 81% of CAHs used 340B savings to increase access to care for low-income and rural patients and 74% reported needing them to keep their hospital doors open.
- Losses of savings from community and specialty pharmacy relationships due to the restrictions placed on 340B discounts by eight drug companies were significant for DSH/RRC/SCHs (-23%) and CAHs (-39%).
- Continuation and/or expansion of these manufacturer restrictions or other losses of 340B funding could lead to cutbacks impacting patients with cancer, diabetes, mental health, and substance use disorders.
- About two-thirds of CAHs and one third of DSH/RRC/SCHs report that if the drug company restrictions become more widespread, the losses would impact their ability to stay open.

Background

Enacted in 1992, the 340B drug pricing program requires drug companies to provide discounts on most outpatient drugs to qualifying safety-net hospitals, clinics, and health centers. The stated congressional intent for the program is "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1] 340B plays a critical role in supporting the safety net. Savings from these discounts enable 340B providers to offer additional programs and services to low-income, rural, and/or vulnerable patients at no additional cost to taxpayers. The care supported by 340B savings comes from drug companies' revenues, not from taxpayer dollars.

Hospitals Face Unprecedented Financial Pressures

COVID-19 has created significant financial challenges for hospitals, particularly those serving the low-income communities hit hardest by the pandemic and small rural hospitals that already were under financial strain.[2,3] A report from KaufmannHall projected hospitals nationwide would lose a combined $54 billion in net income in 2021.[4] Fitch cited escalating expenses due to staffing and high-intensity COVID-19 care as well as patients postponing elective and outpatient care, especially in hard-hit regions, as key factors threatening the financial health of nonprofit hospitals.[5]

Contract Pharmacy Restrictions Are Compounding Financial Strain

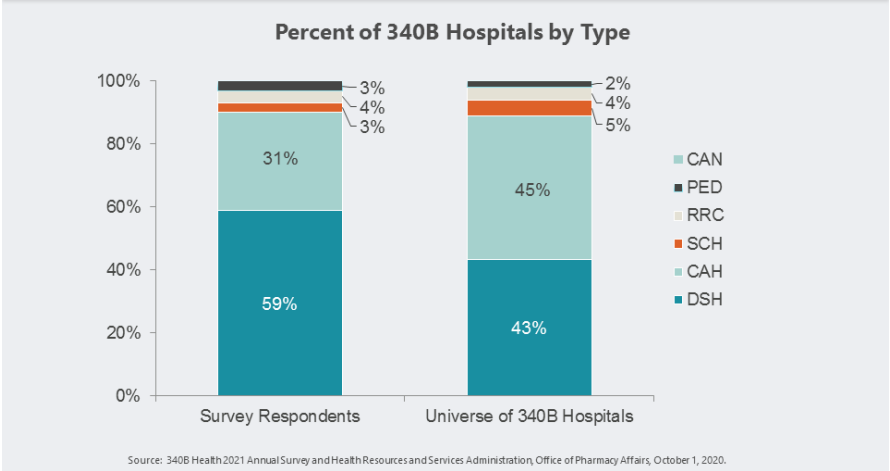
In addition to the financial stress from COVID-19, 340B hospitals also faced significant reductions in 340B savings due to manufacturer-imposed restrictions on community and specialty contract pharmacies. 340B providers receive discounts for drugs dispensed to eligible patients by the covered entity as well as for those dispensed to their patients by community and specialty pharmacies with which they contract. These relationships allow better patient access to the medications and related services they need, and the savings provide critical funding for safety-net providers.

Since July 2020, a growing number of drug companies have announced that they no longer will offer or will limit 340B discounts on outpatient prescription drugs sold to safety-net hospitals and dispensed through community and specialty contract pharmacies, despite government warnings that such actions violate the law. At the time of this survey, eight companies had imposed such restrictions: Eli Lilly, AstraZeneca, Sanofi, Novo Nordisk, Novartis, United Therapeutics, Merck, and Boehringer Ingelheim. Since then, Amgen, UCB, AbbVie, Pfizer, Bristol Myers Squibb, GlaxoSmithKline, Gilead, and Johnson & Johnson have followed suit. The Health Resources & Services Administration (HRSA), which oversees and administers 340B, has determined these restrictions violate the law and has begun the process of notifying drug companies to restore 340B pricing and refund overcharges. In 2021, the agency sent enforcement letters to seven companies ordering them to restore 340B discounts. HRSA also has referred those cases to the Health and Human Services Office of Inspector General (OIG) to consider imposing civil monetary penalties for noncompliance. Eight companies have filed lawsuits challenging HRSA's enforcement actions, which have been dispersed across four federal courts. Meanwhile, 340B providers face significant reductions in 340B savings that are creating financial hardship and harming patients.

Methodology

The survey was administered to 1,552 of 340B Health's member hospitals. Responses were collected from Oct. 7 through Dec. 31, 2021. A total of 510 hospitals responded for a response rate of 33%. DSH hospitals were somewhat over-represented in the sample. Results are presented separately for DSH/RRC/SCHs and CAHs to account for the size differences between these types of hospitals. Outliers were removed from financial data.

510 hospitals responded to the survey with DSH hospitals somewhat over-represented.



Source: 340B Health 2021 Annual Survey and Health Resources and Services Administration, Office of Pharmacy Affairs, October 1, 2020.

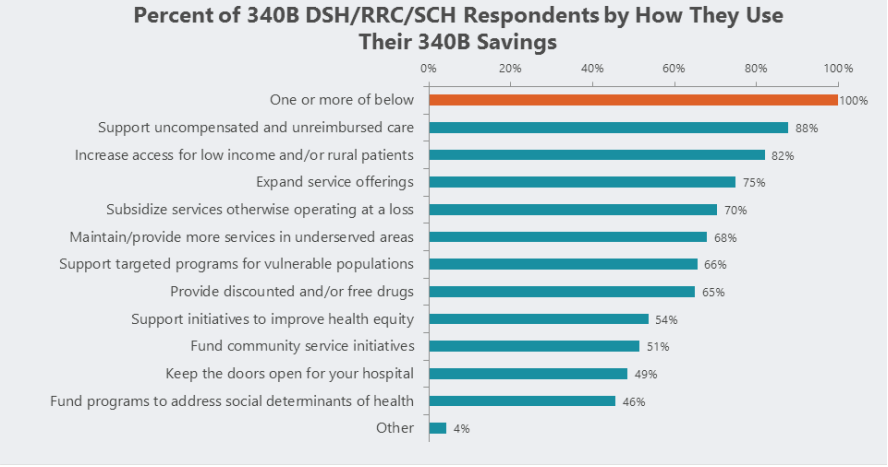
340B Savings Support a Wide Range of Care for Patients with Low Incomes

340B discounts on outpatient drugs create savings that allow safety-net providers to stretch scarce resources as far as possible to reach more patients and provide more comprehensive services.[6] These services, critical to patients with low incomes and those living in rural areas, are at risk because of the manufacturer restrictions on community and specialty contract pharmacy and a pandemic that continues to strain our health care system.

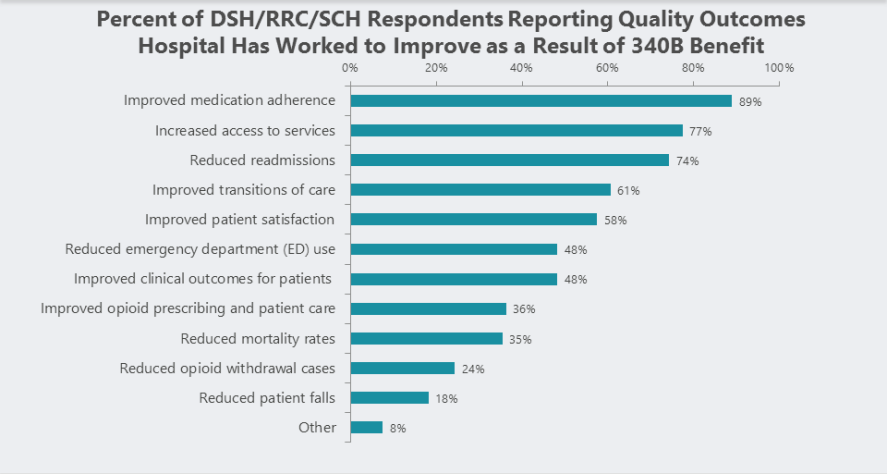
All DSH/RRC/SCHs reported that they use their 340B savings in one or more ways to serve vulnerable patients, and most reported many. The most common uses reported were to support uncompensated and unreimbursed care (88%) and provide access to care for low-income and/or rural patients (82%).

The services funded by 340B savings support improved patient outcomes. For example, 340B hospitals are more likely than non-340B hospitals to offer medication access services, free or low-cost medications, medication therapy management, and discharge medications.[7] Consistent with this research, nearly nine of 10 reported their 340B savings supported programs that improved medication adherence. Increased access and reduced readmissions were close behind.

All 340B DSH hospitals use their savings to support care for low-income and rural patients.



89% percent of safety-net hospitals report the 340B benefit has helped support medication adherence.



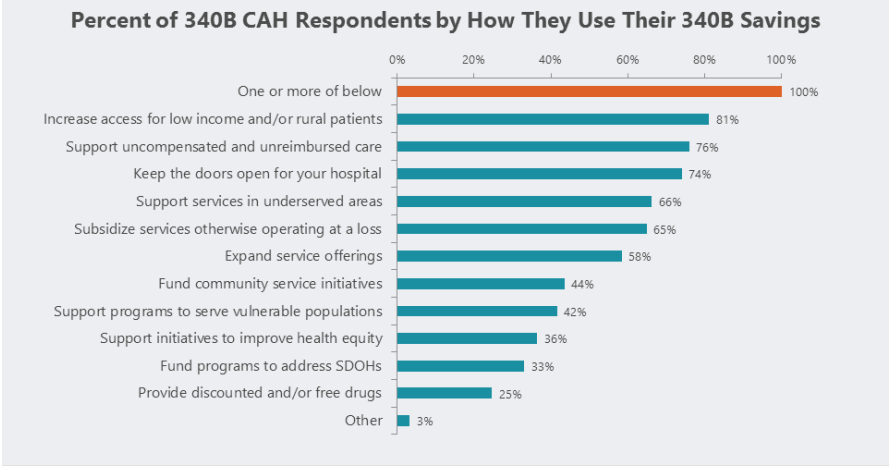
Ways that DSH/RRC/SCHs Use Their 340B Savings

- Provide prescriptions to patients being discharged from hospital regardless of ability to pay.
- Subsidize behavioral health services.
- Run opioid use disorder treatment programs.
- Operate chronic disease management programs for COPD, asthma, and congestive heart failure.
- Subsidize mobile health clinics and telehealth services to underserved communities during the pandemic.

340B Continues to Be a Lifeline for Critical Access Hospitals

About half of 340B hospitals are CAHs, the majority of which serve rural communities. One in five Americans live in rural areas, and CAHs often are the only source of care for Americans in the towns and counties they serve.[8] Many of these areas are sparsely populated and far from urban areas. As such, accessing health care can be a challenge. Rural hospitals are vital to local economies, signaling that a community is a viable place to locate a business, retire, or raise a family. In 1997, Congress created the CAH designation, which provides special Medicare reimbursement for hospitals with 25 beds or fewer and that are at least 35 miles from another hospital. Today nearly three-quarters of rural hospitals are CAHs.[9]

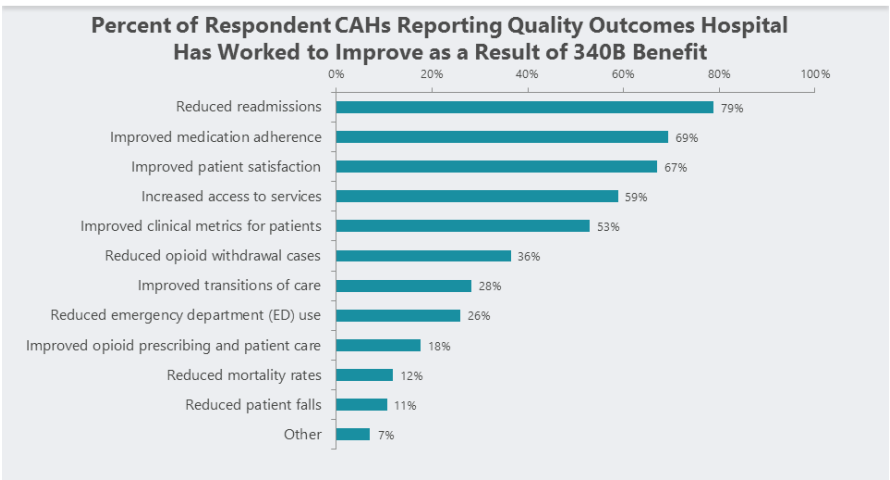
Three-quarters of 340B CAH hospitals rely on 340B savings to keep the doors open.



Despite the CAH program, rural hospitals have continued to struggle. Since 2005, more than 180 rural hospitals have closed,[10] and many remain vulnerable to closure. COVID-19 and manufacturer restrictions on community and specialty contract pharmacies have further strained rural hospitals.

Congress expanded the 340B program to CAHs in 2010, offering a financial lifeline, but many CAHs still struggle. Three-quarters of CAH survey respondents reported that 340B savings help keep their doors open. Contract pharmacies are particularly important to CAHs because they have less of an ability to have their own retail pharmacies and are less likely to provide outpatient drugs in house because of fewer outpatient procedures. Eight in 10 CAHs report they use their savings to increase access for patients with low incomes and/or those living in rural areas and to support uncompensated and unreimbursed care.

The 340B benefit has supported efforts to reduce readmissions for CAHs.



The 340B program also provides CAHs with resources they can use to improve quality. Nearly eight of 10 CAH respondents reported that 340B savings help them lower readmission rates. Other outcomes supported by 340B

savings include improved medication adherence (69%) and improved patient satisfaction (67%). 340B savings have helped more than half of CAHs respond to COVID-19 in their communities including through setting up vaccination clinics, testing sites, and monoclonal antibody infusion centers.

"Without 340B benefit, our small CAH would close its doors. So the 340B program is 100% helping us respond to COVID-19."

Community and Specialty Contract Pharmacy Limits Have Substantial Financial Impact

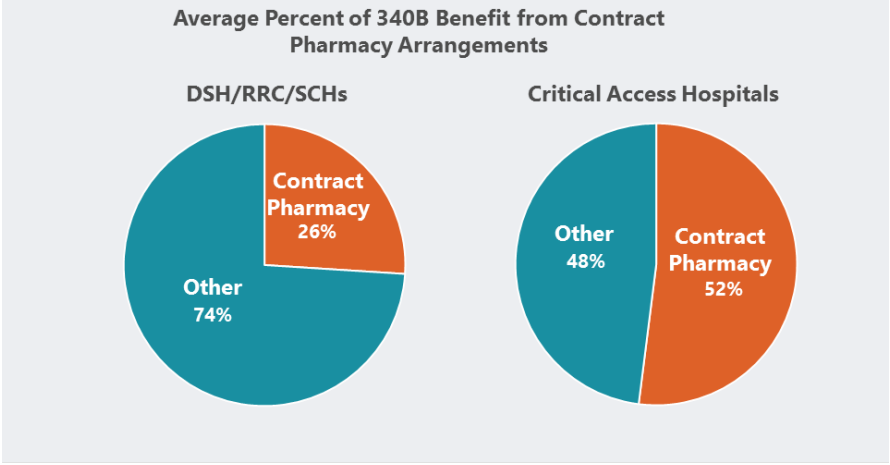
Discounts on drugs dispensed at community and specialty contract pharmacies make up about a quarter of 340B savings for DSH/RRC/SCHs. Among CAHs, savings from these partnerships represent an average of 52% of their overall 340B savings.

The impact of the drug companies' restrictions is growing over time as eight more manufacturers have imposed restrictions than had at the time of the survey, and as the more recent restrictions have time to take full effect. Even with just the first eight manufacturers, the impact has been substantial.

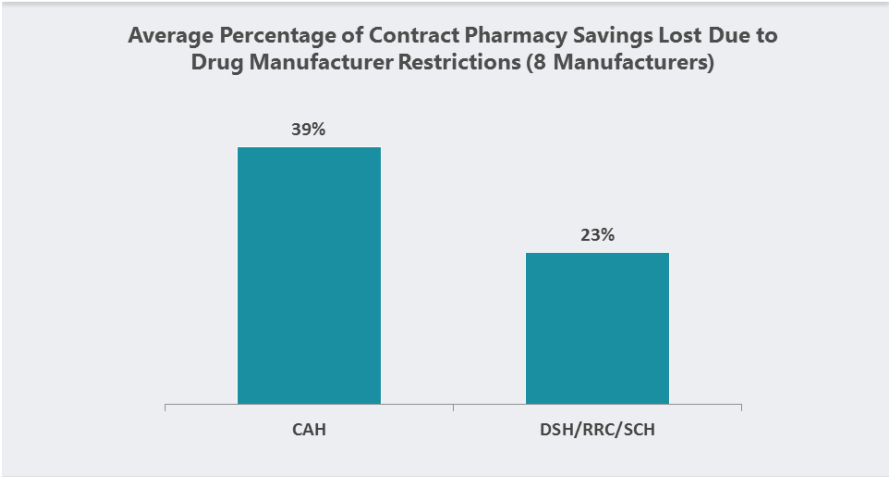
On average, DSH/RRC/SCHs have lost 23% of their community and specialty contract pharmacy savings. For CAHs, the percentage loss is significantly greater, averaging 39%.

Annualized dollar losses are substantial. For CAHs, the median reported loss is $220,000, and 10% of those hospitals face losses of $700,000 or more. For DSH/RRC/SCHs, which often are substantially larger, the median reported loss is $1 million, and 10% of those hospitals reported losses of $9 million or more.

A significant share of 340B savings comes from community pharmacy; for CAHs it's more than half.



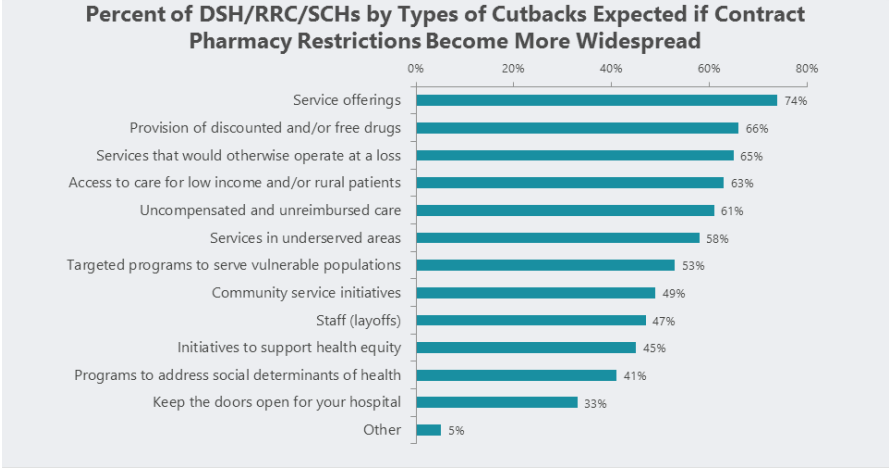
Community pharmacy restrictions have greatly reduced savings for 340B hospitals.



Further Cuts to the 340B Program Would Harm Patients

Losses in 2022 due to manufacturer restrictions on community and specialty contract pharmacy are expected to be considerably higher due to the fact that more drugmakers are restricting discounts, and the policies adopted in 2020 and 2021 will be fully in effect for all of the current year. Unless these disputes are resolved and 340B pricing restored, 340B hospitals indicate they must consider making changes that would lead to less access to care for low-income and rural patients.

If community pharmacy restrictions become more widespread, hospitals anticipate service cuts.

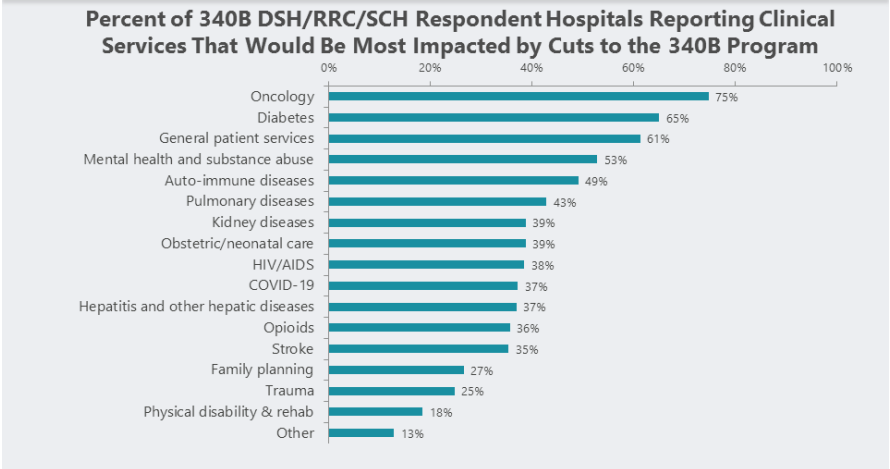


Among 340B DSH/RRC/SCHs, respondents report such losses would lead to reductions in service offerings (74%), provision of discounted and/or free drugs to people with low incomes (66%), and services that otherwise would operate at a loss (65%). A third of DSH hospitals reported more widespread community pharmacy restrictions could impact their ability to stay open.

"Over 800 patients received reduced price medications from the Walgreens in our hospital lobby, and they are not able to anymore."

Across clinical services, reductions in 340B savings would have the greatest impact on hospitals' ability to provide treatments for cancer and diabetes patients. 340B savings not only support access to expensive oncology and diabetes drugs, they also fund support services. These include promotion of cancer screenings in underserved populations and unreimbursed services for individuals with diabetes such as medication management, free insulin and supplies, and prevention initiatives.

Loss of 340B funding would most impact the ability to provide treatments for oncology and diabetes patients.



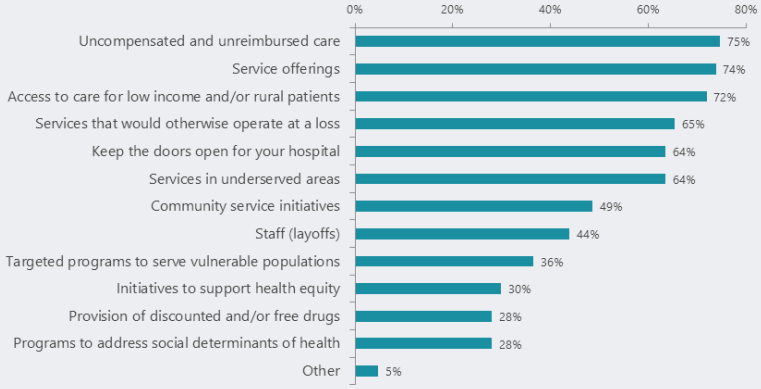
340B Losses Could Force Critical Access Hospitals to Close

340B savings represent a critical funding source for CAHs. About two-thirds of CAHs report that if the drug company restrictions become more widespread, the losses could impact their ability to keep their doors open. Three-quarters said expanded restrictions could reduce their ability to provide uncompensated and unreimbursed care and lead to cutbacks in services.

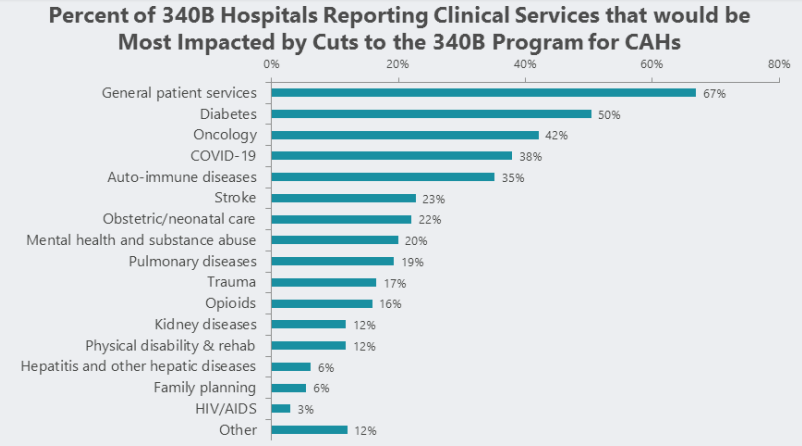
Additional cuts to 340B could harm clinical services. For CAHs, general patient services and diabetes care are most at risk. More than a third noted the response to COVID-19 could be harmed. Cancer care also was an area of concern. Loss of cancer care services in CAHs would increase travel times and expenses for chemotherapy and other cancer treatments for rural populations.

"We have continued to absorb these cuts to our 340B benefit. We will not be able to do this for the long term. This program allows us to keep our doors open. Each dollar we lose we have to find a way to replace. Not easy as a CAH."

If contract pharmacy restrictions become more widespread, many CAHs would be at risk of closing.



For CAHs, loss of 340B funding would impact general patient care and diabetes services the most.



Examples of Service Reductions to Date Due to Contract Pharmacy Restrictions

- Elimination of acute care and emergency services at one hospital campus
- Consolidation of multiple family health clinics to one location
- Reduction in the number of school-based clinics from 19 to two
- Furloughs, reduced compensation, and suspension of employee retirement match
- Ten percent reduction in staffing
- Elimination of a discount card program for uninsured and underinsured patients
- Sunsetting of meds-to-go program for indigent patients discharged from hospital

"[Contract pharmacy restrictions] have significantly reduced our ability to provide discounted medications to our patients of greatest need. We were forced to select a single pharmacy in order to maintain the benefit for some of our patients, but others can't afford to travel the distances required to receive their medications."

"We are no longer able to offer 340B qualified prescriptions for low-income patients at zero or low cost on drugs from restricted manufacturers at more than one pharmacy. This limits access to our medication access program."

[1] Veterans' Health Care Act of 1992. Section 602, Public Law 102-585.
[2] Knudsen J and Chokshi DA. COVID-19 and the Safety Net—Moving from Straining to Sustaining. N Engl J Med 2021; 385:2209-2211. 2021 Dec.
[3] Diaz A, Chhabra KR, Scott JW. The COVID-19 Pandemic and Rural Hospitals—Adding Insult to Injury. Health Affairs. 2020 May.
[4] KaufmanHall. Financial Effects of COVID-19: Hospital Outlook for the Remainder of 2021. 2021 Sep.
[5] Fierce Healthcare. Fitch: COVID-19 resurgence threatens nonprofit hospitals margins, credit ratings. 2021 Aug.
[6] *Ibid.*
[7] Rana I, von Oehsen W, Nabulsi NA et al. A Comparison of Medication Access Services at 340B and Non-340B Hospitals. *Res in Soc and Adm Pharm*. 2021 Mar.
[8] U.S. Census Bureau. https://www.census.gov/library/stories/2017/08/rural-america.html
[9] American Hospital Association. https://www.aha.org/statistics/fast-facts-us-hospitals. Rural Health Information Hub. https://www.ruralhealthinfo.org/topics/critical-access-hospitals
[10] The Cecil G. Sheps Center for Health Services Research. https://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/

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340B Health is an association of more than 1,400 non-profit hospitals. We are the leading advocate and resource for hospitals that serve their communities through participation in the 340B drug pricing program. For more information about us and the 340B program, visit www.340bhealth.org.