340B HEALTH
The affordable prescription for healthy communities

340B PROGRAM HELPS HOSPITALS PROVIDE SERVICES TO VULNERABLE PATIENTS

RESULTS FROM A SURVEY OF 340B HEALTH MEMBERS

The program funds free and reduced-price medications for the needy – and much more. From neighborhood clinics to medication management services and even patient transportation to hospitals, 340B savings improve the health of underserved Americans every day.

May 2016

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ABOUT 340B

The 340B drug pricing program was signed into law in 1992 to ensure healthcare providers that serve large numbers of poor and vulnerable populations could continue their mission to provide care to all regardless of ability to pay. In order to participate in the Medicaid and Medicare Part B markets, pharmaceutical companies must agree to provide outpatient pharmaceuticals to safety-net providers at a discounted rate. These providers use these savings to ensure they are able to provide care to any patient that walks through their doors.

ABOUT 340B HEALTH

340B Health is an association of more than 1,200 hospitals that participate in the 340B drug pricing program. We are the leading advocate and resource for those providers who serve their communities through participation in the 340B program. For more information about us and the 340B program, visit www.340bhealth.org.

EXECUTIVE SUMMARY

For almost a quarter century, the 340B drug pricing program has allowed safety-net healthcare providers across America to deliver affordable medications and more robust clinical services to their neediest patients. To better understand the program's benefits, 340B Health administered an electronic survey to its membership. The survey garnered responses from disproportionate share (DSH) hospitals, critical access hospitals, children's hospitals, sole community hospitals, and rural referral centers.

KEY FINDINGS

Program Savings Reduce Cost and Expand Services for Vulnerable Patients

- *Summary:*
  - 340B is integral to reducing the cost of care for patients, inside and outside of the pharmacy
- *By the numbers:*
  - When asked how hospitals use 340B savings to help their low-income and vulnerable patients, respondents reported increasing patient access to affordable prescription drugs in a number of different ways (percentages total more than 100 percent because hospitals provided multiple responses):
    - 77 percent said 340B enhances the pharmacy department's or clinic's ability to serve the uninsured or underinsured
    - 71 percent said it increases the ability to provide free/discounted drugs to low-income patients
    - 61 percent said it increases the total number of patients served by the pharmacy department
    - 52 percent said it helps maintain an adequate supply of inventory to meet patient demand
    - 49 percent said it enables hospitals to provide an outpatient pharmacy and keep it properly staffed
    - 41 percent said it avoids restrictive formularies and otherwise increases the choices of drugs and certain devices available to patients
    - 33 percent said it allows on-site clinic dispensing instead of relying on commercial pharmacies

  - When asked how hospitals use 340B savings to help their low-income and vulnerable patients, respondents reported improving pharmacy services in the following ways (percentages total more than 100 percent because hospitals provided multiple responses):
    - 67 percent report it funds patient assistance programs
    - 65 percent report it funds patient counseling
    - 62 percent report it funds hospital readmission reduction programs
    - 60 percent report it funds medication therapy management
    - 59 percent report it funds discharge planning

- 47 percent report it funds disease management
- 39 percent report it funds immunization/vaccination programs
- 24 percent report it funds translation services

- When asked how hospitals use 340B savings to help their low-income and vulnerable patients, respondents reported maintaining operations beyond the pharmacy in these ways (percentages total more than 100 percent because hospitals provided multiple responses):
  - 87 percent use 340B to offset low reimbursement from Medicaid
  - 82 percent use 340B to offset low reimbursement from Medicare
  - 75 percent use savings to maintain current level of care (and keep doors open)
  - 71 percent use 340B to offset low reimbursement from commercial payers
  - 61 percent use 340B to help fund community service initiatives
  - 28 percent use savings to fund medical/clinical services for low-income patients

One of the key questions we asked was what would happen if the 340B program disappeared. Given the focused efforts of the drug industry to curtail both hospital and patient eligibility, the query has a way of focusing the mind. One DSH hospital respondent put it this way: "340B savings impact the bottom line for our organization. It does not only affect the pharmacy department. The loss of 340B savings would put the hospital in the red. All services would be affected."

One critical access hospital respondent said, "[340B] helps give us the funds to make our hospital more efficient, prevent readmissions, and provide quality care. Without this, many small hospitals like us would be closed down."

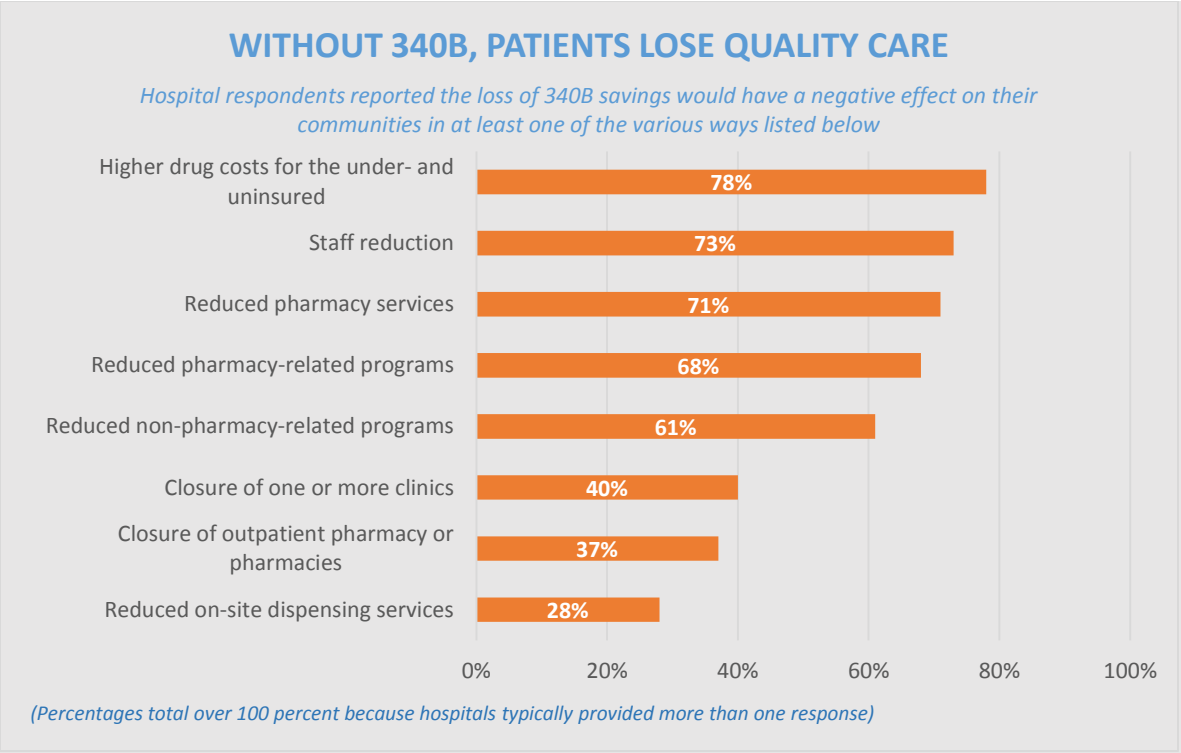

Figure 1: If the 340B program were no longer available, how would this impact the health of your community?

Program Savings Are Critical to Safety-Net Hospitals and the Communities They Serve

- *Summary:*
  - 340B serves as a critical lifeline in advancing the safety-net hospital mission. Hospital operations—beyond the provision of affordable medications—rely on the savings the 340B drug pricing program provides.
- *By the numbers* (answers total more than 100 percent due to multiple responses)*:*
  - 99 percent of respondents said 340B is important to hospital operations
  - 93 percent of respondents characterize 340B as more important than it was five years ago
  - 63 percent describe its importance as "critical"

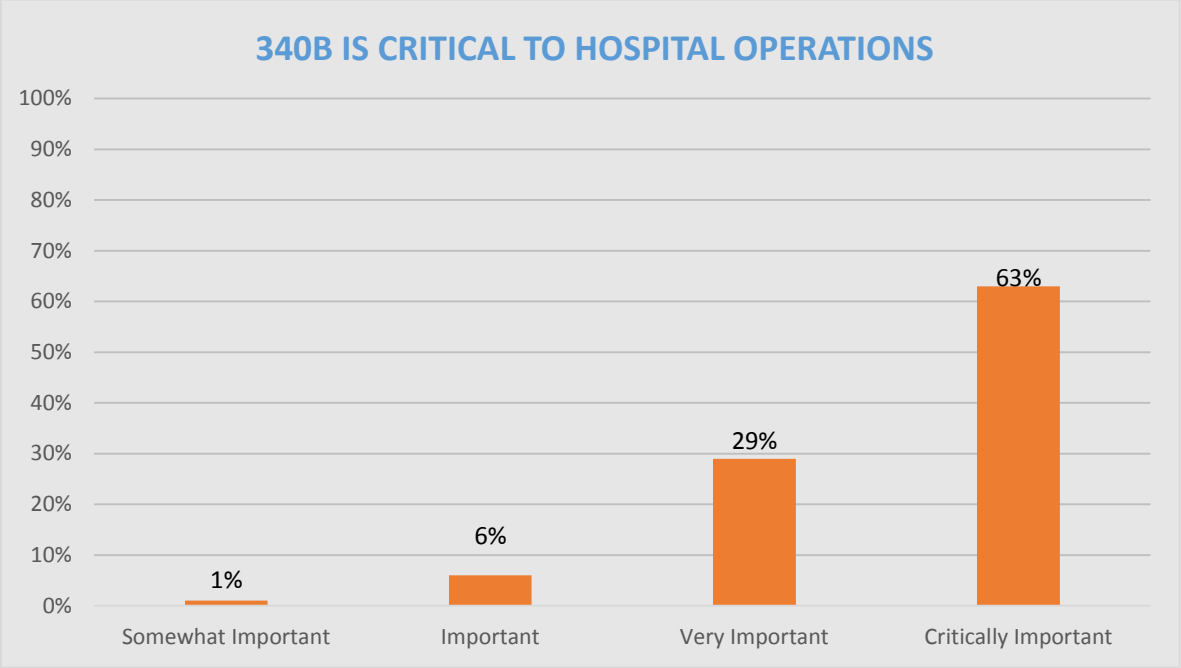

Figure 2: On a scale of 1-5, with 1 being Not Important and 5 being Critically Important, please rate the importance of the 340B program to the operation of your organization.

More Patients Are in Need of Discounted Care

- *Summary:*
  - The Affordable Care Act (ACA) did not obviate the need for 340B. Although many patients have gained coverage under the ACA, it has not diminished the need for 340B to better meet the needs of those who remain under- or uninsured. 340B hospitals continue to treat tens of millions of uninsured or underinsured patients that are in need of affordable care.

- *By the numbers:*
  - 78 percent of respondents reported an increase in the number of underinsured outpatients, versus 1 percent of respondents who reported a decrease

- 42 percent of respondents reported an increase in the number of uninsured outpatients, versus 55 percent of respondents who reported a decrease or no change

340B hospitals treat nearly twice as many low-income patients as other non-340B hospitals.[1] Respondents underscored how important the program is to their patients. A DSH hospital respondent put it this way: “Because of 340B, we have been able to expand our services and reach more patients that otherwise would not get much needed care. It is significant to our hospitals and [its loss] would result in the unfortunate decline in community outreach and services for our vulnerable and less fortunate population."

[1] http://www.340bhealth.org/images/uploads/340BHospitals_May2015Update.png

INTRODUCTION

The 340B drug pricing program "enables covered entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[2] Hospitals that provide very high volumes of care to poor and other vulnerable patients qualify for the program and use their savings to invest in these populations.

340B savings are used in the pharmacy, defraying the cost of expensive drugs for the provider and the patient and ensuring the pharmacy is well-stocked and well-staffed. But 340B savings also fund other programs hospitals and pharmacies provide, ensuring there are as few gaps in care as possible. Patient counseling and financial assistance programs, hospital readmission prevention programs, medication therapy management and discharge planning are an integral part of care thanks to 340B. 340B also enables hospitals to provide mobile clinics and transit vouchers, infusion and cancer care centers, AIDS and mental health services. Ultimately, the savings from 340B help keep the entire safety net intact.

In the decades since the 340B program was established, the U.S. health care system has undergone significant changes, most recently in 2010 when the Affordable Care Act (ACA) went into effect. Despite advances made in health care coverage following the ACA's enactment, 31 million[3] Americans remain underinsured and between 29[4] and 32[5] million are uninsured. At the same time, drug costs are rising at an unprecedented rate.[6]

To better understand benefits of the 340B program, 340B Health administered an electronic survey to its membership. The survey garnered responses from disproportionate share (DSH) hospitals, critical access hospitals, children's hospitals, sole community hospitals and rural referral centers.

[2] Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, codified as Section 340B of the Public Health Service Act at 42 U.S.C. § 256b

[3] "The Problem of Underinsurance and How Rising Deductibles Make It Worse," The Commonwealth Fund, 2014 http://www.commonwealthfund.org/publications/issue-briefs/2015/may/problem-of-underinsurance

[4] "Why Are 29 Million People Still Uninsured?" HealthGrove May 10, 2016 http://affordable-care-act.healthgrove.com/stories/13320/why-are-29-million-people-still-uninsured

[5] "Key Facts about the Uninsured Population," The Kaiser Commission on Medicaid and the Uninsured - Henry J. Kaiser Family Foundation. October 2015. http://kff.org/uninsured/fact-sheet/key-facts-about-the-uninsured-population/

[6] Ifred Islam, "Rising Cost of Drugs: Where Do We Go From Here?", Health Affairs, August 31, 2015 http://healthaffairs.org/blog/2015/08/31/rising-cost-of-drugs-where-do-we-go-from-here/

SECTION 1: PROGRAM SAVINGS REDUCE COST AND EXPAND SERVICES FOR VULNERABLE PATIENTS

The 340B program allows pharmacies to reduce the upfront costs of pharmaceutical inventory to the hospital, which translate into reduced costs for patients. It can also result in more patient programs that reduce gaps in care and lower readmission rates.

A 2015 study conducted by Dobson | DaVanzo found that 340B DSH hospitals serve significantly more low-income patients than non-340B DSH hospitals and provide more uncompensated care. Low-income patients made up about 42 percent of patients at 340B DSH hospitals, which is about two times the number of low-income patients seen at non-340B hospitals. 340B DSH hospitals also account for only about one third of all DSH hospitals, but provide nearly 60 percent of all uncompensated care.[7]

These numbers show the deep commitment 340B hospitals have for their vulnerable patients and communities, as well as reaffirm their need for the 340B program.

340B HELPS PATIENTS GET THE PRESCRIPTIONS THEY NEED

The express purpose of 340B is to help safety-net providers stretch limited resources to meet their missions, and part of their mission is to ensure patients have access to the drugs they need. 340B savings go a long way to this end.

When asked how 340B savings increase patient access to drugs, respondents reported using 340B to help their patients in a number of different ways. More than three-quarters—78 percent—said 340B savings enhance the pharmacy department's ability to serve the under- and uninsured. Seventy-one percent of respondents said the savings increase their ability to provide free or discounted drugs to low-income patients.

The benefits of 340B go further. Sixty percent of respondents said 340B increases the total number of patients their pharmacy serves, with 53 percent saying the program helps them maintain sufficient inventory to meet patient demand. Forty-nine percent said 340B enables their organization to have an outpatient pharmacy at all and keep it properly staffed.

[7] "Analysis of 340B DSH Hospital Services Delivered to Vulnerable Patient Populations", Dobson | DaVanzo, June 2015, http://www.340bhealth.org/files/Dobson_DaVanzo_Final_Report.pdf

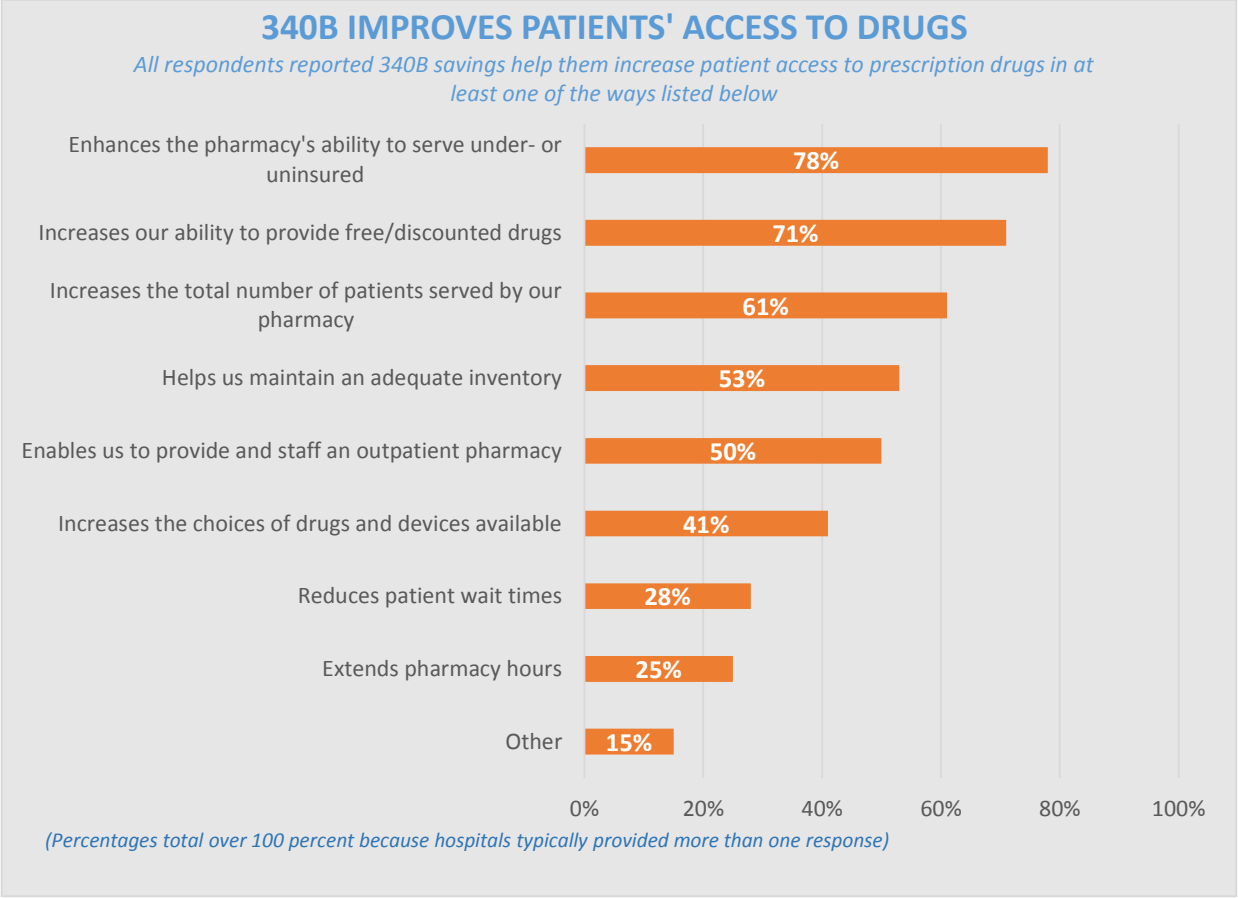

Figure 3: How do you use 340B savings to increase patient access to drugs?

One DSH hospital respondent observed, "We can offer services [with 340B] that we could not otherwise. Chemotherapy, IVIG infusions, osteoporosis prophylaxis, treatment for Pompe disease, rabies treatment—all are high-cost medications."

PHARMACY SERVICES BEYOND PRESCRIPTION PROVISION GET A BOOST FROM 340B SAVINGS

Because of 340B, pharmacies are equipped to help maintain continuity of care for under- and uninsured patients beyond simply ensuring pharmaceutical access. We wanted to know more about some of the ways hospitals are helping these patients, so we asked 340B hospitals what type of assistance they are providing via their pharmacy. We found that respondents are performing at least one of the following services to help their low-income and indigent patients via either their inpatient, outpatient or contract pharmacies:

- Operating a charity or indigent care program that covers drugs
- Referring patients directly to the hospital for assistance
- Assisting with enrollment and participation in prescription assistance programs

- Providing drugs at a free or nominal cost
- Discounting the cost of drugs
- Operating voucher programs
- Waiving patients' copayments

In fact, many other pharmacy services to the vulnerable are available at least in part due to 340B savings. Among the most common are referrals to the hospital's financial assistance department and helping patients enroll in prescription assistance programs.

The following chart shows the full array of pharmacy services and the percent of respondents that use 340B to fund them.

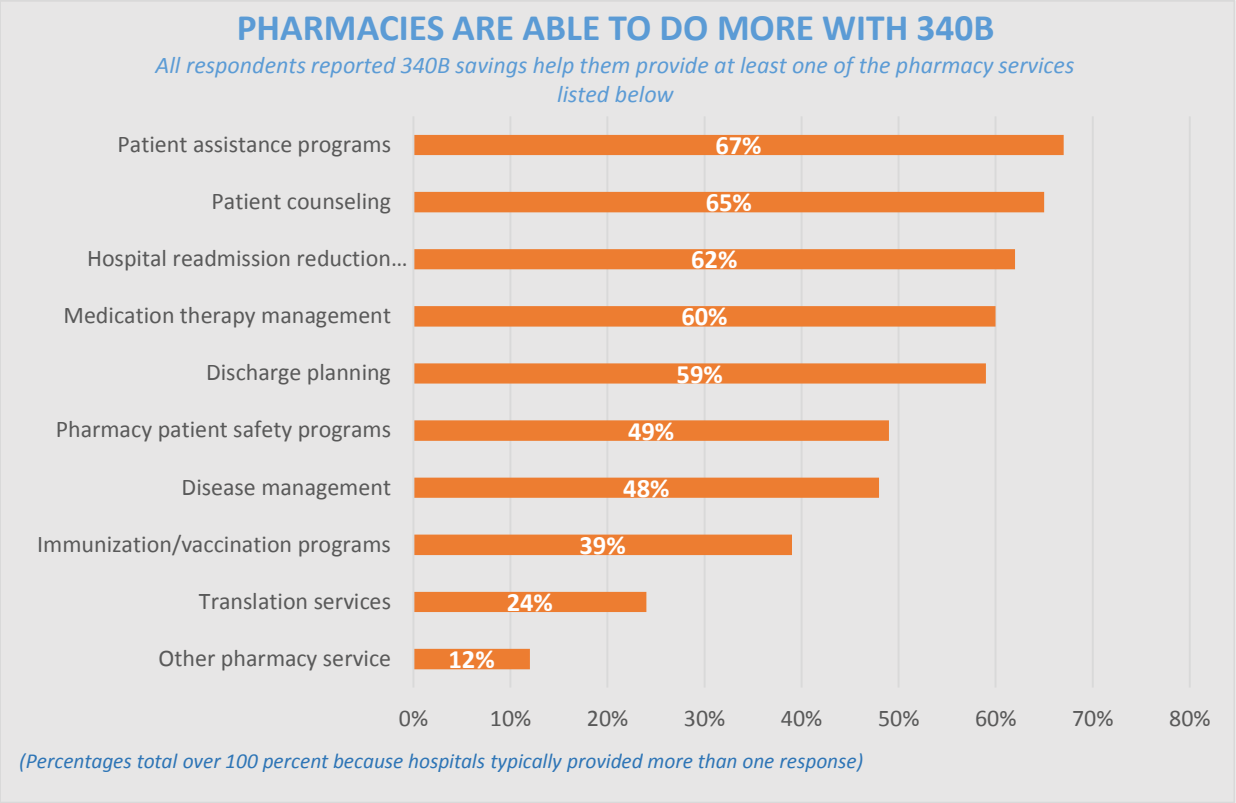

Figure 4: Which pharmacy services are available at least in part through the use of 340B savings?

For a better sense of exactly what these services entail, respondents provided more details in an open-ended answer section. Many cited infusion-care services as a key pharmacy program that would disappear without 340B savings. Others noted that the funding goes toward services like patient transportation and mobile clinics to ensure even the most remote patient or patients who have limited ability to move or travel have access to the care they need.

"340B enables us to utilize savings to build and expand programs that serve our patients and un/underinsured (we are greater than 60 percent Medicaid)," said one children's hospital respondent. "For example, we implemented a discharge prescription bedside program (Med-to-Bed) to improve patient access to medications and education to reduce readmissions. We started an asthma initiative in our Emergency Department to ensure that our patients are discharged with the appropriate rescue and controller medications and understand the importance of compliance. Often times, we will work with our Social Services department to assist patients in covering the cost of the chemotherapy medications, which they would not be able to afford without our help. We are currently working on assisting our Breathmobile (a mobile asthma unit) to provide medications to the underinsured."

A CASE STUDY OF 340B'S BENEFIT

Providence St. Mary Medical Center in Walla Walla, WA, used 340B savings to hire a pharmacist. What follows is a story in a respondent's own words describing how that pharmacist helped a patient avoid a dangerous medication interaction, saving her life.

"An elderly cancer center patient who has been doing well on an oral chemotherapy came to the Cancer Center with complaints of stomach and swallowing pain. Her oncologist diagnosed an inflammation of the esophagus due to an oral yeast infection.

The oncologist consulted with the pharmacist in the Oral Oncology Pharmacy to ask if there would be problems with adding a common antifungal to the patient's therapy. The pharmacist reported that this would result in a dangerous interaction that could cause severe toxicity from her chemotherapy as well as side effects that could lead to a heart attack. The pharmacist recommended a different antifungal as well as a dose reduction in the patient's chemotherapy for the duration of the treatment of her infection to avoid the anticipated toxicities.

This was a complicated change for the patient to manage, so the pharmacist provided additional in-depth counseling to explain the reasons, concerns, and proper way to take her medications. The patient was grateful for the extra care and information, and is having good success with the treatment.

Had the original prescription been written with no pharmacist available for consultation, the prescription would have simply been taken to a local pharmacy that did not have knowledge of her chemotherapy, which is filled by a specialty pharmacy and mailed to her. Providence St. Mary Medical Center used savings from the 340B program to add this pharmacist position in the Cancer Center to provide this type of clinical review, counseling, and safety measures for all patients as well as to implement a medication assistance program. Ongoing savings are used to offset the costs of maintaining the pharmacist position. "

SECTION 2: PROGRAM SAVINGS ARE CRITICAL TO HOSPITALS AND COMMUNITIES

340B is a provider program, designed to help hospitals and other providers that serve high numbers of low-income and other vulnerable patients continue their mission to provide care to all regardless of a patient's ability to pay. Consistent with the legislative intent of the 340B program, the discounts allow participants to maximize the limited resources they have.[8] Savings afforded through the 340B program can translate into benefits that are quantifiable, such as the cost reduction on drug purchases. Other benefits are harder to quantify, like staff or operational improvements funded in part by 340B.

Many respondents indicated the program has become an integral part of the everyday work of their hospital —so much so that 99 percent reported the savings stemming from 340B participation are important to the operation of their institution. The vast majority characterized these savings as "critical." This conviction is reflected by the fact that many respondents would be forced to limit patient services were 340B no longer available. Forty percent of respondents projected a loss of 340B would lead to clinic closures.

SAFETY-NET HOSPITALS RELY ON 340B TO SUPPORT HOSPITAL OPERATIONS NOW MORE THAN EVER

340B's critical role in hospital operations and patient care is not waning. In the five years since the ACA was enacted, 93 percent of respondents said the 340B drug pricing program has increased in importance.

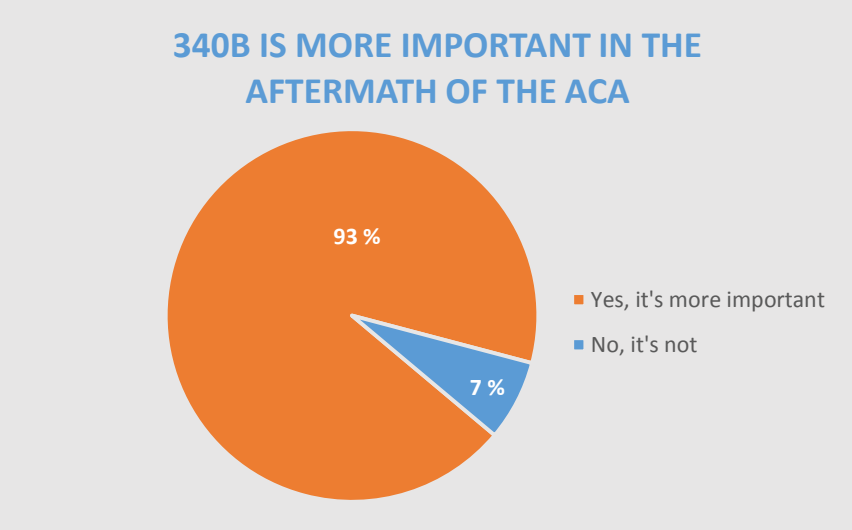

Figure 5: Has the importance of 340B to your hospital increased in the last five years since the enactment of the Patient Protection and Affordable Care Act (ACA) in 2010?

[8] H.R. Rep. 102-384,102d Cong., pt. 2, at 12 (2d Sess. 1992).

For many hospitals, the reason for this is threefold: low reimbursement rates across various types of insurance; higher drug costs; and the high cost of caring for the under- or uninsured. Both hospitals and patients are feeling the astronomic rise in drug prices. This is particularly problematic in areas such as oncology care where the price of cancer drugs have increased tenfold since the year 2000 to more than $100,000, even though the average household income has decreased by about 8 percent.[9]

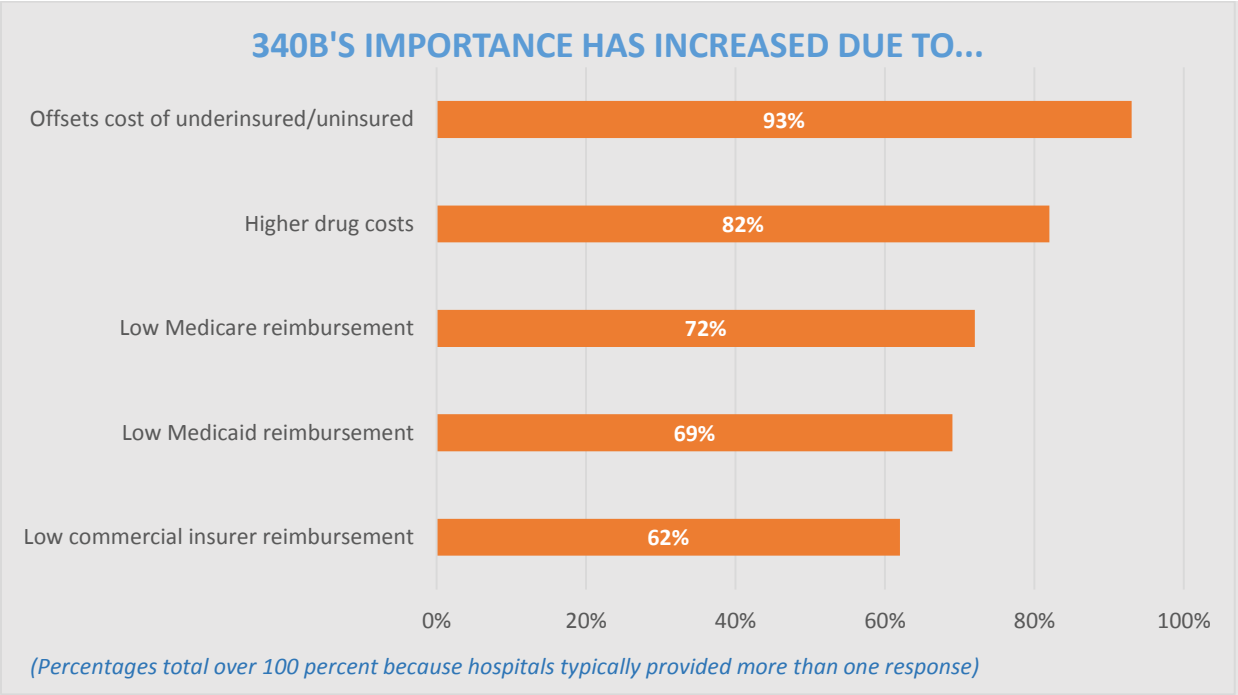

Figure 6: If yes, 340B's importance has increased in the past 5 years, why?

When asked to rank the importance of the 340B program to the operation of their organization, 99 percent ranked the program as important and 92 percent of respondents ranked 340B savings as "very important" or "critically important."

Respondents further clarified that 340B played a valuable role in helping to cover the cost of critical services and care.

[9] Hagop Kantarjian, MD and S. Vincent Rajkumar, MD. "Why Are Cancer Drugs So Expensive in the United States, and What Are the Solutions?", *Mayo Clinic Proceedings,* 2015
http://www.mayoclinicproceedings.org/article/S0025-6196(15)00101-9/abstract

Eighty-seven percent of respondents use 340B to offset low Medicaid reimbursement, and 82 percent use 340B to offset low Medicare reimbursement. Even commercial payer reimbursement can be lacking, with 71 percent of respondents using 340B to offset low reimbursement from private insurers.

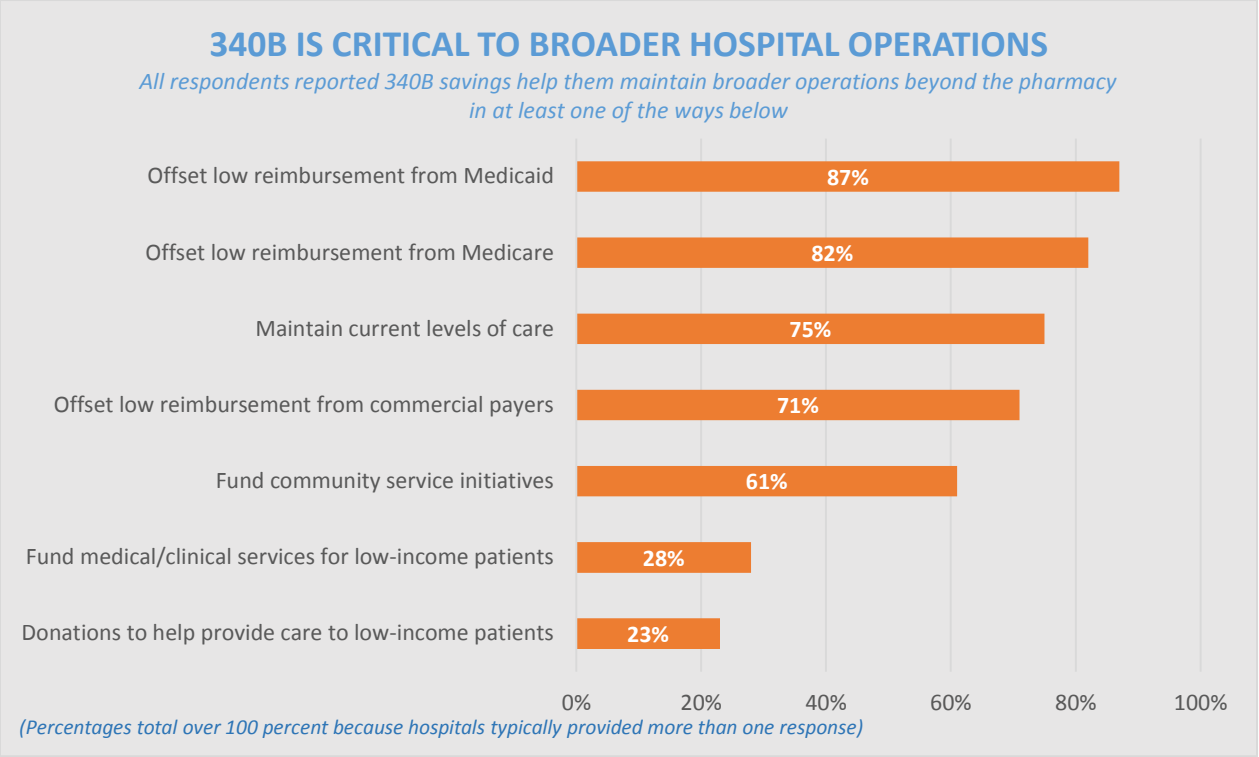

Figure 7: How does your hospital use 340B savings to maintain broader operations beyond the pharmacy?

When asked how 340B helps further their hospital's safety-net mission, many made it clear that without the program there would be no mission—in some cases, there might not even be a hospital.

"It keeps the doors open by supporting other cash-strapped areas of the hospital," said one DSH hospital respondent. A critical access hospital respondent put it this way: "[340B] helps give us the funds to make our hospital more efficient, prevent readmissions, and provide quality care. Without this, many small hospitals like us would be closed down."

"Without 340B, our hospital would post an overall loss for the year, resulting in a reduction of services provided to low-income and vulnerable patients," said another DSH hospital respondent.

LOSING 340B WOULD DEVASTATE HOSPITALS AND THE COMMUNITIES THEY SERVE

Two recent dangers to 340B come from (1) the false perception that the program has become less necessary since the Affordable Care Act went into effect and (2) the increased push to severely limit patient eligibility under the program. This survey found that should the program be restricted or no

longer available, many safety-net hospitals would face a myriad of negative impacts on hospital services and patient care, ranging from higher costs to clinic closures.

Were 340B discontinued, 78 percent of hospitals anticipated higher drug costs for the under- and uninsured. Seventy-three percent expected they would have to cut staff without 340B savings. With fewer staff would come fewer services: 71 percent anticipated fewer pharmacy services, 68 percent projected fewer pharmacy-related programs, and 61 percent projected a reduction in programs outside the pharmacy.

If 340B disappeared today, the impact would be devastating to hospitals and far reaching for patients.

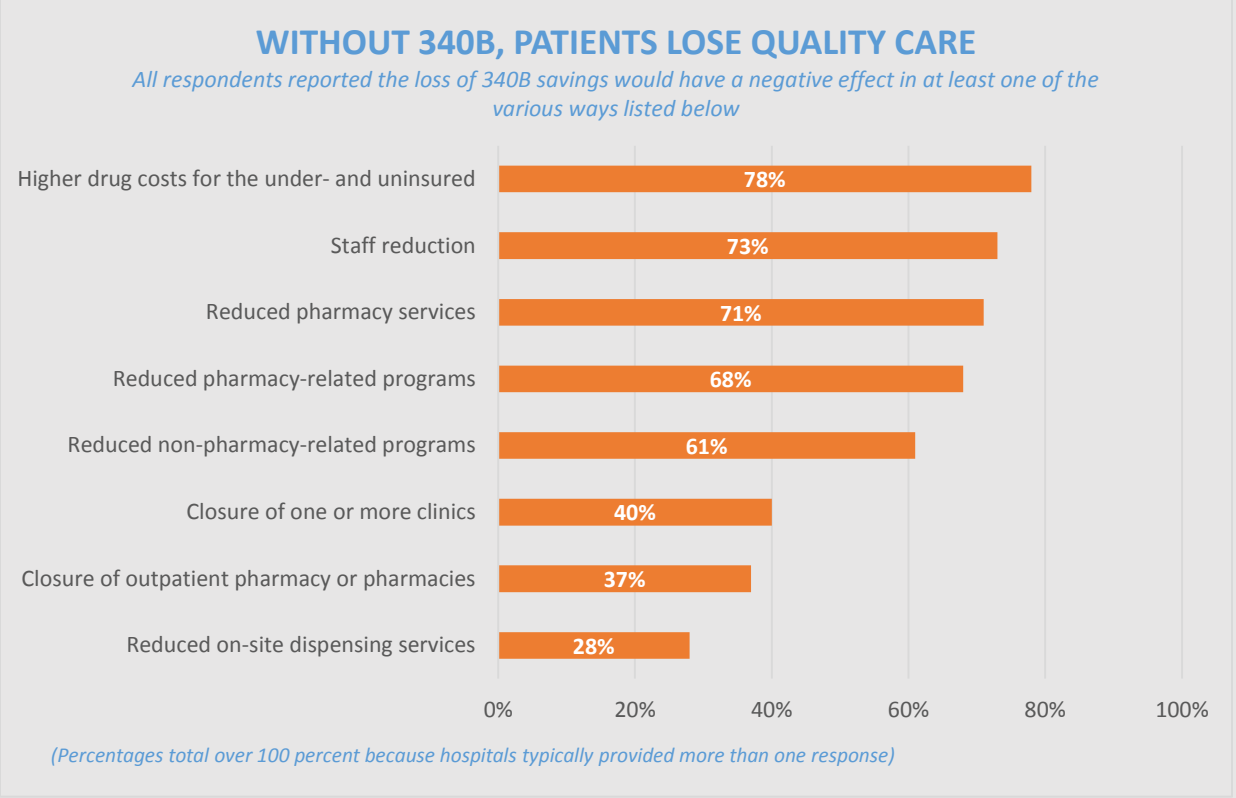

Figure 8: If the program were no longer available, how would this impact the health of your community?

When asked to go into detail about what effect losing 340B would have on hospitals and their patients, respondents were not optimistic. Some named specific programs that would lose funding or disappear altogether, such as infusion services, home health and hospice care, obstetric care, and prescription pharmacy clinics. Many DSH hospital respondents forecasted the closure of their clinics altogether. Others would no longer be able to operate independently and would be forced to affiliate with a larger facility.

“We provide many services that we would have to consider discontinuing,” said one sole community hospital respondent. “Many of these are provided at a loss and the 340B program allows us to provide these expanded services to our population. They would go without these services or would have to drive

to obtain these services elsewhere." Research has found that 340B hospitals offer significantly more money losing but important specialized services than non 340B hospitals.

"[Loss of 340B savings] would likely cause the closing of our prescription assistance pharmacy and our infusion clinic…we have the only infusion clinic that takes uninsured oncology patients in a three-county area," said a DSH hospital respondent.

"Without this additional revenue [from 340B], our entire facility would be in jeopardy, and our next closest hospital is 60 miles away. 340B assists in keeping our doors open," said one 15-bed critical access hospital respondent.

From these responses, it is clear that entire communities, not just hospitals, rely on 340B savings.

SECTION 3: MORE PATIENTS ARE IN NEED OF DISCOUNTED CARE

While millions more Americans have some type of medical coverage because of the ACA, there are still tens of millions of others who remain uninsured or underinsured. This survey found that although many have gained coverage under the ACA, it has not diminished the need for 340B to better meet the needs of those who remain under- or uninsured.

340B HOSPITALS ARE SEEING MORE UNDERINSURED PATIENTS, NOT LESS

When asked to compare to previous years, hospitals reported that they are seeing even more underinsured patients. Seventy-eight percent of respondents said the number of patients with insurance but still in need of financial assistance has increased. Twenty-two percent of respondents saw no change.

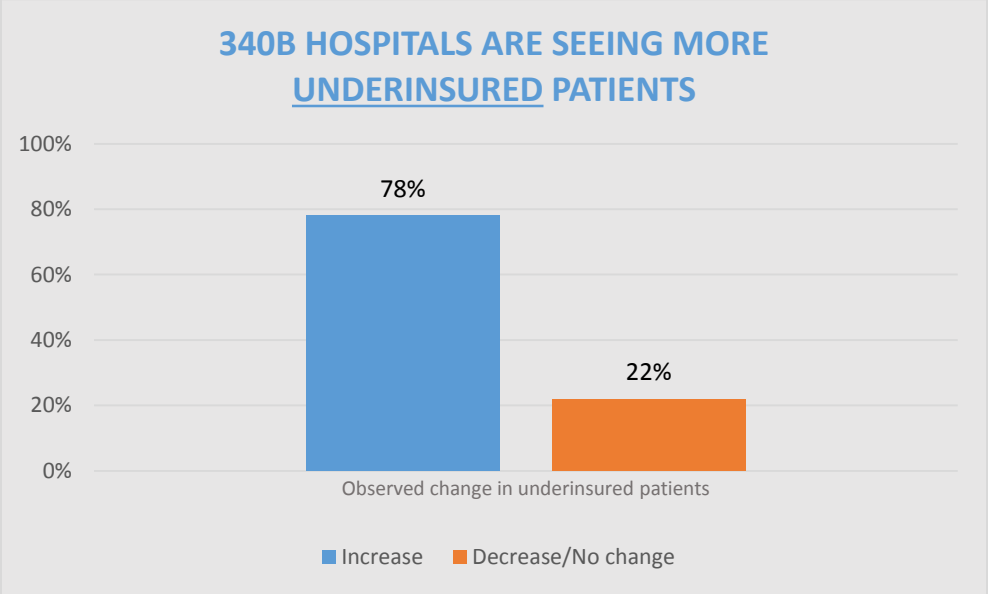

Figure 9: How does the number of patient visits with insurance but still in need of financial assistance compare with previous years?

Not only did a majority of respondents report an increase in the number of underinsured—which makes sense, given the bare-bones plans with high deductibles that form the lowest tier of insurance coverage under the ACA—but a significant portion of hospitals are still reporting an increase in the number of their uninsured patients.

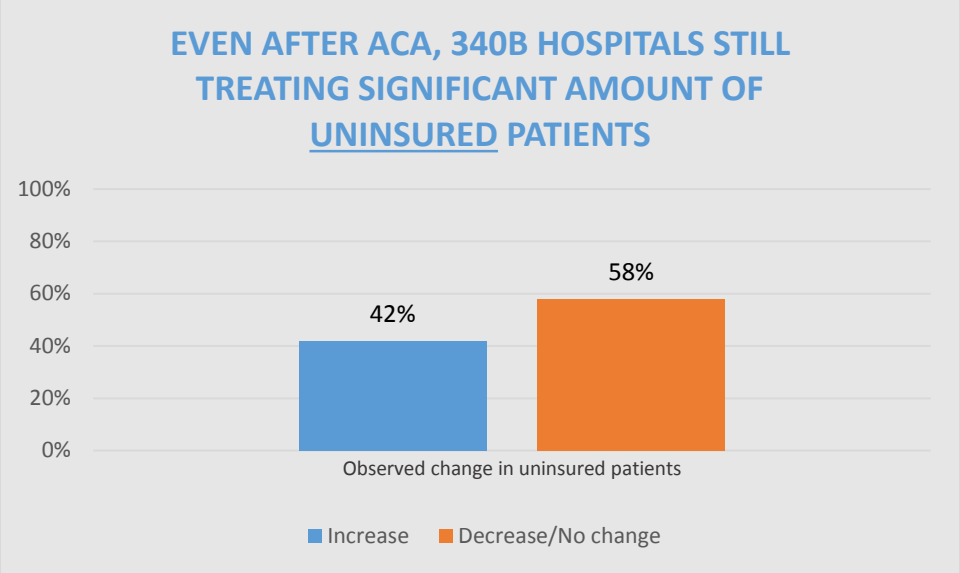

Figure 10: Has your hospital seen a change in the number of self-pay/uninsured outpatient visits in 2015 compared with previous years?

One Georgia DSH hospital respondent summarized the confluence of problems with the ACA and their significant under- and uninsured population: "Access to prescription medications is critical to our uninsured and underinsured patient population. Our outpatient pharmacies filled 850,000 prescriptions in 2014 and 52 percent were for uninsured patients who paid $5 or less per prescription. With the Affordable Care Act cutbacks on DSH funding and Georgia not expanding Medicaid, the 340B program is vital to keeping our doors open."

If these numbers hold as respondents expect, patients and hospitals will continue to face hard choices.

"We are located in the Iron Range and there have been many layoffs work slowdowns related to the taconite/steel industry… With the poverty level as high as it is and patients attempting to save money by choosing the high deductible plans, we often hear them complain that it is either food or medications," said one respondent from a sole community hospital.

340B ensures that fewer people must choose between food and medicine in a financially sustainable way. The same respondent continued, "It is financially foolish to not get medications into the hands of these individuals. If they end up being hospitalized we incur far greater costs than if we discount medications to them heavily. This makes sense from both a short-term and long-term period. Keeping them on their medications prevents or lessens the possibility of long-term complications from not taking their medications."

The issue of insured patients in need of financial aid is multifaceted. Most hospitals agreed that copays are too high, it is difficult for patients to meet deductibles, and many plans have insufficient drug benefits, as reflected in the graph below.

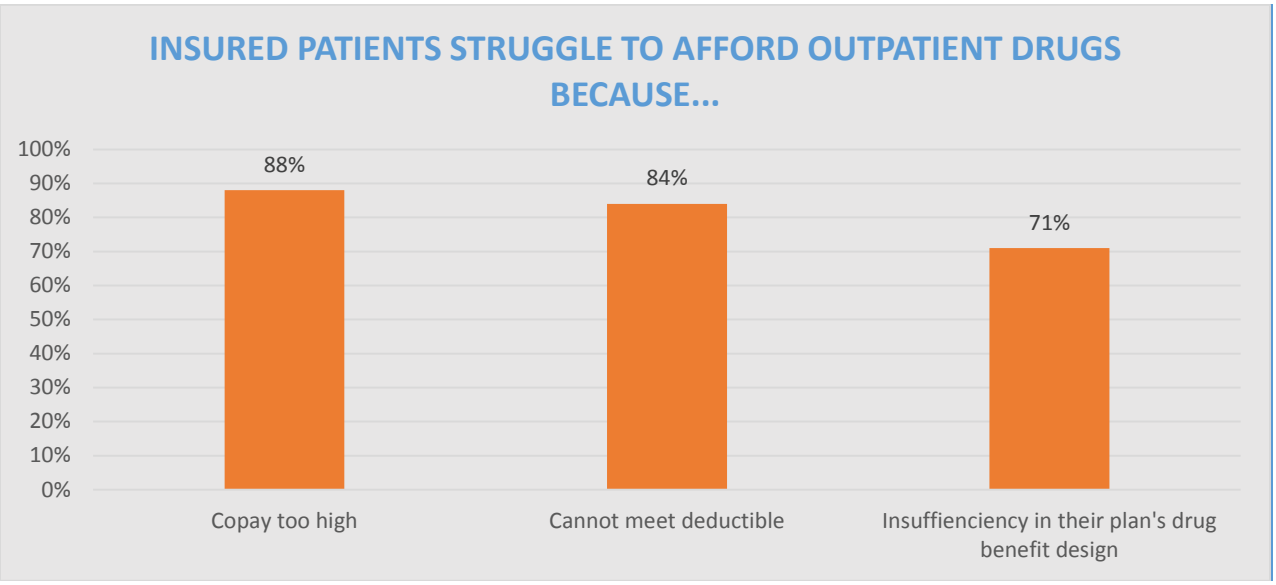

Figure 11: For insured patient with financial need, what are the reasons that they need financial assistance obtaining outpatient drugs?

CONCLUSION

According to the survey results, safety-net hospitals and the communities they serve need the 340B program now more than ever. 340B is a provider drug discount program, but it has a much wider impact than access to less expensive pharmaceuticals. The responses were uniform across 340B Health's membership—disproportionate share hospitals, critical access hospitals, children's hospitals, sole community hospitals and, rural referral centers. They all agree that 340B is important to their operations and more necessary now than it was five years ago. Patients rely on the program to get access to life-saving medication and patient services, both inside and outside the pharmacy.

340B Health member hospitals shared that they are facing a significant rise in the number of underinsured patients, despite the reduction in overall uninsured in the U.S. following the implementation of the Affordable Care Act.

Without 340B, America's safety net would be devastated. Possible closures as a result of losing these drug discounts would put a massive strain on a system already stretched to its limits. What is best for Americans and the hospitals that make up our safety net is to continue strengthening the 340B program. Its benefits are often unsung, but nonetheless vital to the health of our most vulnerable patients and communities.