340B HEALTH

340B Health Annual Survey 2022: Vital 340B-Supported Patient Services Threatened as Manufacturer Restrictions Cut Into Savings

EXECUTIVE SUMMARY

In November and December 2022, 340B Health conducted its annual survey of hospital members to learn about how they use their 340B savings to support care for patients with low incomes and living in rural areas. The survey also explored program operations and finances, including the impact of manufacturer restrictions on 340B savings through community and specialty contract pharmacies. With 633 member hospitals responding, this report presents findings for disproportionate share (DSH) hospitals, rural referral centers (RRCs), and freestanding children's hospitals (PEDs), which are larger urban and rural hospitals, separate from critical access hospitals (CAHs), which are smaller and predominantly rural, have 25 beds or fewer, and are located more than 35 miles from another hospital. An insufficient number of sole community hospitals (SCHs) responded to group them separately. No cancer hospitals responded.

In 2022, nearly half of 340B hospitals faced declining savings as manufacturer restrictions on 340B discounts at contract pharmacy expanded. These reductions made it more challenging for 340B hospitals to use the program savings as intended, which is to leverage scarce federal resources to support programs and services for patients with low incomes and living in rural areas. Survey results include:

- **340B savings are declining for many hospitals.** In 2022**,** 56% of CAHs and 43% of DSH/RRC/PED 340B hospitals saw a decline in 340B savings. This percentage has grown markedly since 2019, from 11% and 6% respectively, as drugmakers ramped up restrictions on access to 340B discounts at community and specialty pharmacies. Other research finds restrictions have cost 340B hospitals billions of dollars in safety-net support.

Billions

of dollars of 340B savings lost due to drug company restrictions

- **Community and specialty pharmacies are a vital access point to 340B discounts.** Because the majority of CAHs (88%) and DSH/RRC/PEDs (53%) do not operate their own retail pharmacies and very few operate specialty pharmacies, relationships with community and specialty pharmacies are critical to accessing discounts on the drugs their patients use. Placing restrictions on the use of specialty contract pharmacies allows manufacturers to avoid high-dollar discounts for their costliest drugs. Manufacturers target other drugs to skirt substantial penalties for past price increases above the rate of inflation. Savings from these relationships account for about half of 340B savings for CAHs and a quarter for DSH/RRC/PEDs.

- **Community and specialty pharmacy restrictions already have led to cuts; more are expected if they continue.** At the time of the survey, one in three CAHs and one in 10 DSH/RRC/PEDs report contract pharmacy restrictions have forced them to cut programs and services for patients living with low-incomes or in rural areas. Nearly all reported they would need to make cuts if these restrictions become more widespread and/or permanent. Since that time, more have imposed restrictions, and many have tightened existing restrictions.

- **These restrictions cause direct harm to patients.** Patients unable to obtain discounted drugs at community and specialty pharmacies are losing access to critical medications. Some have ended up in the hospital or emergency department after their price for a drug spiked and they were unable to afford their prescription.
- **More broadly, restrictions on community and specialty pharmacies threaten:**
  - **Programs and services for patients living with low incomes and in rural areas.** All 340B hospitals surveyed reported using their 340B savings to support programs and services for patients in need. Top reported uses for 340B savings for DSH/RRC/PEDs include increasing access to care for low-income and/or rural patients (85%), providing unpaid care (85%), and expanding service offerings (83%). Other uses include subsidizing services that operate at a loss, making capital improvements, and providing discounted or free drugs.
  - **Access to care for rural communities**. Eighty-four percent of CAHs use 340B savings to maintain or provide more unpaid care, and 75% reported relying on 340B savings to keep their hospital doors open.
  - **Improved patient outcomes.** Hospitals use 340B savings to improve specific outcomes such as reducing readmissions and emergency department visits or improving medication adherence. Programs supported by 340B help patients reach clinical goals such as lower A1C levels for diabetes and reduced viral loads for HIV/AIDS and hepatitis.
  - **Access to critical clinical services.** The patients most likely to be impacted by cuts to 340B for DSH/RRC/PEDs are those with cancer (78%), diabetes (66%), and mental health and substance use disorders (50%). For CAHs, general patient care services (66%) and diabetes care (50%) are most at risk.

Hospitals Report Service Reductions Due to Contract Pharmacy Restrictions

- Closed services and laid off staff
- Closed or consolidated outpatient behavioral health units
- Capped census in long-term-care unit
- Cut insulin patient assistance program
- Closed a rural health clinic
- Withdrew support from 17 school-based clinics

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 health care safety net. Savings from these discounts enable 340B providers to offer additional programs and services to low-income, rural, and vulnerable patients at no additional cost to taxpayers. The care supported by 340B savings comes from drug companies' revenues, not from taxpayer dollars.

New Financial Pressures Emerge for Hospitals Post-COVID

Prior research found that the financial performance of 340B hospitals suffered more than non-340B hospitals during the COVID-19 public health emergency.[2] The populations disproportionately served by 340B hospitals—Medicaid patients and Medicare patients with low incomes as well as patients identifying as Black or Hispanic—were also disproportionately impacted by COVID-19. [3,4,5] While pandemic-related relief provided a temporary reprieve, hospitals still face precarious financial situations, with inflation and labor shortages fueling skyrocketing costs and analysts predicting "significantly depressed" margins in 2023.[6]

Community and Specialty Pharmacy Restrictions Are Exacting an Additional Toll on the 340B Safety Net

In addition to the financial stress from COVID-19, 340B hospitals also face billions of dollars in reductions in 340B savings due to manufacturer-imposed restrictions on community and specialty contract pharmacies.[7] 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 enable 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 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 the government's position that such actions violate the law. At the time of this survey, 18 companies had imposed such restrictions.[8] Since that time, five additional manufacturers have imposed restrictions. Conditions manufacturers have imposed for continued access to 340B pricing at contract pharmacies include an onerous data submission process. However, since this survey was conducted, some of the largest drugmakers have reneged on this option and further tightened restrictions.

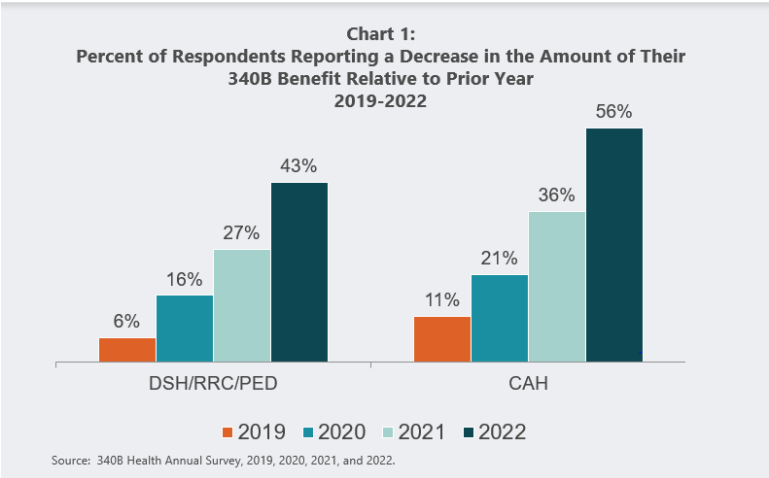
Both the Trump and Biden administrations have taken the position that these restrictions are unlawful. The Health Resources & Services Administration (HRSA), which oversees and administers 340B, has issued violation letters directing many of the companies to reinstate 340B discounts. The agency has referred some cases to the Health and Human Services Office of Inspector General (OIG) for potential civil monetary penalties for noncompliance. Ten of these drug companies have filed lawsuits challenging HRSA's enforcement actions in federal court. Lower court decisions that addressed six of these lawsuits are on appeal, with one appellate court striking down HRSA's violation letters against three drug companies and two other appellate courts still considering lawsuits by three other companies.

FINDINGS

More Than Half of 340B CAHs and Nearly Half of DSH/RRC/PEDs Saw a Decline in 340B Savings in 2022

The financial support for safety-net hospitals from the 340B program has grown consistently over time. Prior to drugmakers restricting access to community and specialty pharmacy, only a small percentage of survey respondents reported a decline in year-over-year 340B savings. Since 2019, the portion reporting a decline increased from 6% to 43% for DSH/RRC/PEDs and from 11% to 56% for CAHs (Chart 1). This finding is consistent with earlier research finding that losses of 340B savings are in the billions due to manufacturers imposing restrictions on community and specialty pharmacy.[9]

Share of Hospitals With Declining Savings is Rising

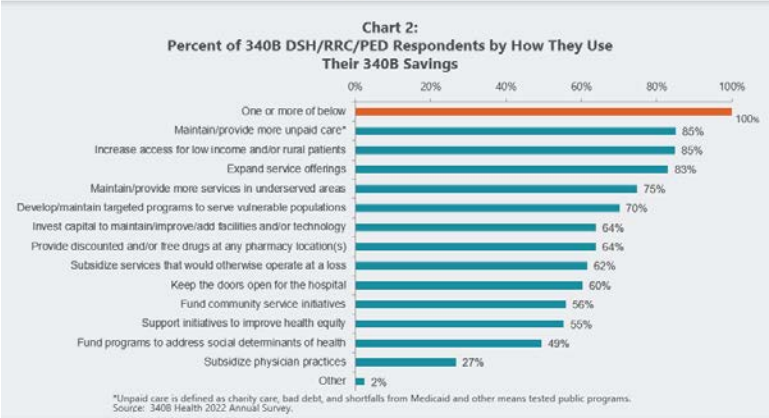


Vital Services Are at Risk as Drugmaker Restrictions Cut Into Safety-Net Resources

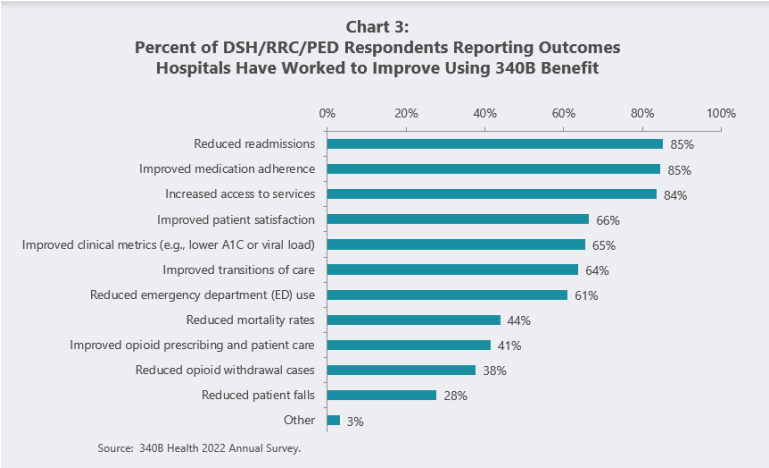
340B discounts on outpatient drugs create savings that enable safety-net providers to stretch scarce resources as far as possible to reach more patients and provide more comprehensive services.[10] These services, critical to patients with low incomes and those living in rural areas, are at risk because of the manufacturer restrictions on community and specialty contract pharmacy.

Larger 340B hospitals (including DSH, RRC, PED) use their 340B savings in a wide variety of ways including providing unpaid care (85%), increasing access to patient care services for low-income and/or rural patients (85%), providing more services in underserved areas (75%), and many other initiatives such as capital improvements, subsidizing services that operate at a loss, and providing free and discounted drugs (Chart 2). 340B supports improved patient outcomes (Chart 3). More than eight in 10 respondents report 340B supports reduced readmissions and improved medication adherence. This is consistent with published research finding that 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.[11] 340B-supported programs help patients better manage their diseases leading to lower A1C levels for patients with diabetes and reduced viral load for patients with HIV/AIDS or hepatitis.

340B DSH/RRC/PEDs Use 340B Savings in Many Different Ways



340B Supports Improved Outcomes

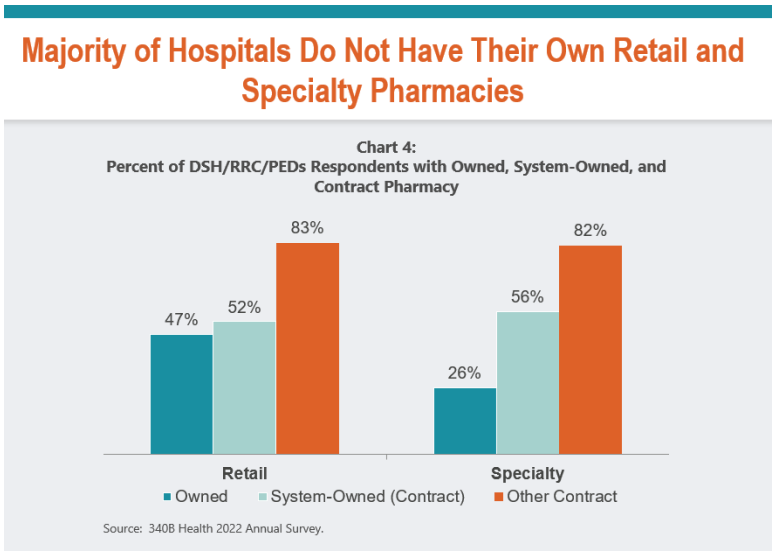


Even with contract pharmacy restrictions in place, DSH/RRC/PEDs reported that relationships with community and specialty pharmacies account for more than a quarter of their 340B benefit. More than half do not operate their own retail pharmacies and three-quarters do not have their own specialty pharmacies, making these relationships the only means of accessing 340B savings for many drugs (Chart 4). The vast majority contract with community retail (83%) and specialty (82%) pharmacies that are not owned by their systems, and just more

28%
of 340B savings for DSH/RRC/PEDs come from community or specialty contract pharmacy

"[Our hospital] provides services that would lose money without our 340B benefit, including our birthing center, ambulance service, and diabetes self-management support." Urban DSH hospital in Midwest

than half contract with pharmacies that are wholly owned by their health care systems. System-owned pharmacies are increasingly subject to restrictions.



Research has found that overall 340B savings for manufacturers imposing restrictions dropped by up to 41% or $1.1 billion for 340B hospitals for the five drugmakers that had a full year of restrictions in place for 2021, the most recent year for which data are available.[12] This translates into billions of dollars for the 23 that now have such restrictions, even without considering that some of the largest manufacturers have tightened these restrictions further in 2023. One in 10 DSH/RRC/PEDs surveyed report that they have already had to cut programs and services for patients with low incomes or living in rural areas, and more than eight in 10 anticipate doing do if these restrictions become permanent or more widespread. These hospitals report that the services most at risk for cuts include oncology (78%), diabetes (66%), and mental health and substance use (50%).

340B-Supported Program Reduces Emergency Department Visits and Hospitalizations

New research documents how 340B-supported programs improve patient outcomes. A health care system in the Midwest implemented a prescription assistance program at multiple sites associated with one rural and two urban 340B hospitals. These facilities serve communities where up to 30% of the population lives in poverty and about 15% live without health insurance. By passing along 340B discounts at in-house and community pharmacies, the program enabled patients to obtain medications for only $15 for a 90-day supply that otherwise would cost $350 a month without insurance coverage. In addition to benefiting from these savings, patients enrolled in the program experienced a 30% reduction in the rate of emergency department visits and hospitalizations, for average savings of more than $1,000 in health care costs.[13]

Community and Specialty Pharmacy Restrictions Compound Financial Pressures on CAHs

340B supports access to health care for the one in five Americans who live in rural areas.[14] Many rural areas are sparsely populated and far from urban areas. Rural hospitals also are vital to local economies, signaling that a community is a viable place to locate a business, retire, or raise a family. A recent report found that hundreds of rural hospitals are at risk of closing as expenses outstrip revenues.[15] COVID-19 took a toll, and workforce shortages and inflation are driving up expenses. Fifty-six rural hospitals have closed since 2019 alone.[16]

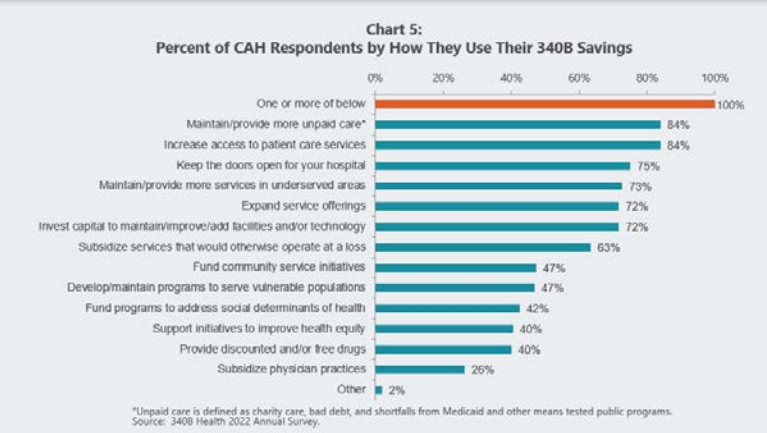
In 1997, Congress created the CAH designation, which provides special Medicare reimbursement for hospitals with 25 beds or fewer and that are at least 35 miles from another hospital. Today, nearly three-quarters of rural hospitals are CAHs.[17] Recognizing the often precarious finances of rural hospitals, Congress expanded 340B in 2010 to include CAHs as well as SCHs and RRCs, which HRSA categorizes as predominantly rural.[18] Today, 71% of rural hospitals participate in 340B.[19] The vast majority are CAHs.

48%

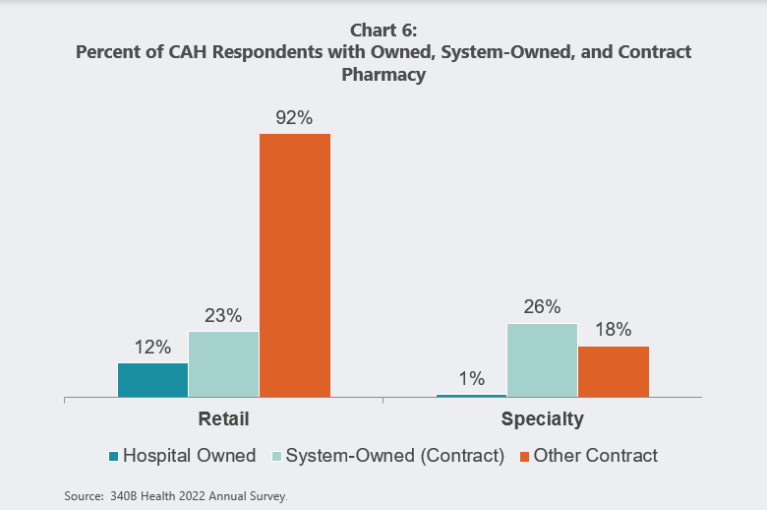
of 340B savings for CAHs come from community or specialty contract pharmacy

340B provides needed financial support to CAHs. Seventy-five percent of CAHs report that 340B helps them keep their doors open. These resources also support unpaid care (84%) and enable a majority of CAHs to increase access to patient care services (84%) and provide more services in underserved areas (73%) (Chart 5). CAHs report that 340B savings improve outcomes including reducing readmissions (81%) and improving medication adherence (63%).

340B CAHs Use 340B Savings in Many Different Ways



CAHs Depend on Contract Pharmacies



With limited resources to operate their own retail pharmacies, CAHs depend more heavily on community pharmacy relationships to access 340B discounts on drugs. Only 12% of CAHs report operating their own retail pharmacies and only 1% operate specialty pharmacies (Chart 6). A small percent contract with pharmacies owned by their systems which are often subject to restrictions. Meanwhile, the vast majority of CAHs have at least one contract pharmacy relationship and on average depend on these relationships for nearly half of their 340B savings. The contract pharmacy restrictions have cut more deeply into 340B savings for CAHs.[20] As the restrictions continue and become tighter, CAHs are facing increased financial pressure. One in three report that they have already had to cut programs and services because of these restrictions, and nine in 10 expect to do so if they continue.

CAHs report that the loss of 340B benefit would most impact their ability to provide unpaid care (79%), general patient care service offerings (78%), access to patient care services for people with low incomes or living in rural areas (73%), and services that otherwise would operate at a loss (72%). Two-thirds (67%) could have to close their doors. Diabetes care was of concern to half.

"Our CAH uses 340B benefit to provide comprehensive service to all patients regardless of ability to pay, clinical pharmacy services, outpatient infusion services, and safety and facility upgrades to ensure continued high-quality patient care." Rural CAH in the South

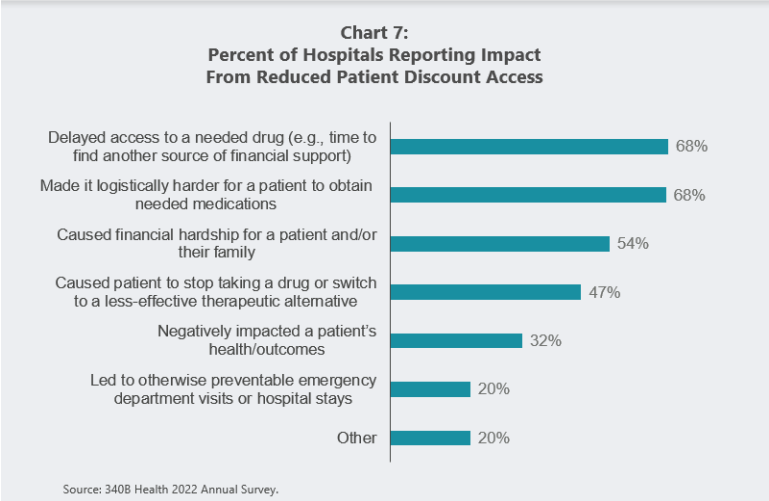
340B Associated With Increased Access to Cancer Care in Rural Communities

People living in rural communities face substantially higher mortality rates for cancer, in part because of limited access to oncology services close to where they live. New research published in *Health Affairs* finds that hospitals enrolling in 340B between 2012 and 2018 were 8.3 percentage points more likely to have added oncology services as of 2020. 340B helps eliminate barriers to hospitals offering cancer care including the high cost of procuring drugs and operating these services, which can be insurmountable for rural hospitals.[21]

Losing Access to Discounted Drugs at Community and Specialty Pharmacies Harms Patients

Nearly half of non-CAH 340B hospitals and about a quarter of CAHs offer reduced priced drugs or otherwise lower out-of-pocket costs for patients with low incomes at community or specialty pharmacies. This is one of the multiple ways that 340B hospitals help their patients access affordable drugs. Other support includes extending charity care and financial assistance, providing patients with discounted or free medications at discharge, and offering discounted drugs through hospitals' own retail or specialty pharmacies. Providing discounted drugs at community pharmacies creates an important access point for patients with low incomes who often do not have the time or resources to travel to the hospital to obtain their medications.

Patients Receiving Discounts at Contract Pharmacies Experienced Harm



Manufacturer restrictions are causing patients to lose access to critical medications. Patients face logistical challenges if the only remaining contract pharmacy is a city bus ride away or perhaps more than 30 miles away for patients living in rural areas. Respondents report examples of patients going to a pharmacy that had lost access to 340B pricing and not taking home their prescription because of the substantially higher price. For many drugs, such as insulin or psychiatric medications, skipping even a dose can lead to significant harm (Chart 7).

CONCLUSION

In 2022, nearly half of 340B hospitals faced declining savings as manufacturer restrictions on 340B discounts at contract pharmacy expanded. These cuts are challenging the ability of 340B hospitals to continue to leverage scarce federal resources to support programs and services for patients with low incomes and living in rural areas. Most hospitals reported that they would need to make cuts if these restrictions become more widespread, and many already have. Since the survey was administered late last year, additional manufacturers have imposed restrictions, and existing restrictions have tightened. At risk are patient care services, targeted programs to support health and social needs for rural and vulnerable populations, a variety of specialty services, and the improved patient outcomes these services support.

METHODOLOGY

The survey was administered to 1,560 hospitals that are members of 340B Health. Responses were collected from Nov. 9 through Dec. 31, 2022. A total of 633 hospitals responded for a response rate of 41%. DSH hospitals were somewhat over-represented and CAHs were under-represented in the sample. Results are presented for DSHs, RRCs, and PEDs separately from CAHs to account for the size differences between these types of hospitals. SCHs are not included because they do not fit well in either size grouping, and there were too few to group separately (23). No cancer hospitals responded to the survey.

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