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Policy Brief

Overview of the 340B Drug Pricing Program

The 340B Drug Pricing Program was created by Congress in 1992 to allow eligible healthcare organizations to purchase outpatient drugs at a discount from pharmaceutical manufactures. It is meant to help safety net providers, such as hospitals and clinics, to better meet the health needs of lower-income populations and to augment federal resources (Commonwealth Fund, *The Federal 340B Drug Pricing Program: What It Is, and Why It Is Facing Legal Challenges,* September 8, 2022). Retail pharmacies eligible to participate in the program are referred to as contract pharmacies and healthcare organizations providing care are referred to as covered entities. Over the years, a range of covered entities have gained access to the program to better serve their patients, this includes Critical Access Hospitals (CAHs) along with federally-certified Rural Health Clinics (RHCs) if they are provider-based and the hospital they serve is in the program. A majority of North Dakota RHCs are provider-based and owned by the CAH. Independent RHCs are not eligible, nor are Rural Emergency Hospitals (REHs). Health Center programs (rural and urban) are eligible (e.g., Federally Qualified Health Centers (FQHCs), including Community Health Centers, Migrant Health Centers, healthcare for the homeless, and healthcare for residents of public housing) (Health Resources and Services Administration, *340B Drug Pricing Program, October 2024*). The discounts can range from 25-50%.

There has been significant growth in use of the program with about 8,100 covered entities in 2000 (both urban and rural) expanding to over 50,000 by 2020 (Commonwealth Fund, September 8, 2022). The economic volume continues to grow as well. According to HRSA, total discounted purchases reached approximately $44 Billion in 2021 (HRSA, *2021 340B Covered Entities Purchases, August 2022*). Disproportionate Share Hospitals (DSH) comprise the largest component of 340B covered entities accounting for $34 billion (77 percent) of the $44 billion. DSH is a hospital category that treats vulnerable populations such as the elderly, people with disabilities, and children, generally uninsured or Medicaid populations. The second highest covered entity are Health Center program facilities, such as FQHCs, at $2.2 billion (5 percent). This contrasts with CAHs, which account for only $621 million (1.4 percent). The primary provider of healthcare services in rural North Dakota are CAHs, for which there are 37. The North Dakota CAHs own and operate 51 federally certified provider based RHCs out of a total of 57 RHCs, the other six are independent. While nationally CAHs are a relatively small component of the 340B program, in North Dakota, their participation is high. For purposes of this study, we concentrate on the CAHs in North Dakota as their role is significant in rural healthcare access and delivery of care.

There has been increasing controversy associated with the program, with an emergent number of court cases pitting the pharmaceutical industry against the federal government. As more states enact laws to protect access for patients, some states are now in court. There are different viewpoints regarding who really benefits, how cost savings are applied, the level of transparency, and the level of accountability. In general, the federal government contends the program to be beneficial to addressing access to care and the cost of medications for people who have economic barriers, while the pharmaceutical

industry believes they bear the total cost of the program while hospitals and other providers are reaping untold financial benefit. From the viewpoint of the industry, 340B is a questionable benefit to patients; yet the industry is accountable for the cost as it is not covered by taxpayers. Rural providers seeking cost savings for their patients, appreciate the added benefit of being able to apply those cost savings to meet other community health needs that could not otherwise be addressed; it is a means to better manage and redirect resources that community members seek. The program is intended to benefit lower income and/or uninsured patients; additionally, in rural areas it can have an even more profound impact for health and community services that benefit not only the local community, but also the region and multiple communities (**Congressional Research Service**, *Litigation Continues Over Use of Contract Pharmacies in 340B Drug Discount Program, May 23, 2024*).

Some of the specific hurdles include a growing number of drug manufacturers that have announced restrictions on covered entities, including the number of contracted pharmacies they engage. Some are limited to only one contracted pharmacy. The argument is this restricts duplicate discounting and unlawful distribution to non-patients; they also believe that HRSA does not monitor and police this adequately. Safety net providers push back, saying this limits the full potential of the patient benefit and the benefit to the broader community. For rural providers, a CAH service area is typically a larger geographical region covering a number of towns. A limit of only one contracted pharmacy, likely in the town with the hospital and/or clinic, can create a geographical access issue. HRSA started issuing violation letters to manufacturers in 2021; manufacturers fired back; various courts have made decisions that sometimes favors the industry and others that backed the federal government and still others are waiting to decide (**Congressional Research Service**, *Litigation Continues Over Use of Contract Pharmacies in 340B Drug Discount Program, May 23, 2024*).

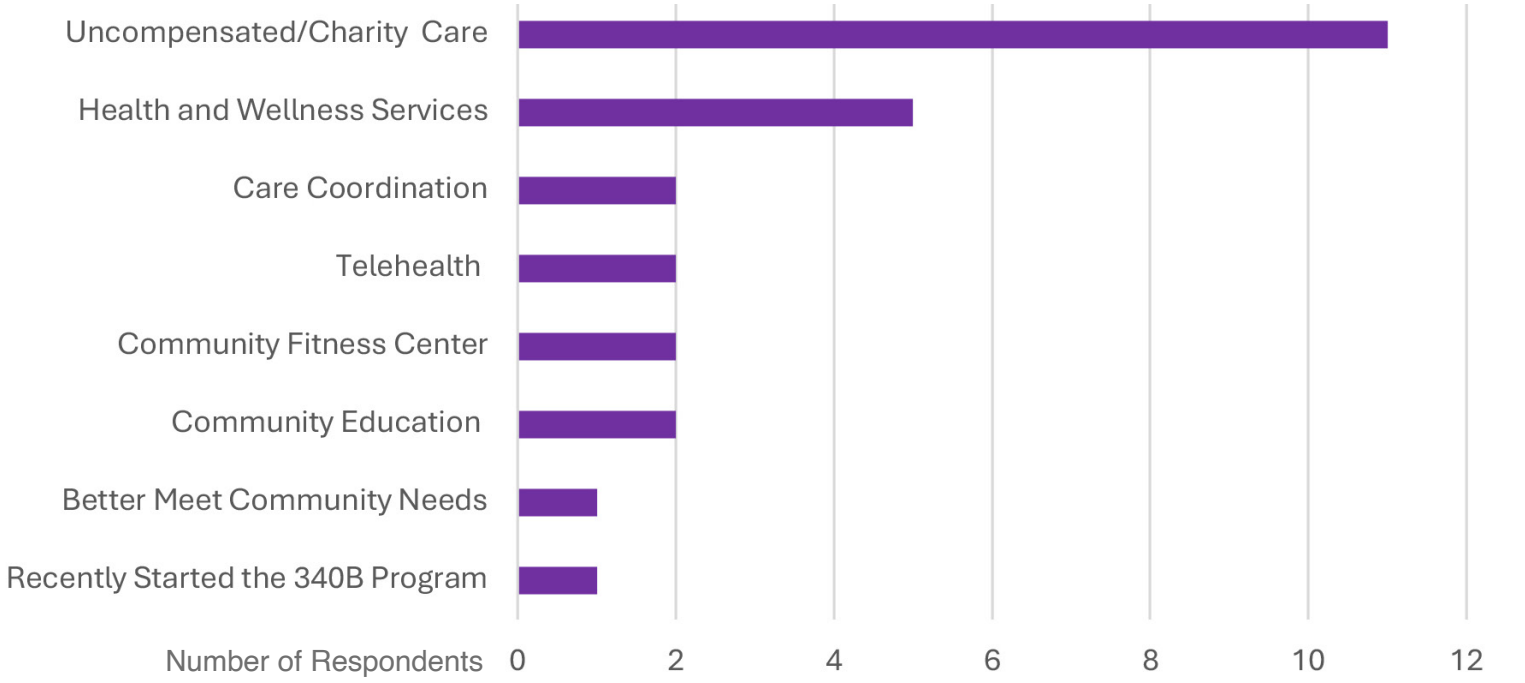
By the end of 2023, there were 30 states that had enacted legislation creating state safeguards for the continued operation of 340B. This includes prohibiting drug manufacturers and/or Pharmacy Benefit Managers (PBM) from restricting 340B drug access to covered entities and discriminatory PBM practices. A PBM is a middle-man or intermediary between the insurance company, public payers, employers, and the pharmacy.

Key Findings from the CAH 340B Survey

- Twenty-seven of the 37 North Dakota CAHs responded.
- All of the CAHs surveyed found the 340B Program to be important, with 17 of 21 CAHs rating it 10 (extremely important) on a 0-10 scale. Four CAHs rated it 8 on the 10-point scale.
- Majority of the CAHs contract with a pharmacy (25 of 27).
- About half contract with one pharmacy (10 of 21 CAHs) and half contract with 2 or 3 (11 of 21 CAHs).
- Majority of CAHs contract with a pharmacy in the same community as the hospital (16 of 20 CAHs) with 4 of 20 contracting with pharmacies in multiple communities.
- Seven of 9 CAHs responding said the distance between the CAH and Contracted Pharmacy was less than 50 miles. One CAH was 50-100 miles away, and one CAH contracted with an out-of-state pharmacy.
- Seventeen CAHs provided financial data showing the overall economic impact of the program to the CAH and community. A plurality (8 of 17) indicated that 340B had a financial impact of $400,000-$800,000 annually; four CAHs stated $100,000-399,000; and five CAHs stated the annual impact was $1 million or more (including one at over $2 million).

Sixteen CEOs responded to an open-ended question regarding how the hospital uses the savings accruing from the medication discount to address community health needs. There is an expectation that hospitals and other covered entities will re-invest the differential or savings in ways to better meet the needs of lower-income populations and other community health needs. Hospitals generally used the savings for a range of community services providing community benefit. Thus, the answers exceed the 16 who responded as the hospitals employ multiple community strategies. Some CAHs indicated as many as seven efforts for community service/benefit. CRH applied qualitative content analysis to establish categories, findings include the following:

How 340B Program Cost Savings Are Used for Community Benefit



Health and wellness services included: foot care, injury screens for high school athletes, community meals-on-wheels program, patient transportation, medical alert units, publicly placed AED's, Bone Builders exercise program, vaccinations, Sharps Program (needle stick injuries and waste disposal), prevention, locum coverage, and expanded lab services capacity.

Analysis

It is apparent that the 340B drug pricing program has great utility for rural North Dakota. While the significance of CAHs, nationwide, from a dollar impact in the $44 billion associated with the program (CAHs $621 million or 1.4 percent of dollar discounts) is small, in a rural state such as North Dakota, the program may have a higher impact in terms of savings that can be reinvested in the community and facility to better meet local area health needs. The North Dakota data supports that contention. The savings to a North Dakota CAH can be substantial covering a range of $100,000 to over $2 million on a yearly basis. Most of the CAHs fell in a range of $400,000 to $800,000; however, there were a number at $1 million or more. The 340B program effectively provides CAHs the ability to avail themselves of lower drug costs, address critical needs for uncompensated care, provide cost and service benefits to patients, and to use savings to address a broader array of community health needs.

What the Data Means – Analysis?

- There is a high level of participation in the program in North Dakota.
- On a scale of 0-10 (with 10 being "extremely important") 17 of 21 responding CAHs rated the 340B program to be extremely important (score of 10) and 4 other CAH CEOs rated it an 8, also quite high.
- The financial impact of 340B to a CAH and its community is significant ($100,000 to in excess of $1 million annually) providing additional financial resources to address community health issues, many of which do not have consistent financing.
- Many CAHs contract with only one contracted pharmacy generally in the same town as the CAH; however, about the same number of CAHs contract with multiple pharmacies and in some cases, this includes pharmacies in neighboring towns. The distance is generally less than 50 miles. CAHs are regional providers serving a relatively large geographical area and at times need to partner with contracted pharmacies in multiple locations as a means to provide access and to assure reduced prices for lower incomed patients.
- CAHs use the cost savings accruing from 340B to address a range of community health concerns. Virtually all CAHs use some savings to address uncompensated care/bad debt costs that are on

their books. And most use it to address other community health needs: health and wellness services, care coordination, telehealth, community fitness, community education, and additional efforts to better meet community health needs. Some specific areas include Meals-on Wheels, community AEDs, home monitoring devices, Bone Builders exercise for elders, transportation, care coordination, and more.

Twenty-seven of the state's 37 CAHs responded to the survey, and 25 of those 27 indicated they use 340B pricing; thus, there is strong support for 340B discount pricing as a means to help lower-income patients and families secure necessary medications. The CAHs rate the importance of the program to be "extremely important." CAH CEOs understand the potential of using the savings to address the costs of uncompensated care and to financially support community health programs that beneficial to the public.

The financial impact for a CAH and its community is significant ranging from about $100,000 to over $1 million annually. Through 340B, additional financial resources are made available that have not previously been options. Those funds are used to buy down the cost of uncompensated care and to invest in a range of important health initiatives. Some of these community health efforts are outside the normal operations of a rural hospital (e.g., meals-on-wheels, Bone Builders exercise program, patient transportation, medical alerts, and more). Frequently, there are few funding options in rural communities, civic groups are small and have limited financing, so if funding is available, it tends to fall to the hospital to initiate and lead the effort for the community.

A common assumption made by the pharmaceutical industry and other critics of the 340B program is that a covered entity (e.g. CAH) will only need to work with one contracted pharmacy. In fact, some pharmaceutical manufacturers are mandating that it be only one. The survey shows that in rural North Dakota this is not necessarily the case. While 45 percent of respondents said they work with only one contracted pharmacy, another 45 percent indicated they work with two or three contracted pharmacies. Distance can be a factor. While most of the CAHs responding to the survey indicated that their contracted pharmacy is less than 50 miles, there are some that are over 100 miles away. Rural hospitals and clinics can have a large service area that extends well beyond the community hosting the hospital. North Dakota has 37 CAHs, yet the state has 53 counties; thus, many CAHs serve the needs of neighboring counties. If the number of contracted pharmacies is limited, it may exacerbate access for patients by interfering with their choices and adding to their out-of-pocket costs. From a rural health access perspective, either manufacturer rules or statutory policy that limits access to contracted pharmacies (e.g. number and or geographical location) is problematic. Policymakers need to be aware of this factor. A program such as 340B can simultaneously lower medication costs for patients, facilitate enhanced access, and provide new financial resources to address previously unattended health needs.

Safety net providers, such as CAHs, are to use the drug discount to benefit lower income/uninsured patients and to support health service access. Addressing uncompensated care and the associated cost is common; however, it is not mandatory. Nevertheless, most CAHs do so. The survey provides evidence that North Dakota CAHs cover a wide range of services, including uncompensated care or bad debt, but in addition the following: health and wellness services, care coordination, telehealth, community fitness, community education, and additional efforts to better meet community health needs. It is important to note that many CAHs indicated multiple efforts/services to address community health needs, not simply one; in one case, the CEO identified seven programs or areas of need that their 340B savings were supporting. The list is impressive and diverse. Supporting Meals on Wheels, community access to AEDs, bone builders for senior exercise and wellness, and medical alert systems are not only a valid use of repurposed funding, it is also more secure and dependable than relying solely on community fundraising. Rural communities gladly support local efforts when and if they have available funds. However, funding in rural America can be at best unpredictable. For communities with a CAH that engages with a contracted pharmacy the medication cost savings are a vital and valuable re-investment into community health. These are choices that rural hospitals make; it is important to note that they generously apply cost savings to community needs.

Conclusion

The 340B Drug Program has been in existence for over 30 years, and with the addition of CAHs and their provider-based RHCs as covered entities through the Affordable Care Act in 2010, it has become an important rural health program. It is an initiative that assists on the cost

side of the ledger for patients and providers, and on the community health services side as well. North Dakota CAHs have shown strong support for the 340B Drug Discount program as it lowers outpatient medication costs for patients and CAHs with the added benefit that savings can be used to address uncompensated care and important community health concerns. Rural communities are afforded the ability to address neglected and/or underfunded health needs. Overall, North Dakota CAHs find it to be "extremely important." From a rural health policy perspective, this is an important finding. Rural hospitals and their primary care clinics are essential safety net providers typically serving a large geographical area. North Dakota has 53 counties but has only 37 CAHs. The CAHs operate 51 provider-based RHCs so the rural hospitals have significant service area coverage including some of the most remote and frontier areas of this state. Rural populations tend to be older, poorer, and have less insurance coverage; additionally, in a state like North Dakota where 38 of the 53 counties are remote/frontier (having seven or less people per square miles) distance/population density is also a barrier for access to care. Thus, public policy that works to improve access to care, control costs, and improve health status is critically important. Actually, this emphasis on improved health, better care, and lowered costs has become an important part of U.S. health policy and the restructuring of both our healthcare delivery and related payment systems.

While a relatively small program, 340B helps to meet rural community health needs: it is part of a growing policy recognition that the American health system must be more focused on improving population health, addressing the social drivers of health, and addressing health equity. It can help to level the playing field. Rural health providers have a responsibility to their community members. Addressing uncompensated care is important, but so too is providing a range of additional services that would likely not be present or sustainable without the financial assistance of the local health facilities. In a rural community, the rural hospital is generally regarded by community members as the primary provider of healthcare. This frequently means they are also viewed as the primary financial sponsor of all community health services. However, barely half of the CAHs have positive margins. They are not "flush" with funds to support other community health needs. 340B has energized the ability of rural hospitals to support those additional functions. Many rural health and/or human service functions are extremely vulnerable with limited financial options (e.g., Meals on Wheels, wellness and fitness services and centers, home monitoring, and local transportation). While this study represents only one state, there is strong evidence that rural North Dakota hospitals do apply 340B savings to address care for the underserved. Some national studies have questioned the application of 340B savings being directed toward this population group. At least in rural North Dakota, rural hospitals are actually addressing this issue.

From a public policy perspective, it is important to recognize the 340B drug pricing program is an important element in meeting the needs of rural Americans. It helps to meet an important public health goal of addressing and lowering the cost of medications for vulnerable populations and creates an avenue for rural hospitals to address a broad array of community health issues. Not only do patients directly benefit, but other community members do as well. While the program directly lowers outpatient drug costs for lower-income patients and the provider, it is important for policymakers to understand that North Dakota CAHs repurpose much of those savings to address critical community needs, such as a range of health and wellness services: patient education, care coordination, transportation, meals-on-wheels, wellness services and education, community fitness centers, medical alerts, vaccinations, telehealth, sports physicals, foot care, expanded lab services, and much more. In North Dakota, CAHs are essential not only in providing healthcare, but in a value-based care structure they are pivotal in prevention of disease, addressing overall population health concerns such as the social drivers of health, care coordination, and health equity. The 340B program contributes to this menu.

There are criticisms of the program, much of it originating from the pharmaceutical industry. At this time a significant level of litigation is wrapped around 340B. About 30 states have stepped up to either pass or consider legislation meant to support rural and other necessary providers that rely on 340B. One way the pharmaceutical industry is seeking to lessen the utility of the program is to limit the number of contracted pharmacies that a rural hospital can engage, to only one. On the surface that may sound sufficient; however, this study finds that North Dakota CAHs do contract with multiple pharmacies. Additionally, CMS had attempted to lower the Medicare payment rate for 340B; however, courts have ruled against that interpretation. In our rural community health systems, we know access to care is a continuing issue, limiting the

number of contracted pharmacies or lowering payment will only exacerbate access concerns. There are also concerns regarding transparency. The refrain is: what are these rural providers doing with the savings? Does it support low income individuals or is it a profit center for providers? The federal Government Accountability Office and the Department of Health and Human Services Office of Inspector General have examined 340B and have identified issues: limited oversight, lack of transparency, duplicate discounts, and Disproportionate Care Hospitals (The 340B Drug Pricing Program: Background, Ongoing Challenges, and Recent Developments, USC Schaeffer Center, October 14, 2021). These concerns need to be addressed; nevertheless, limiting or eliminating a valued rural health program is not warranted.

This North Dakota study, while not the final assessment, does establish evidence that the 340B Drug Pricing Program does provide benefit to rural patients:

- Highly used and regarded as extremely important by rural hospitals
- Increases access to care via contracted pharmacies
- Contracted pharmacies are not solely located in the community hosting the hospital, establishing access points in surrounding communities and supporting the need to maintain the option of multiple contracts
- Hospitals experience a range of financial impact from $100,000 to over $1 million annually, most reported $400,000-$800,000
- Hospitals direct funds that are gained via the price discount to uncompensated care costs and community health services such as health and wellness, care coordination, telehealth, Meals-on-Wheels, AEDs, home monitoring, community education, high school physicals, foot care, medical alerts, Bone-Builders exercise programs, vaccinations, and more.

Recommendations:

- **Congressional Policy.** At the time of this writing, there are three proposed bills in Congress (endorsed by the National Rural Health Association) that should be supported (HR 2534 Support the PROTECT 340B Act; S 5021/HR 7635 Preserve Contract Pharmacy Access; and S 4587/HR 8144 Rural 340B Access Act). The bills address a number of concerns: prohibiting insurers and PBMs from discriminating against 340B covered entities or their contract pharmacies; allowing covered entities to work with more than one contract pharmacy; and expanding the program to include the new hospital category of Rural Emergency Hospital.
- **Greater oversight from HRSA and greater transparency.** A legitimate concern in the growth of 340B is that it has not always been for the benefit of the patient and has expanded to include providers that seek more financial gain. In North Dakota, it is clear the program works for the patients and the ability of CAHs to initiate or sustain essential community health endeavors. North Dakota CAHs already track their own 340B data relevant to addressing uncompensated care needs and economic benefit to the patient along with how the cost savings are applied for community benefit. CAHs, as part of their federal tax filings (Schedule H Form 990) of the Affordable Care Act, establish evidence of their commitment to serving community benefit in exchange for their tax-exempt status. It is not an undue hardship for CAHs to provide 340B evidence.

For more information

Visit the CRH webpage for additional rural health publications and information.
https://ruralhealth.und.edu/publications

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