340B – A Missed Opportunity To Address Those That Are Medically Underserved

2023 Update

To examine whether 340B covered entities are positioned to serve low-income and vulnerable patients, the Alliance for Integrity and Reform of 340B (AIR340B) engaged Xcenda to analyze whether 340B disproportionate share hospitals (DSHs) and their associated child sites and contract pharmacies are located in medically underserved areas (MUAs).

This issue brief builds on a November 2021 analysis, which found that a majority of 340B DSHs, and their associated child sites and contract pharmacies, are not located in MUAs and, therefore, raises questions as to whether these providers are well-positioned to help close health gaps and reach low-income and vulnerable populations consistent with the intent of the 340B program.

AIR 340B Alliance for Integrity & Reform

Introduction

According to the Centers for Disease Control and Prevention (CDC), health equity is achieved "when every person has the opportunity to attain his or her full health potential" and no one is "disadvantaged from achieving this potential because of social position or other socially determined circumstances."[1] Addressing health equity is a key priority of the Department of Health and Human Services and the Biden Administration more generally.[2,3] Ensuring that government healthcare programs work to support health equity is a key part of that agenda.[4]

One way to identify areas of health inequity is through the Health Resources & Services Administration's (HRSA's) medically underserved area (MUA) designation. HRSA designates certain areas as MUAs based on having too few primary care providers, high infant mortality rates, high poverty rates, or a large elderly population. HRSA programs and grants "provide healthcare to people who are geographically isolated and those who are economically or medically vulnerable."[5]

If targeted to MUAs when appropriate, safety net programs could play an important role in advancing health equity. One such program, known as the 340B Drug Pricing Program, was created to help support safety-net providers (known as "covered entities") serving low-income and vulnerable patients.[6] The program allows certain qualifying hospitals and safety-net clinics to purchase outpatient prescription drugs at a discount.

One *Health Affairs* study analyzing the 340B program stated that it "was intended to give assistance to low-income and uninsured patients."[7] There is a clear overlap between the characteristics that define an MUA and the patient populations intended to be supported by the 340B program. In fact, HRSA both identifies MUAs and oversees the 340B program. Given the relationship between MUAs and the intended population served by the 340B program, we analyzed the correlation between 340B DSHs, their associated child sites and contract pharmacies, and the likelihood they were located in MUAs. This analysis was conducted to help determine whether these providers were well positioned to improve health equity and provide access to care for low-income and vulnerable populations.

> **"Just 35% of 340B DSHs are in MUAs, which is lower than what was found in the original study in 2021. Additionally, child DSH sites and DSH - contracted pharmacies are even less likely to be in an MUA."**

Background

There are 16 different types of covered entities eligible to participate in the 340B program according to the statute.[8] The analysis focuses on the covered entity type responsible for the largest share of 340B sales, DSHs. According to HRSA, DSHs account for about 80% of 340B sales.[9] These hospitals qualify for 340B based, in part, on the share of Medicaid and low-income Medicare inpatients they treat, even though the 340B program applies to covered outpatient drugs. Thus, these hospitals can potentially remain eligible for the 340B program even if the outpatient care they provide targets wealthier patients.

This can create a disparity between the 340B program's original mission as a safety-net program and an eligibility metric that does not forbid hospitals from expanding outpatient services in more affluent areas.

As Table 1 shows, the population located near 340B DSHs located in an MUA is more economically vulnerable as compared to the population living near 340B DSHs located outside of an MUA. For example, 340B DSHs in an MUA are in areas with a greater percentage of households living in poverty (16% vs 9% for 340B DSHs not in MUAs), which is reflected in the 22% lower mean annual incomes for areas near 340B DSHs in an MUA (almost $31,977 compared to $40,940). There is also a higher unemployment rate in the areas surrounding 340B DSHs in MUAs (7% vs 5%) and fewer people over 25 with college degrees (30% vs 39%).

Table 1: Average Demographics For 340B DSHs By MUA Status (Determined By Hospital Zip Code)

Metric	Hospitals in MUAs	Hospitals not in MUAs
Median age	36	38
Percentage of households in living in poverty	16%	9%
Mean income per capita	$31,977	$40,940
Unemployment rate	7%	5%
Percentage of individuals over age 25 with college degree or higher	30%	39%

The analysis also included off-campus outpatient facilities associated with 340B DSHs, known as "child sites," and DSHs' associated contract pharmacies, which are pharmacies that 340B covered entities contract with to dispense 340B medicines. While the 340B statute did not authorize or even mention child sites or contract pharmacies, both were borne out of HRSA guidance upon which DSHs (and other covered entities) have relied to extend the reach of 340B and to generate more profits through the program.[10] Extending the reach of 340B would be a worthy goal if patients and communities were benefiting from more affordable medicines through increased covered entity resources, but the updated analysis and original research has indicated this is not the case.

In 1994, the first year of the child site guidance, there were 25 total child sites registered in HRSA's database.[11] Today, there are 23,693 child sites associated with 340B DSHs, compared to 21,841 in 2021 (8.5% increase in just 2 years).[11] Hospitals profit by obtaining 340B discounts for medicines furnished to patients at these child sites, often located in wealthier areas. The 340B profit potential strengthens incentives for prescribing more medicines and more expensive medicines.[12,13]

The 340B program can be profitable for covered entities and for-profit contract pharmacies. As of 2022, there were nearly 32,000 unique 340B contract pharmacy locations compared to just 1,300 in 2010[14]; that was the year when HRSA updated its guidance to allow hospitals and other covered entities to use an unlimited number of contract pharmacies, instead of allowing covered entities with no on-site pharmacy to contract with one off-site pharmacy.[15] DSHs have an average of 25 contract pharmacies each—more than the average of any other type of covered entity.[16] And for good reason: according to one analysis, "the average profit margin on 340B medicines commonly dispensed through contract pharmacies is an estimated 72% compared with just 22% for non-340B medicines dispensed through independent pharmacies."[17]

Over the years, there has been an increasing number of DSHs participating in 340B, and these hospitals, in turn, have a growing number of child sites and contract pharmacies they leverage to increase 340B profits.

As a result, many policy experts have questioned whether DSHs, their child sites, and their contract pharmacies are using the program and the profits they generate to help uninsured and low-income patients access affordable healthcare services and the medications they depend on. From research by Rena Conti, PhD, Associate Research Director of Biopharma and Public Policy for Boston University, and Peter Bach, MD, MAPP, Director of Memorial Sloan Kettering's Center for Health Policy and Outcomes:

> *We found that 340B DSHs serve communities that are poorer and have higher uninsurance rates than the average US community. However, beginning around 2004, newly registered 340B DSHs have tended to be in higher-income communities compared to hospitals that joined the 340B program earlier.*

We also found that, compared to 340B DSHs, their affiliated clinics [child sites] tended to serve communities with socioeconomic characteristics that were more similar to the average US community: the clinics served communities with lower poverty rates and higher mean and median income levels than their 340B DSH parents did. These results suggest that the expansions among 340B DSHs run counter to the program's original intention."[7]

This analysis builds on prior research and adds to the growing body of work questioning the 340B program and whether it is helping underserved populations by addressing health gaps in MUAs.

" This updated analysis and original research are consistent with a 2018 New England Journal of Medicine study suggesting that hospitals use the 340B program for financial gain and act contrary to the goals of the 340B program.

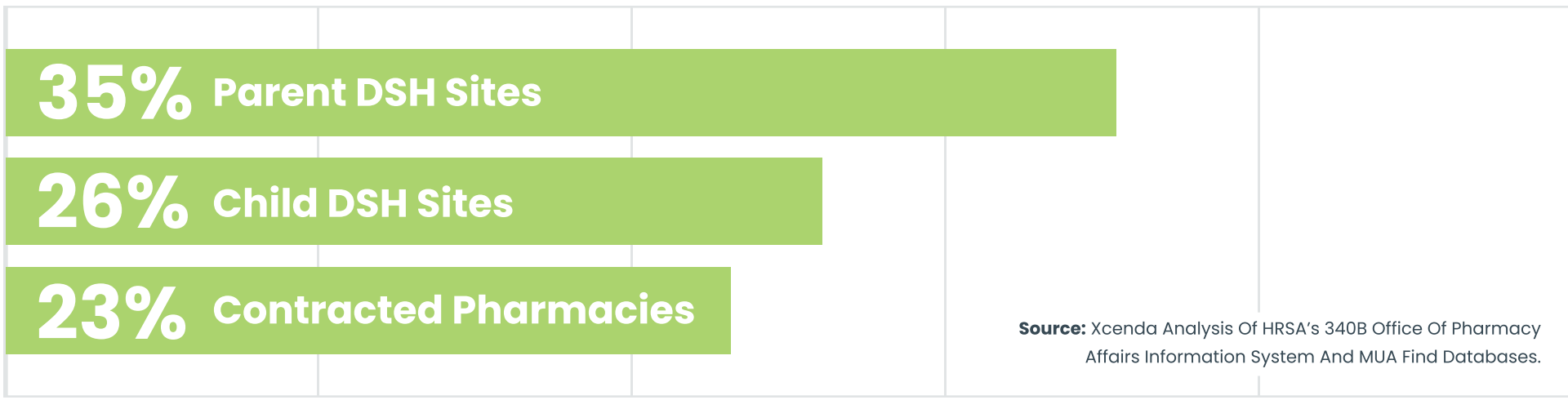
Analysis

Using HRSA's 340B Office of Pharmacy Affairs Information System and MUA Find databases, locations of 340B DSHs, their child sites, and contract pharmacies were analyzed.

It was then determined how many of these 340B DSHs, child sites, and contract pharmacies were in MUAs and, therefore, well positioned to help close health gaps and reach low-income and underserved populations.

Results: According to HRSA's Covered Entity Daily Report on April 15, 2023, there were 1,196 DSHs registered in the 340B program (6.0% increase from 2021), which had 23,693 child sites (8.5% increase) and relationships with 18,988 contract pharmacies (5.3% increase). Figure 1 shows the percentage of those providers located in MUAs.

Figure 1: Percentage Of 340B DSHs, Associated Child Sites, And Contract Pharmacies Located In MUAs



Source: Xcenda Analysis Of HRSA's 340B Office Of Pharmacy Affairs Information System And MUA Find Databases.

Despite the increase in the number of 340B DSHs, associated child sites, and contract pharmacies since 2021, the proportion of these provider sites located in MUAs did not increase. DSHs are intended to "serve a significantly disproportionate number of low-income patients," yet, only 35% of 340B DSHs are in MUAs, a decrease from the 38% of 340B DSHs in MUAs found in the 2021 analysis.

340B DSH child sites are less likely to be in an MUA compared to parent DSHs. This is consistent with the earlier study showing that child sites are often in wealthier areas than their associated parent DSH.[7] The percentage of child DSH sites in MUAs has decreased, from 29% in 2021 to 26% in 2023. Even fewer 340B DSH-associated contract pharmacy locations are in MUAs—a fact that is not surprising since these pharmacies are typically for-profit chain pharmacies.[17] This analysis found that the percentage of contract pharmacies associated with 340B DSHs located in MUAs has decreased in the last 2 years (26% in 2021 vs 23% in 2023).

Conclusion: 340B DSHs Are Not Expanding Access In MUAs

The 340B Drug Pricing Program was created to help low-income and vulnerable patients access medicines at safety-net facilities.

However, the vast majority of 340B-registered DSHs, their child sites, and associated contract pharmacies are not located in MUAs. This analysis not only reinforces the 2021 research, it also demonstrates that the situation is deteriorating. While the total number of 340B DSHs and associated child sites and contract pharmacies continues to grow, there is now a smaller share of these providers located in MUAs, as compared to 2 years ago. A trend that runs counter to the needs of vulnerable patients and communities intended to benefit from the 340B program.

Having such a small share of 340B DSHs, associated child sites, and contract pharmacies located in MUAs is antithetical to the mission of the 340B program and further marginalizes communities already experiencing disparities in health outcomes.

A 2018 *New England Journal of Medicine* analysis of 340B spending found compelling evidence that financial gains for hospitals were not associated with expanded care or lower mortality among low-income patients.[12] In fact, the analysis suggested that hospitals use the 340B program for financial gain and act contrary to the goals of the program, which include serving low-income patients.

> **"There is a very small share of 340B DSH hospitals, their child sites, and associated contract pharmacies located in areas of the United States that are most in need of these providers —specifically MUAs, which have too few primary care providers, high infant mortality rates, high poverty rates, and/or large elderly populations.**
>
> **And the percentage of these providers located in MUAs is shrinking. This analysis found the total percentage of 340B DSH parent sites, associated child sites, and contract pharmacies in MUAs has decreased 3% in just 2 years."**

The results of that study, along with recent data[18] raise the following questions: if the 340B program was designed to support covered entities serving low-income and vulnerable patients, why are so few 340B DSHs located in the most medically underserved communities? Additionally, if 340B DSHs are extending their use of the 340B program through child sites and contract pharmacies, why are they choosing to locate their outpatient sites and contract with for-profit pharmacies that are rarely in MUAs, rather than expanding their footprint to increase access for patients in MUAs?

Congress and HRSA should consider revisiting the eligibility standards for the 340B program. Eligibility standards must ensure that the 340B program supports only true safety-net facilities and prevents the program from being used solely as a profit center for hospitals and pharmacies that do not serve low-income and underserved patients in the communities where they live.

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