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340B and health equity: a missed opportunity in medically underserved areas

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 provides grants and oversees programs that "provide healthcare to people who are geographically isolated and those who are economically or medically vulnerable."⁵ 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.

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 low-income and uninsured Americans gain more affordable access to medicines at statutorily specified healthcare safety-net providers (known as "covered entities") that are expected to serve a higher proportion of vulnerable patients.



The **340B** program can play a vital role in advancing health equity.

One <u>Health Affairs</u> 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 population intended to be supported by the 340B program. In fact, HRSA both identifies MUAs and oversees the 340B program. As such, we analyzed how often 340B disproportionate share hospitals (DSHs) and entities associated with them were located in MUAs to help determine whether they were well positioned to improve health equity by targeting underserved populations most in need of better access to care.

Background

There are 15 different types of covered entities eligible to participate in the 340B program according to the statute. We centered our analysis on the type of covered entity responsible for the largest share of 340B sales, DSHs. According to a Medicare Payment Advisory Commission (MedPAC) report, DSHs account for about 80% of 340B sales.⁸ These hospitals qualify for 340B based on the share of Medicaid and low-income Medicare inpatients they treat, even though the 340B program applies to outpatient care only. Thus, these hospitals remain in the 340B program even if the outpatient care they provide targets wealthier patients. This creates a mismatch between the 340B program's original mission as a safety-net program and the eligibility criteria that allow hospitals to remain eligible for 340B discounts even as they expand to provide more outpatient care in more affluent areas.

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Our analysis is consistent with a 2018 <u>New England Journal of</u> <u>Medicine</u> study suggesting that hospitals use the 340B program for financial gain and act contrary to the goals of the 340B program.

Our analysis also included outpatient clinics affiliated with 340B DSHs, known as "child sites," and DSHaffiliated contract pharmacies, which are pharmacies that 340B entities contract with to dispense 340B medicines. Both child sites and contract pharmacies were borne out of HRSA guidance upon which DSHs have relied to extend the reach of 340B and to generate more profit.

In 1994, the first year the child site guidance was in place, there were 25 child sites registered in HRSA's database.⁹ Today, there are 39,136 child sites, of which 21,841 are affiliated with a 340B DSH. Hospitals profit more by obtaining 340B discounts for patients at these child sites, which then creates an incentive to prescribe more medicines and more expensive medicines.^{10,11}

Similarly, the 340B contract pharmacy program is very profitable for covered entities and for-profit pharmacies. Today, there are nearly 30,000 unique 340B contract pharmacy locations compared to just 1,300 in 2010¹²; that was the year when HRSA updated its guidance to allow hospitals and other covered entities to have an unlimited number of contract pharmacies, instead of limiting the program to covered entities with no on-site pharmacy.¹³ DSHs now have an average of 25 contract pharmacies each—more than the average of any other type of covered entity.¹⁴ 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."

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

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. From a report by Rena Conti, PhD, Associate Research Director of Biopharma and Public Policy for Boston University, and Peter Bach, MD, MAPP, Director of Memorial Sloan Kewttering's <u>Center for Health Policy</u> <u>and Outcomes</u>:

"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 adds to past research, furthering the conversation about the 340B program and whether it is helping underserved populations by addressing health gaps in MUAs.

Analysis

According to the Centers for Disease Control and Using HRSA's <u>340B Office of Pharmacy Affairs</u> <u>Information System</u> and <u>MUA Find</u>, Xcenda analyzed the locations of DSHs, their child sites, and contract pharmacies.

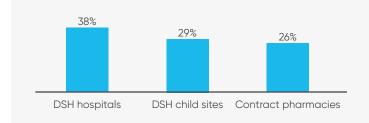
We then determined how many of these 340B DSHs, child sites, and contract pharmacies were located in MUAs and, therefore, well positioned to help close health gaps and reach low-income and underserved populations.

Results: According to HRSA's <u>Covered Entity</u> <u>Daily Report</u> on August 12, 2021, there were 1,129 340B-enrolled DSHs, which had 21,841 child sites and relationships with 18,024 340B-enrolled contract pharmacies. Figure 1 shows the percentage of those facilities located in MUAs.



Just 38% of 340B DSHs are in MUAs, and their child sites and contract pharmacies are even less likely to be in an MUA.

Figure 1. Percentage of Facilities in MUAs



Despite the stated DSH purpose of "serving a significantly disproportionate number of low-income patients," less than 4 in 10 DSHs are in MUAs. Additionally, 340B child sites are less likely to be in an MUA compared to DSHs. This is consistent with the earlier study showing that child sites are often in wealthier areas than DSHs.⁷ Even fewer contract pharmacy locations are in MUAs, which is not surprising since these pharmacies are typically for-profit chain pharmacies.¹⁵

In other words, there is a very small share of DSH hospitals, their child sites, and affiliated 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 population.

The nonprofit hospitals and clinics that participate in 340B should have a responsibility to help advance health equity, which is a key part of President Biden's larger agenda on racial equity.³ However, the 340B program does not ensure that 340B hospitals target locations most in need of improved access to medical care when registering child sites or establishing contract pharmacy relationships.

Conclusion: 340B DSHs Are Not Targeting MUAs

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

However, our analysis shows that the vast majority of 340B-enrolled DSHs, their child sites, and affiliated contract pharmacies are not located in areas where healthcare providers are needed to help reach these patients. Having so few 340B hospitals, clinics, and contract pharmacies located in MUAs is antithetical to the mission of the 340B program.

A 2018 <u>New England Journal of Medicine</u> 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.¹⁰ In fact, the analysis suggested hospitals use the 340B program for financial gain and act contrary to the goals of the program to serve low-income patients.

Our analysis is consistent with those findings and raises the following questions: if the 340B program was designed to support covered entities serving low-income and vulnerable patients, why are so few 340B hospitals located in the most medically underserved communities? Additionally, if 340B DSHs are permitted to extend their use of the 340B program through child sites and contract pharmacies, why are they choosing to affiliate with outpatient practices and for-profit pharmacies that are rarely in MUAs, rather than expanding their footprint to increase access in such MUAs?

Congress and HRSA should consider revisiting the eligibility standards for the 340B program to ensure these standards permit only true safety-net facilities to be eligible for 340B discounts and to prevent the 340B 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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