What's in a Name? Rural Referral Centers Capture 340B Discounts Without Serving Rural, Vulnerable Patients

Introduction

The 340B Drug Pricing Program is intended to help low-income and vulnerable patient populations and the true safety-net providers that serve them, including many providers located in rural areas. Unfortunately, policy changes over time have led to more gaming and program abuses at the expense of underserved patients.

The 340B program requires pharmaceutical manufacturers participating in Medicare Part B and Medicaid to offer steep discounts to certain health care facilities and recipients of federal grants, known as "covered entities," for outpatient medicines dispensed to qualifying 340B patients. Covered entities, in turn, may bill and collect the full reimbursement for drugs from most payers.[1] These covered entities include certain safety net clinics, such as federally qualified health centers, and disproportionate share hospitals (DSHs), which are hospitals that qualify for the 340B program based on their share of Medicaid and low-income Medicare inpatients. In 2010, the Patient Protection and Affordable Care Act expanded 340B eligibility and drug discounts to children's hospitals, freestanding cancer hospitals, rural referral centers (RRCs), critical access hospitals and sole community hospitals.[2]

The focus of this paper is on RRCs, one of the hospital types eligible to participate in the 340B program. Despite the designation of "rural referral center" suggesting that a hospital is located in a rural area and/or serves predominately rural patients, there is no requirement that a RRC meet either of these criteria, although some RRCs do. We analyzed the location of RRCs – finding that over the years the share of RRCs located in a rural area continues to decline. Our analysis also found a clear gap between the socioeconomic characteristics of the population served by many 340B RRCs and the patient population intended to be supported by the 340B program. The findings indicate a cause for Congress to revisit 340B eligibility for RRCs.

The RRC Designation is an Easier Pathway to 340B Discounts for Hospitals

RRCs saw their volume of 340B sales at the discounted 340B price increase 35% from 2020 to 2021—more than twice the rate of increase for the program overall.[3] While the name "rural referral center" suggests these hospitals are required to treat rural patients, that is in fact not the case.[4]

In 2016, in response to two court decisions, the Centers for Medicare and Medicaid Services (CMS) established a national policy allowing hospitals to qualify as RRCs without being located in a rural area or treating rural patients.[5] Under this new policy, any urban hospital with 275 or more beds could qualify as a rural referral center without treating rural patients and also qualify for higher Medicare

reimbursement based on being in a higher-cost urban area.[6] This change in CMS policy led more hospitals to qualify as RRCs and capture 340B discounts.[7]

For both DSHs and RRCs, the key quantitative eligibility metric to qualify for 340B is the disproportionate share adjustment (DSA) percentage, which is a proxy for safety-net hospitals treating a significant number of Medicaid and low-income Medicare inpatients. Yet, the key difference is that RRCs can qualify for 340B based on treating a smaller share of low-income inpatients.[8] Unlike DSHs, which account for 78% of all 340B sales at the 340B price,[9] RRCs cannot qualify for 340B discounts for orphan drugs.[10]

Several past studies have suggested that the eligibility criteria for DSHs does not identify true safety-net hospitals that focus on care for low-income and vulnerable communities. The formula used for both DSHs and RRCs is based only on the inpatient care that a hospital provides—ignoring outpatient care—and does not factor in charity care provided to uninsured patients. An analysis found outpatient beneficiaries receiving 340B medicines at DSHs were less likely to be low-income, compared to the patients receiving inpatient treatment.[11] A separate recent study found that about two-thirds of 340B DSHs provide below-average levels of charity care, when compared to all short-term acute care hospitals.[12] Another study in the *New England Journal of Medicine* found that 340B DSH eligibility was not associated with additional "provision of safety-net or inpatient care for low-income groups."[13]

A 2022 *Wall Street Journal* article describes how some of the most successful and largest nonprofit health systems in the United States now qualify as RRCs and gain access to 340B discounts without serving rural patients.[14] While still a small share of total purchases, RRCs increased their drug purchases under the 340B program by more than 700% over 5 years, a faster rate than any other type of 340B hospital.[15] Despite providing a financial windfall to these hospitals, many low-income patients served at these providers were found to not benefit from lower medicine costs or financial assistance.[16]

Results

The analysis found that in 2022, just 16% of RRC covered entities participating in 340B were located in a rural area, a share that declined as the number of RRCs grew (Figure 1). For this analysis, we defined a hospital as being in a rural area if it is located in a non-metropolitan county, as defined by the US Department of Agriculture Economic Research Service Rural-Urban Continuum Codes.[17] Nearly half (48%) of all RRCs were in metro areas located more than 20 miles away from the nearest rural area.

Figure 1: As the number of RRCs increased, the share located in rural areas declined, 2018-2022[18]

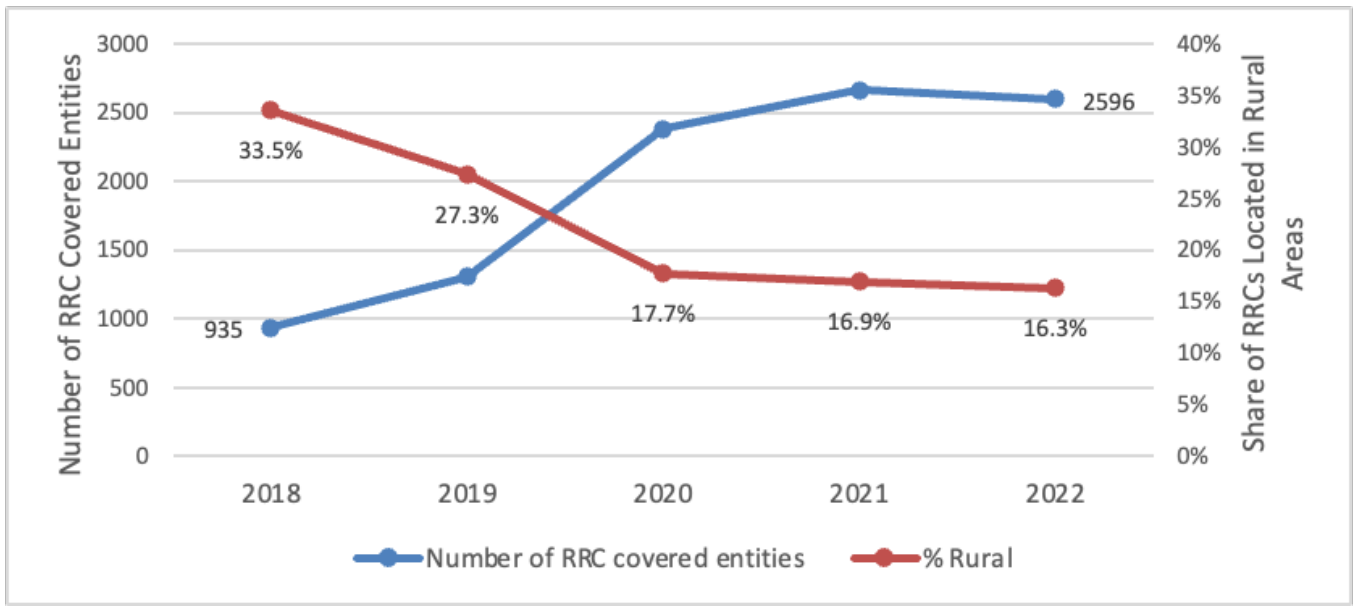
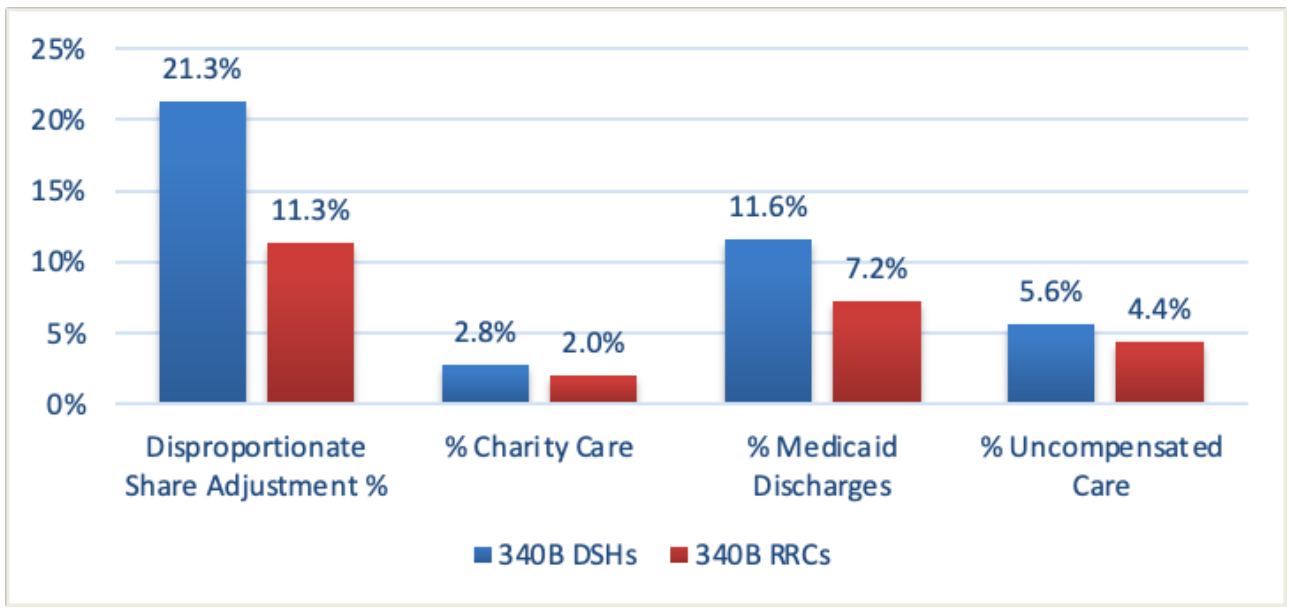


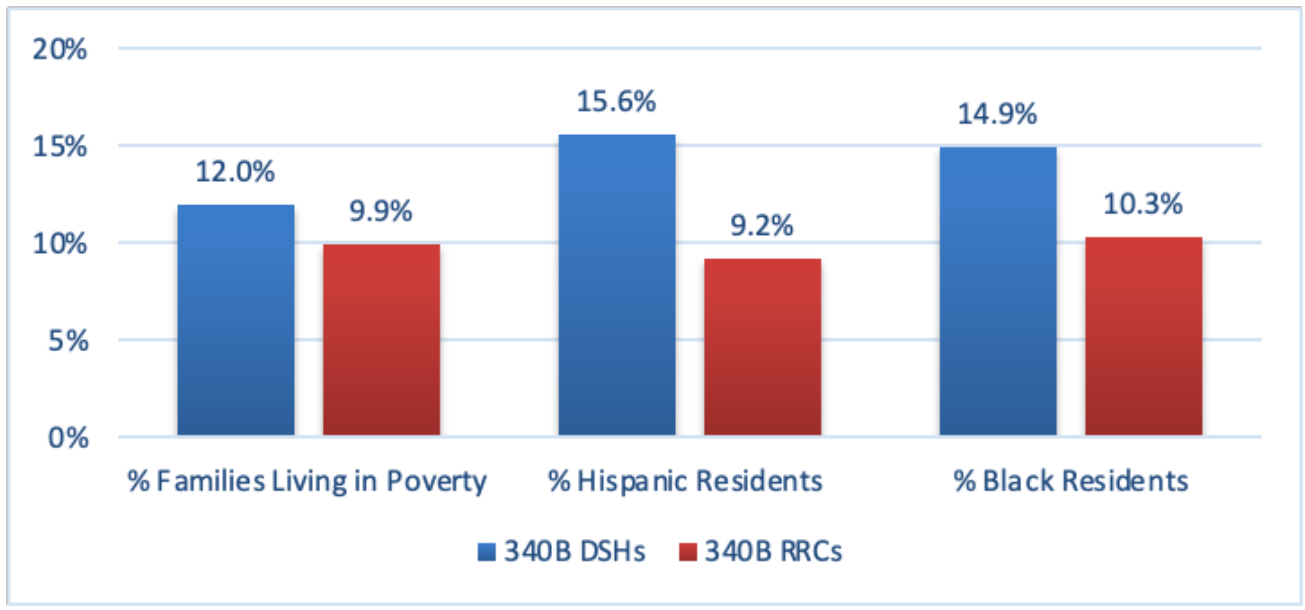
Figure 2 shows that 340B RRCs appear to serve lower rates of low-income and vulnerable patients than 340B DSHs. Compared to DSHs, RRCs served a lower share of Medicaid patients (7.2% vs 11.6%), had a lower disproportionate share adjustment (DSA) percentage (11.3% vs 21.3%), and reported a lower share of charity care (2.0% vs 2.8%) and uncompensated care (4.4% vs 5.6%).[19]

Figure 2: Performance of RRCs compared to DSHs across a variety of 340B program metrics



The findings in Figure 3 show 340B RRCs were less likely to be in areas with a high percentage of families living in poverty (9.9% vs 12.0%) as compared to 340B DSHs.[20] With regards to demographics, these RRCs were in areas with lower shares of Hispanic (9.2% vs 15.6%) and Black (10.3% vs 14.9%) residents compared to DSHs.

Figure 3: Socioeconomic characteristics of the communities served by RRCs and DSHs



Considerations for Policymakers

The analysis found that RRCs participating in the 340B program perform worse across a variety of metrics related to safety net status that are vital to the 340B program, as compared to 340B DSHs. The RRC designation offers some hospitals access to the benefits of the 340B program without serving rural patients.

Gaining access to the 340B program may prove to be very profitable for some RRCs. A pre-COVID-19 study of the profitability of urban hospitals and different classifications of rural hospitals found that, compared to other types of rural hospitals, RRCs had the highest profitability in every year between 2016 and 2018.[21]

As the number of RRCs has grown over the past few years, the share of RRCs participating in 340B that are in rural areas has declined. At the same time, the RRCs in non-rural areas have no requirement to treat rural patients. These trends, among other data points, suggest the 340B program has become more about expanding hospital revenue and less about serving vulnerable patients. Hospitals appear to be taking advantage of loopholes to grow their 340B program footprint, without caring for more underserved, rural patients. Congress should update 340B eligibility standards for RRCs to require they treat a meaningful share of rural patients.

This work was completed on behalf of AIR340B; the analysis was conducted by Xcenda.

References

[1] Under Medicaid fee-for-service, 340B covered entities are reimbursed for 340B drugs at an amount equal to their "actual acquisition cost" plus a "professional dispensing fee." 81 Fed. Reg. 5169, 5317-18 (Feb. 1, 2016). https://www.govinfo.gov/content/pkg/FR-2016-02-01/pdf/2016-01274.pdf

[2] 42 U.S.C. § 256b(a)(4)(M)-(O).

[3] Fein A. The 340B Program Climbed to $44 Billion in 2021 – With Hospitals Grabbing Most of the Money. Drug Channels. August 15, 2022. Accessed May 10, 2023. https://www.drugchannels.net/2022/08/the-340b-program-climbed-to-44-billion.html

[4] 42 U.S.C. 1395ww(d)(5)(C)(i).

[5] Geisinger Community Medical Center v. Sec'y, U.S. Dep't of Health & Human Servs., 794 F.3d 383 (3rd Cir. 2015); Lawrence + Memorial Hospital v. Burwell 812 F.3d 257 (2nd Cir. 2016); 81 Fed. Reg. 23428 (April 21, 2016).

[6] If a hospital has fewer than 275 beds, it may still qualify as an RRC by (i) meeting certain requirements related to referral patterns of its patient population and the distance patients live from the facility, or (ii) demonstrating that, among other factors, the number of cases treated at the hospital exceeds specified volume thresholds and that those cases are more complex than average. 42 C.F.R. 412.96(b)(2), (c).

[7] Fein A. The 340B Program Climbed to $44 Billion in 2021 – With Hospitals Grabbing Most of the Money. Drug Channels. August 15, 2022. Accessed May 10, 2023. https://www.drugchannels.net/2022/08/the-340b-program-climbed-to-44-billion.html

[8] RRCs must have a disproportionate share adjustment percentage of at least 8%. DSHs must have a disproportionate share adjustment percentage greater than 11.75%, or meet the definition of a "Pickle" hospital, which requires the hospital to be located in an urban area, have 100 or more beds, and demonstrate that its net inpatient care revenues (excluding any of such revenues attributable to Medicare or Medicaid), during the cost reporting period in which the discharges occur, for indigent care from state and local government sources and Medicaid exceed 30% of its total of such net inpatient care revenues during the period. 42 U.S.C. § 256b(a)(4)(O), (L); 42 U.S.C. § 1395ww(d)(5)(F)(i)(II)

[9] Calculations based on HRSA OPAIS data. Fein A. The 340B Program Climbed to $44 Billion in 2021 – With Hospitals Grabbing Most of the Money. Drug Channels. August 15, 2022. Accessed May 10, 2023. https://www.drugchannels.net/2022/08/the-340b-program-climbed-to-44-billion.html

[10] 42 U.S.C. § 256b(e).

[11] ADVI. Medicare Patient Demographics at 340B Covered Entities. July 2022. Accessed May 10, 2022. https://www.advi.com/insight/medicare-patient-demographics-at-340b-covered-entities

[12] AIR340B. Left Behind: An Analysis of Charity Care Provided by Hospitals Enrolled in the 340B Discount Program. November 2019. Accessed May 10, 2023. https://340breform.org/wp-content/uploads/2022/02/AIR340B_LeftBehind_2022.pdf. Freestanding cancer hospitals, rural referral centers, children's hospitals, and sole community hospitals were excluded from this analysis.

[13] Desai S, McWilliams JM. Consequences of the 340B Drug Pricing Program N Engl J Med. February 2018. Accessed May 10, 2023. https://www.nejm.org/doi/full/10.1056/nejmsa1706475

[14] Mathews A, Overberg P, Walker J, McGinty T. Many Hospitals Get Big Drug Discounts. That Doesn't Mean Markdowns for Patients. Wall Street Journal. December 2022. Accessed May 10, 2023. https://www.wsj.com/articles/340b-drug-discounts-hospitals-low-income-federal-program-11671553899

[15] Ibid

[16] Ibid

References Cont.

[17] To define nonmetro under the USDA Rural-Urban Continuum Codes, U.S. counties are first grouped according to their official metro-nonmetro status as defined by the Office of Management and Budget. Nonmetro counties are classified along two dimensions. First, the nonmetro counties are divided into three urban-size categories (an urban population of 19,999 or more, 2,500 to 20,000, and less than 2,500) based on the total urban population in the county. Second, nonmetro counties in the three urban-size categories are sub-divided by whether the county is adjacent to one or more metro areas. A nonmetro county is defined as adjacent if it physically adjoins one or more metro areas and has at least 2% of its employed labor force commuting to central metro counties. Nonmetro counties that do not meet these criteria are classed as nonadjacent. USDA Economic Research Service. Rural-Urban Continuum Codes. https://www.ers.usda.gov/data-products/rural-urban-continuum-codes/documentation/#Methodology.

[18] The percentage located in non-rural areas was defined by looking at the total number of unique zip codes for the RRC covered entities.

[19] Total based on 340B covered entities participating in 2020, to align with fiscal year 2020 hospital cost reporting.

[20] Based on 340B covered entities participating in 2022.

[21] Maxwell A, Howard HA, Pink G. 2016-2018 Profitability of Urban and Rural Hospitals by Medicare Payment Classification. April 2020. Accessed May 10, 2023. https://www.shepscenter.unc.edu/download/19974

Methods

The analysis employed data sources as shown in Table 1. 340B RRCs were assessed nationally and compared against key attributes of 340B DSH participants.

Table 1: Data Sources

Data Source	Purpose
Health Resources and Services Administration and 340B Office of Pharmacy Affairs Information System database (accessed in October 2022)	Identify RRC participants in the 340B program and their locations
US Department of Agriculture Economic Research Service Rural-Urban Continuum Codes	Identify metropolitan/nonmetropolitan locations of participants
Fiscal years 2018 to 2021 Medicare hospital cost reports	Quantify the percentage of hospital costs attributable to charity care and uncompensated care; the DSA percentage; and the distribution of hospital discharges among Medicare, Medicaid, and commercial/ other patients
Cubit zip code demographics data, sourced from the US Census Bureau's American Community Survey	Construct area-level metrics at the zip code level to characterize the demographics (e.g., percent of families living in poverty, educational attainment) of the surrounding population