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RESEARCH ARTICLE

Expansion of the 340B Program's Child Sites and Health Disparities Among Medicare Beneficiaries with Asthma

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ABSTRACT

Background: Under the 340B Drug Pricing Program, drug manufacturers are required to provide discounts to participating safety-net providers including hospitals serving a disproportionate share (DSH) of low-income patients. The program has experienced substantial growth in participating DSH providers due in part to growth in 340B DSH child sites, which are outpatient sites included on the DSH hospitals' cost report. However, child sites are not required to be easily accessible to vulnerable patients.

Objectives: The objective of this study was to determine whether the 340B program's expansion of child sites was associated with fewer health disparities for asthma-related care.

Research Design: We conducted a retrospective analysis of Medicare beneficiaries treated for moderate to severe asthma at 340B DSH hospitals with and without child sites.

Measures: We evaluated five drug treatment measures and five adverse outcome measures related to asthma occurring within the first 12 months of the diagnosis date.

Results: For Medicare beneficiaries treated for asthma at 340B hospitals with and without child sites, we identified risk-adjusted disparities in drug treatments and adverse health outcomes based on race/ethnicity, dual eligibility status, and socioeconomic status. Statistically significant disparities across the ten outcomes were more likely to occur within 340B hospitals with child sites than 340B hospitals without child sites. Differences in the magnitudes of the disparities varied by vulnerable subgroup.

Conclusions: Our findings suggest that the growth in 340B child sites have not universally expanded access to higher quality care for vulnerable patients, and as such policy changes may be needed.

Key Words: 340B, disparities, asthma, Medicare

Introduction

Section 340B of the Public Health Service Act was enacted in 1992 to help "stretch scarce federal resources as far as possible, reaching low-income and/or uninsured patients and providing more comprehensive services" by providing discounts on outpatient drugs to certain providers known as 340B covered entities (CEs).[1] Under the statute, potential CEs include disproportionate share hospitals (DSH), which serve a disproportionate share of low-income patients. To participate in the 340B program, these hospitals must have a DSH adjustment percentage of at least 11.75 percent, meet specific classification requirements, and comply with the group purchasing organization prohibition. In 1994, the Health Resources Services Administration (HRSA), which administers the 340B program, issued guidance that allowed 340B DSH hospitals to include their outpatient sites (known as 'child sites') in the 340B program if the outpatient facility is included on the "parent" hospital's Medicare cost report. This guidance does not require child sites to meet a threshold of low-income patients similar to the DSH minimum threshold for parent hospitals. Furthermore, there are no requirements that could influence the location or accessibility of child sites, and thereby, increase the access of vulnerable patients to high quality care.

The number of DSH hospitals and child sites participating in the 340B program has grown dramatically since the program's inception. According to our analyses of data from HRSA, between 2000 and 2019, the number of DSH hospitals participating in the 340B program increased from 105 to 1,124 hospitals, which represents an average annual growth of 14%. The growth in 340B DSH child sites has been even greater; from 2000 to 2019, the number of 340B DSH child sites grew from 78 to 20,496 (36% average annual growth). Among the 1,124 340B DSH hospitals in 2019, 927 have at least one child site and 459 have at least 10 sites.[2]

In alignment with the intent of the 340B program, child sites were likely permitted as a mechanism for increasing access points of care for targeted patients. Child sites can help to reduce barriers experienced by vulnerable patients and increase their access to quality care when they are situated in convenient and easily accessible locations. Thus, the proliferation of child sites might be expected to reduce or eliminate disparities in treatments and adverse outcomes.

Previous studies have focused on learning more about the patient populations these providers are serving as the program evolves. A 2014 study assessed patterns in the expansion of DSH hospitals and found that 340B DSH child sites participating in the program in 2004 or later were in higher-income communities with higher rates of health insurance coverage, as compared to child sites participating in the program prior to 2004.[3] A separate analysis evaluating the overlap of medically underserved areas (MUAs) and 340B DSH hospitals and child sites found that 38% of 340B DSH hospitals and 29% of DSH child sites are located in MUAs.[4] Furthermore, an unpublished study found that Medicare patients who were treated at 340B DSH child sites were less likely to be vulnerable compared to patients at 340B DSH hospitals, non-340B hospitals, and the off-campus clinics of non-340B hospitals.[5] Recent investigations by the New York Times and the Wall Street Journal highlighted how some participants in the 340B program have selectively opened child sites in wealthier neighborhoods and use 340B drug discounts to increase profits by treating patients with private insurance.[6,7] The results of these studies suggest that child sites may not reduce barriers to access quality care for vulnerable populations.

By comparing the health disparities of Medicare beneficiaries with moderate to severe asthma treated in 340B DSH hospitals systems to the health disparities of beneficiaries treated in non-340B hospital systems, a prior study provides evidence that 340B DSH hospital systems are not benefiting vulnerable patients with greater reductions in access barriers. The authors did not find fewer or smaller disparities in treatment and adverse outcomes among the 340B DSH hospital systems' beneficiaries.[8] This current study expands on the Tripp et al work by evaluating whether the growth in 340B child sites, specifically, is contributing to the program objectives of reaching more vulnerable patients and providing more comprehensive services through an assessment of how well 340B DSH hospitals with child sites address disparities in

health care. Health disparities, broadly, are "…differences and/or gaps in the quality of health and healthcare across racial, ethnic, and socio-economic groups."[9] Disparities in health care access and treatment generate an estimated $93B in excess medical expenditures and $42B in lost productivity each year.[10] This study focuses on beneficiaries with newly diagnosed moderate or severe asthma because of the higher prevalence of asthma in vulnerable populations and the observed disparities in treatment and adverse outcomes. Asthma care is also a targeted hospital quality improvement area identified by the Agency for Health Research and Quality.[11]

There are well documented disparities in asthma treatment and outcomes among vulnerable populations. A 2014 study found that Hispanic patients with asthma had 43% lower odds of receiving a maintenance drug compared to non-Hispanic White patients.[12] Another study reported lower controller medication receipt, initiation and use among racial and ethnic minorities with asthma.[13] A study that evaluated the relationship between socioeconomic status (SES) correlates, treatment failures and asthma exacerbations found that low income was associated with greater risk.[14]

Vulnerable populations with asthma are also at greater risk for adverse outcomes such as emergency department (ED) use and hospitalizations. Data from the 2015 Behavioral Risk Factor Surveillance Survey and the Asthma Call-Back Survey revealed that 32% of Black patients and 23% of Hispanic patients had reported an ED visit due to asthma symptoms in the previous 12 months, compared to only 14% of White patients.[15] An observational study of patients with severe asthma between 2018 and 2020 found that Black and Hispanic patients experienced higher rates of exacerbations and asthma-related hospitalizations.[16] Further, a meta-analysis of 65 studies from 1995 to 2022 found that patients from ethnic minority groups had a substantially higher rate of ED visits, hospitalizations and ventilation compared to White patients.[17] Low SES leads to treatment and outcome disparities among asthma patients as well. A systematic review and meta-analysis of 61 asthma-related studies found that lower SES was associated with increased ED utilization and hospitalization.[18]

The objective of this study was to determine whether the 340B program's expansion of child sites was associated with fewer health disparities for asthma-related care from 2017 to 2019 by examining differences in treatment and adverse outcomes by race/ethnicity, dual Medicare and Medicaid eligibility status, and socioeconomic status. If the expansion of child sites helps 340B hospitals meet the objectives of the program, we expect that there would be fewer disparities in treatment and outcomes among 340B hospitals with child sites compared to 340B hospitals without child sites. This study contributes to the literature by measuring disparities in treatment and health outcomes of vulnerable patients with moderate to severe chronic asthma within 340B health systems and evaluating whether child sites help reach more vulnerable patients.

Methods

We conducted a retrospective analysis of Medicare fee-for-service (FFS) beneficiaries treated for moderate to severe asthma at 340B hospitals that met the DSH qualification criteria and their child sites. 340B DSH hospitals (henceforth, 340B hospitals) and their child sites were identified using The Office of Pharmacy Affairs Information System database. These hospitals participated in the program at any point between 2017 and 2019.
The beneficiaries included in this analysis were newly diagnosed with moderate to severe chronic asthma treated at the 340B hospitals and child sites. We used Medicare FFS claims (2017-2019) to identify beneficiaries with at least one inpatient or two outpatient claims within 30 days of each other with the diagnosis of interest, and no asthma-related claims in the previous 12-months. The first date the asthma diagnosis appears in claims is considered the diagnosis date. The ICD-10 diagnosis codes used to identify asthma were J454x and J455x. Beneficiaries were attributed to a hospital based on the plurality of their non-infusion outpatient claims.

Our analysis focused on disparities defined by three patient characteristics that are associated with access challenges to quality healthcare. Those

characteristics are race/ethnicity (White vs non-White), dual enrollment status for Medicare and Medicaid (dual eligible vs non-dual eligible), and socioeconomic status (low SES vs high SES). Beneficiary race/ethnicity and dual enrollment status were obtained from the Master Beneficiary Summary File (MBSF). We used the 2019 AHRQ SES index from the Acxiom InfoBase® and mapped it to beneficiaries using the five-digit zip code of the beneficiary's address. Beneficiaries were identified as low SES if they resided in a zip code whose SES index was in the lowest quartile of the metric, and high SES if the zip code SES index was within the highest quartile.

We evaluated five drug treatment measures and five adverse outcome measures related to asthma occurring within 12 months of the diagnosis date. The treatment measures are number of days to drug therapy initiation from the diagnosis date, proportion of beneficiaries receiving maintenance drugs (drugs used to control symptoms of asthma), proportion of beneficiaries receiving novel therapies (new biologic therapies used to control symptoms of asthma and approved by the United States Food and Drug Administration [FDA] in 2017 or later), proportion of beneficiaries receiving rescue drugs (drugs used for the immediate relief of symptoms), and the proportion of beneficiaries receiving any outpatient drug treatment. Receipt of outpatient drugs reflects the access to outpatient drugs, which the 340B program is designed to provide. Higher quality care is defined as fewer days to therapy start and receipt of maintenance drugs and/or novel therapy drugs, which implies the beneficiary is managing their asthma sooner, with newer innovations. Lower quality care is defined as a delay to therapy start or receipt of rescue drugs, which may indicate uncontrolled asthma.

The five adverse outcome measures are the occurrence of an acute asthma event, all-cause ED visits, receipt of inhalation treatments, inpatient admissions due to asthma, and all-cause mortality within one year of diagnosis. Visits to the hospital or child site for an adverse outcome indicate that asthma is not being properly managed. The treatment and outcome measures were identified using Medicare FFS claims. See tables **Supplemental Digital Content 1 and 2** for details on measure construction and drugs included in the analysis.

Our study estimated risk-adjusted rates for each outcome measure across 340B hospitals with child sites and 340B hospitals without child sites, separately, using a generalized linear model (GLM). Each model controlled for age, gender, and clinical risk factors. Age and gender were identified using the MBSF, and clinical risk factors were identified in FFS claims using the CMS Hierarchical Condition Category (HCC) indicators from the CMS-HCC model (version 24). The covariates included in each model were selected using a least absolute shrinkage and selection (LASSO) estimator. We estimated a GLM with the selected covariates for each outcome on a reference sample (beneficiaries receiving care at 340B hospitals without child sites), a sample for whom, in aggregate, the average expected (model-predicted) value equals the average actual value of the outcome. We applied each model to the sample of beneficiaries treated at 340B hospitals with child sites and created observed and expected rates for all beneficiaries. Finally, we used the delta method to derive estimates of standard errors for each group. We report within-group differences and between-group differences; statistically significant differences were measured based on p-values ≤ 0.05.

Results

The sample was comprised of 41,964 beneficiaries attributed to 1,032 340B hospitals with child sites and 3,211 beneficiaries attributed to 262 340B hospitals without child sites. **Table 1** shows that 72% of the sample is female, the average age is 69 years old and beneficiaries have 3 HCC indicators, on average. 340B hospitals with child sites are more likely to be urban, large (500+ beds), and teaching hospitals (**Table 2**).

Table 1. Comparison of Beneficiary Characteristics

Hospital Group	Beneficiary Subgroup	N	Average Age[1]	Percent Female[2]	Average Number of Disease HCCs[3]
All Unique Beneficiaries in Sample					
All		44,396	68.8	72%	2.96
340B with Child Site(s)		41,225	68.7	72%	2.96
340B without Child Site		3,171	69.5	71%	3.00
Race/Ethnicity					
340B with Child Site(s)	Non-White	9,350	64.9	75%	3.11
	White	31,875	69.8	71%	2.91
340B without Child Site	Non-White	902	66.6	75%	3.13
	White	2,269	70.7	70%	2.95
Medicare-Medicaid Dual Eligibility Status					
340B with Child Site(s)	Dual	12,573	60.6	77%	3.61
	Non-dual	28,652	72.3	70%	2.67
340B without Child Site	Dual	1,022	62.2	75%	3.61
	Non-dual	2,149	73.0	70%	2.71
Socioeconomic Status					
340B with Child Site(s)	Low SES	16,642	66.6	74%	3.30
	High SES	24,501	70.2	71%	2.69
340B without Child Site	Low SES	1,390	67.3	73%	3.22
	High SES	1,779	71.2	70%	2.62

Source: Medicare Beneficiary Summary File and Medicare FFS Claims, 2017-2019

SES = Socioeconomic Status, HCC = Hierarchical Condition Categories

[1] All differences in age within a beneficiary subgroup and between 340B hospitals with child sites and 340B hospitals without child sites by vulnerable subgroup are statistically significant at the 0.05 level.

[2] None of the differences in percent female within a beneficiary subgroup and between 340B hospitals with child sites and 340B hospitals without child sites by vulnerable subgroup are statistically significant at the 0.05 level.

[3] None of the differences in the average number of HCCs within a beneficiary subgroup and between 340B hospitals with child sites and 340B hospitals without child sites by vulnerable subgroup are statistically significant at the 0.05 level.

Table 2: Comparison of Hospital Characteristics

	340B with Child Site(s)	340B without Child Site
Number of Hospitals	1,032	262
Urban vs Rural*		
Urban	81%	73%
Rural	19%	27%
Hospital Bed Size*		
<100 Beds	16%	29%
100-499 Beds	59%	66%
500+ Beds	25%	5%
Ownership Status		
For Profit	3%	6%
Government	20%	21%
Not-For-Profit	56%	53%
Other	20%	20%
Teaching Status*		
Not a Teaching Hospital	65%	79%
Small Teaching Hospital	22%	14%
Large Teaching Hospital	13%	6%

Source: CMS Provider of Services (POS) file, 2021

* The differences in the distributions between 340B hospitals with child sites and 340B hospitals without child sites are statistically significant at the 0.05 level.

DISPARITIES BY RACE OR ETHNICITY

Our analysis found differences in drug treatment patterns between non-White and White beneficiaries for select outcome measures in 340B hospitals with and without child sites (**Table 3**). Non-White beneficiaries treated at 340B hospitals without child sites were less likely to receive a maintenance drug (6.2% vs 11.4%, p<0.01) or novel therapy (12.0% vs 23.0%, p<0.05). Similarly, non-White beneficiaries treated at 340B hospitals with child sites were less likely to receive a maintenance drug (8.2% vs 10.8%, p<0.01) or a novel therapy drug (17.5% vs 23.4%, p<0.01) than White beneficiaries, and more likely to receive a rescue drug (21.8% vs 18.6%, p<0.01).

Table 3. Risk-Adjusted Racial Disparities for Medicare Beneficiaries with Asthma Treated at 340B Hospitals with and without Child Sites

	340B Hospitals without Child Sites			340B Hospitals with Child Sites			Net Difference (Child Sites – No Child Site)
	Non-white (n= 943)	White (n= 2,268)	Difference (Non-White - White)	Non-White (n= 10,093)	White (n= 31,871)	Difference (Non-White - White)	
Drug Treatment Outcome Measures							
Maintenance drug	6.2%	11.4%	-5.2%***	8.2%	10.8%	-2.6%***	2.6%
Rescue drug	22.4%	19.0%	3.4%	21.8%	18.6%	3.2%***	-0.2%
Any outpatient drug	25.8%	26.4%	-0.6%	27.2%	25.8%	1.4%	2.0%
Days to drug therapy start†	74.5	72.0	2.6	86.0	79.7	6.3	3.8
Novel therapy†	12.0%	23.0%	-10.9%**	17.5%	23.4%	-5.9%***	5.0%
Adverse Outcome Measures							
Acute asthma event	12.6%	9.7%	2.9%	12.1%	9.2%	2.9%***	0.0%
ED visit	73.2%	62.8%	10.5%***	69.3%	60.2%	9.2%***	-1.3%
Inhalation treatment	38.9%	29.7%	9.2%***	36.8%	29.9%	6.9%***	-2.3%
Inpatient admission	7.2%	4.0%	3.2%*	7.8%	3.6%	4.2%***	1.0%
Death	7.3%	4.9%	2.4%	4.2%	4.8%	-0.6%	-3.0%

Source: Medicare FFS Claims, Enrollment and Acxiom Data, 2017 – 2019,

† The outcome measure was analyzed on a subset of our sample limited to beneficiaries who received outpatient drug therapy. Thus, the sample size for these measures is smaller than indicated in the table.

Asterisks represent statistical significance: * p<0.10, ** p<0.05, *** p<0.01

We also observed higher rates of adverse outcomes for non-White beneficiaries compared to White beneficiaries. In 340B hospitals without child sites, non-White beneficiaries had higher rates of ED visits (73.2% vs 62.8%, p<0.01) and inhalation treatment (38.9% vs 29.7%, p<0.01) than White beneficiaries. Non-White beneficiaries also experienced meaningfully greater mortality than White beneficiaries, although the difference was not statistically significant. Differences in adverse outcomes by race or ethnicity were more likely to occur in 340B hospitals with child sites. Non-White beneficiaries treated at 340B hospitals with child sites had higher rates of acute asthma events (12.1% vs 9.2%, p<0.01), ED visits (69.3% vs 60.2%, p<0.01), inhalation treatment (36.8% vs 29.9%, p<0.01), and inpatient stays (7.8% vs 3.6%, p<0.01) than White beneficiaries.

When we evaluate the net differences in disparities, overall, the findings did not show that racial disparities in the quality of drug treatments or adverse outcomes statistically differed between 340B hospitals with and without child sites. However, the magnitude of the disparities observed tended to be larger among 340B hospitals without child sites across several outcomes. The observed disparities between non-White and White beneficiaries were meaningfully larger for receipt of a maintenance drug, receipt of a novel therapy and inhalation treatment among those treated at 340B hospitals without child sites.

DISPARITIES BY DUAL ELIGIBLE STATUS

Disparities in drug treatment for asthma between dual eligible and non-dual eligible beneficiaries were identified for two of five measures within

340B hospitals without child sites, and for the five treatment measures within 340B hospitals with child sites (**Table 4**). Dual eligible beneficiaries treated at 340B hospitals without child sites were less likely to receive a novel therapy (12.4% vs 24.2%, p<0.01) and more likely to receive rescue drugs (24.6% vs 17.7%, p<0.01). At 340B hospitals with child sites, dual eligible beneficiaries started drug therapy 9 days later (87.1 days vs 78.1 days, p<0.01), were less likely to receive a maintenance drug (8.5% vs 11.0%, p<0.01) or novel therapy (13.0% vs 26.9%, p<0.01), and were more likely to receive a rescue drug (24.5% vs 17.0%, p<0.01) or any outpatient drug (29.8% vs 24.4%, p<0.01) than non-dual eligible beneficiaries.

Table 4. Risk-Adjusted Disparities for Dual and Non-Dual Eligible Medicare Beneficiaries with Asthma Treated at 340B Hospitals with and without Child Sites

	340B Hospitals without Child Sites			340B Hospitals with Child Sites			Net Difference (Child Sites – No Child Site)
	Dual (n= 1,040)	Non-Dual (n= 2,171)	Difference (Dual – Non-Dual)	Dual (n= 12,854)	Non-Dual (n= 29,110)	Difference (Dual – Non-Dual)	
Drug Treatment Outcome Measures							
Maintenance drug	8.0%	10.9%	-2.9%*	8.5%	11.0%	-2.5%***	0.4%
Rescue drug	24.6%	17.7%	6.9%**	24.5%	17.0%	7.5%***	0.6%
Any outpatient drug	29.5%	24.6%	4.9%*	29.8%	24.4%	5.4%***	0.5%
Days to drug therapy start†	82.3	67.0	15.3*	87.1	78.1	9.0***	-6.2
Novel therapy†	12.4%	24.2%	-11.8%***	13.0%	26.9%	-13.9%***	-2.1%
Adverse Outcome Measures							
Acute asthma event	11.7%	9.9%	1.7%	11.1%	9.3%	1.7%***	0.0%
ED visit	72.5%	62.3%	10.2%***	70.7%	58.2%	12.6%***	2.4%
Inhalation treatment	38.0%	29.6%	8.4%***	37.4%	28.9%	8.5%***	0.1%
Inpatient admission	7.3%	3.7%	3.6%**	7.2%	3.4%	3.7%***	0.1%
Death	6.5%	5.2%	1.2%	5.4%	4.3%	1.1%***	-0.1%

Source: Medicare FFS Claims, Enrollment and Acxiom Data, 2017 – 2019,

† The outcome measure was analyzed on a subset of our sample limited to beneficiaries who received outpatient drug therapy. Thus, the sample size for these measures is smaller than indicated in the table.

Asterisks represent statistical significance: * p<0.10, ** p<0.05, *** p<0.01

Dual eligible beneficiaries with asthma were also more likely to experience adverse outcomes than non-dual eligible beneficiaries at 340B hospitals with and without child sites. Among those treated at 340B hospitals without child sites, dual eligible beneficiaries were more like to have an ED visit (72.5% vs 62.3%, p<0.01), inhalation treatment (38.0% vs 29.6%, p<0.01), and an inpatient admission (7.3% vs 3.7%, p<0.05). Dual eligible beneficiaries treated at 340B hospitals with child sites were more likely to have an acute asthma event (11.1% vs 9.3%, p<0.01), ED visit (70.7% vs 58.2%, p<0.01), inhalation treatment (37.4% vs 28.9%, p<0.01), inpatient admission (7.2% vs 3.4%, p<0.01), and death (5.4% vs 4.3%, p<0.01) than non-dual eligible beneficiaries.

The comparison of results between 340B hospitals with and without child sites show no statistically significant net differences in the disparities observed for dual eligible beneficiaries. Despite the lack of statistical significance, the magnitudes of the disparities were meaningfully larger for beneficiaries treated at 340B hospitals with child sites for receipt of a novel therapy and ED visits.

DISPARITIES BY SOCIOECONOMIC STATUS

There was evidence of socioeconomic disparities in drug treatment for asthma at 340B hospitals with and without child sites (**Table 5**). Among beneficiaries treated at 340B hospitals without child sites, there were no statistically significant differences in drug treatment between those with low and high SES. However, the magnitudes of the differences for the number of days to drug therapy start and receipts of any outpatient drug, a novel therapy, and a rescue drug were large. At 340B hospitals with child sites, beneficiaries with low SES

were less likely to receive a maintenance drug (8.6% vs 11.2%, p<0.01) or novel therapy (16.0% vs 26.5%, p<0.01), but more likely to receive a rescue drug (22.4% vs 18.0%, p<0.01) or any outpatient drug (28.0% vs 25.0%, p<0.05) compared to beneficiaries with high SES.

Table 5. Risk-Adjusted Differences for Low and High SES Medicare Beneficiaries with Asthma Treated at 340B Hospitals with and without Child Sites

	340B Hospitals without Child Sites			340B Hospitals with Child Sites			Net Difference (Child Sites – No Child Site)
	Low SES (n= 540)	High SES (n= 744)	Difference (Low SES – High SES)	Low SES (n= 6,035)	High SES (n= 11,205)	Difference (Low SES – High SES)	
Drug Treatment Outcome Measures							
Maintenance drug	9.2%	9.0%	0.2%	8.6%	11.2%	-2.5%***	-2.7%
Rescue drug	22.4%	17.8%	4.6%	22.4%	18.0%	4.4%***	-0.1%
Any outpatient drug	28.2%	23.3%	4.8%	28.0%	25.3%	2.6%**	-2.2%
Days to drug therapy start†	73.3	82.2	-8.9	81.8	80.5	1.3	10.2
Novel therapy†	15.9%	20.5%	-4.6%	16.0%	26.5%	-10.5%***	-5.9%
Adverse Outcome Measures							
Acute asthma event	11.1%	9.8%	1.4%	10.9%	10.0%	0.9%	-0.5%
ED visit	69.2%	63.3%	5.9%*	66.8%	59.2%	7.6%***	1.7%
Inhalation treatment	33.3%	31.9%	1.3%	36.3%	28.0%	8.3%***	7.0%
Inpatient admission	7.7%	4.5%	3.1%	6.9%	3.8%	3.1%***	0.0%
Death	4.8%	6.1%	-1.3%	5.4%	4.3%	1.1%*	2.4%

Source: Medicare FFS Claims, Enrollment and Acxiom Data, 2017 – 2019,

† The outcome measure was analyzed on a subset of our sample limited to beneficiaries who received outpatient drug therapy. Thus, the sample size for these measures is smaller than indicated in the table.

Asterisks represent statistical significance: * p<0.10, ** p<0.05, *** p<0.01

Socioeconomic disparities were also present within select adverse outcomes. As we reported for treatment outcomes, large differences in adverse outcomes existed for beneficiaries treated at 340B hospitals without child sites, but none were statistically significant. Among beneficiaries treated at 340B hospitals with child sites, those with low SES were more likely to have an ED visit (66.8% vs 59.2%, p<0.01), receive inhalation treatment (36.3% vs 28.0%, p<0.01) and have an inpatient admission (6.9% vs 3.8%, p<0.01) compared to beneficiaries with high SES.

The net differences in the disparities reported for low SES beneficiaries treated at 340B hospitals with and without child sites were not statistically significant, although the magnitudes in the disparities differed. The magnitudes of the disparities were larger at 340B hospitals with child sites for receipt of maintenance drugs, novel therapy drugs, and inhalation treatment. While low SES beneficiaries have slighter longer time to treatment at 340B hospitals with child sites, at hospitals without child sites they had a much shorter time to treatment than high-SES beneficiaries.

Discussion

This study found that there are risk-adjusted disparities in drug treatment and health outcomes for Medicare beneficiaries with asthma based on race, dual eligible status and socioeconomic status treated at 340B hospitals with and without child sites. Statistically significant differences across the ten outcomes were more likely to occur within 340B hospitals with child sites than 340B hospitals without child sites. The limited number of 340B hospitals without child sites likely contributed to the lack of statistical significance; the magnitudes of the differences in treatment and adverse outcomes were often similar or larger than those of 340B hospitals with child sites.

Non-White, dual eligible and low SES beneficiaries treated a 340B hospitals were more likely to receive any outpatient drug compared to White, non-dual eligible or high SES beneficiaries.

Increasing access to drugs is a key objective of the 340B program, and this result appears aligned with the program's objective; however, the proportion of beneficiaries receiving any outpatient drug was driven by the receipt of a rescue drug, which indicates uncontrolled asthma.

There is evidence to suggest that 340B child sites may help address racial or ethnic disparities in drug treatments and adverse outcomes for Medicare beneficiaries with moderate to severe asthma. While the net differences reported between 340B hospitals with and without child sites were not statistically significant, the results indicate that disparities were meaningfully larger at 340B hospitals without child sites for receipt of maintenance drug, novel therapy, inhalation treatment and mortality. Thus, the location of child sites may reduce barriers to access care for non-White patients. Alternatively, in the case of dual eligible and low SES beneficiaries, there is evidence to suggest that child sites have no association to a slightly harmful association with disparities in drug treatments and adverse outcomes. Child sites have not addressed the barriers affecting treatment and outcomes for low-income patients with moderate to severe asthma.

Our study had three main limitations. First, this study only included medications administered at hospitals and child sites and does not include Medicare Part D claims data. As a result, there may be Part D drugs used for asthma treatment or maintenance that are not captured in this analysis. Our selection of beneficiaries and the drugs examined were identical across subgroups and hospital types. We anticipate that any use of Part D drugs in addition to Part B drugs will be similar across samples within our analysis. Second, the sample size of beneficiaries treated at 340B hospitals without child sites is much smaller than the number with child sites. As a result of a limited sample size, some of the differences reported for 340B hospitals without child sites were large in magnitude, but not statistically significant. Third, our analysis does not assess whether changes in disparities follow changes in the registration of child sites. Thus, conclusions about causality are suggestive.

Conclusion

These results raise questions as to whether growth in the 340B program through child sites helps to reduce or eliminate treatment barriers and adverse outcomes for vulnerable patients with moderate to severe asthma. In particular, the disparities in drug treatments and adverse outcomes for dual eligible and low-SES beneficiaries treated at 340B hospitals with child sites were not smaller than those observed at 340B hospitals without child sites. When 340B hospitals select child sites to register with the 340B program, they may have an incentive to select sites likely to be accessed by a less vulnerable patient population to maximize their revenue; the 340B program does not preclude such behavior. Unlike 340B hospitals, there is no threshold for the treatment of low-income populations for child sites to participate in the program. Furthermore, 340B rules allow for participants to obtain discounts on drugs for all non-Medicaid patients, yet provide no direction for how the savings from the discounts are to be used. This may lead to misaligned incentives on how to select child sites. Because 340B child sites can use 340B discounts on any of their patients, they may strategically select locations with more profitable patient populations. Simultaneously, savings from discounts may not necessarily be used to reduce treatment barriers.

A policy brief by the National Rural Health Association concluded that the lack of reporting requirements on how savings are used has led to a dearth in reliable information regarding the full scope of the 340B program.[19] Implementing standards for reporting will promote transparency in the 340B program and improve accountability for 340B covered entities to ensure they meet the program's objectives with these savings.

Policymakers and interested stakeholders continue to explore a wide range of options to strengthen the 340B program and to realign its focus on vulnerable populations. One example is the draft legislation known as the Supporting Underserved and Strengthening Transparency, Accountability, and Integrity Now and for the Future of 340B Act (SUSTAIN 340B Act).[20] It was released in early 2024 by a bipartisan group of senators and calls for patient assistance, transparency, and enhanced integrity. The goals of this act and other policy options are to ensure that vulnerable patients are

the focal point of the program by considering guardrails in the use of 340B discounts, perhaps through modifying participation requirements for child sites. Realigning the focus of the 340B program on vulnerable populations complements HRSA's strategic plan,[21] and CMS's broad efforts to improve health equity and eliminate disparities in health care.[22]

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List of Supplemental Digital Content

Supplemental Digital Content 1: Description of Outcome Measures

Outcome Measure	Description
Receipt of a maintenance drug†	Beneficiary received an asthma maintenance drug within 12 months of the diagnosis date
Receipt of a rescue drug†	Beneficiary received an asthma rescue drug within 12 months of the diagnosis date
Receipt of any outpatient drug	Beneficiary received an asthma medication in an OP setting within 12 months of the diagnosis date.
Days to drug therapy start	The difference in days between diagnosis date and the earliest asthma drug utilization date observed.
Receipt of a novel therapy	Beneficiary received a novel asthma drug within 12 months of the diagnosis date
Acute asthma event	An acute asthma event (diagnosis code J45.51) occurred within 12 months of the diagnosis date
Emergency department visit	An emergency department visit (revenue center codes 0981, 0450-0459) occurred within 12 months of the diagnosis date
Inhalation treatment	An inhalation treatment (HCPCS 94644, 94645, 94640) occurred within 12 months of the diagnosis date
Inpatient admission related to asthma	An inpatient admission with diagnosis code J45.4x or J45.5x occurred within 12 months of the diagnosis date
All-cause mortality	Beneficiaries that died within 12 months of diagnosis date

† The list of drugs is specified in Table A.2.

Notes: HCPCS = Healthcare Common Procedure Codes

Drug Type	HCPCS Code	Drug Brand Name (Generic Name)	Description
Maintenance	J0517	Fasenra (Benralizumab)	Injection, 1 mg
Maintenance	J2182	Nucala (Mopolizumab)	Injection, 1 mg
Maintenance	J2357	Xolair (Omalizumab)	Injection, 5 mg
Maintenance	J2786	Cinqair (Reslizumab)	Injection, 1 mg
Maintenance	J7626	Budesonide	Inhalation solution, FDA-approved final product, non-compounded, administered through DME, unit dose form, up to 0.5 mg
Maintenance	J7631	Cromolyn Sodium	Cromolyn sodium, inhalation solution, FDA-approved final product, non-compounded, administered through DME unit dose form, per 10 milligrams
Rescue	J7611	Albuterol Sulfate	Inhalation solution, FDA-approved final product, non-compounded, administered through durable medical equipment (DME), concentrated form, 1 mg
Rescue	J7612	Levalbuterol Concentrate	Inhalation solution, FDA-approved final product, non-compounded, administered through DME, concentrated form, 0.5 mg
Rescue	J7613	Albuterol Sulfate	Inhalation solution, FDA-approved final product, non-compounded, administered through DME, unit dose, 1 mg
Rescue	J7614	Levalbuterol HCL	Inhalation solution, FDA-approved final product, non-compounded, administered through DME, unit dose, 0.5 mg

Supplemental Digital Content 2: Drugs Included in this Analysis for the Treatment of Asthma
Notes: DME =Durable Medical Equipment; FDA = Food and Drug Administration; HCPCS = Healthcare Common Procedure Codes