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The Association of 340B Program Drug Margins with Covered Entity Characteristics

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Abstract

The 340B Drug Pricing Program aims to help facilities serving low-income and uninsured patients to stretch scarce resources by allowing covered entities to purchase outpatient drugs at federally mandated discounted rates while often receiving reimbursement for them at higher rates by commercial payers and Medicare. Despite increasing focus on the expansion and impact of the program, profit margins under 340B have not been fully explored. We aimed to examine drug-, facility-, and geographic-level factors that influence drug margins among 340B covered entities. We conducted a cross-sectional analysis of predictors of facility-level 340B margins for 5 drug classes in a multivariable regression model using 2021 data linked across multiple proprietary and public datasets. Regression results show that drug, facility characteristics, and geographic healthcare market-level characteristics influence drug margins under the 340B program. Adjusted 340B margins were higher in hospital outpatient departments than free-standing offices (ie, hospital-affiliated physician offices and independent, 340B eligible clinics) and among covered entities in more concentrated (ie, less competitive) markets. Covered entity market power, quantified by a facility-level measure of non-340B drug margins indicating pricing power, and area wealth were both associated with higher 340B drug margins. Margins on 340B drugs were higher among facilities in stronger bargaining positions and those serving wealthier areas. These findings add to the growing body of literature on expansions of the 340B program into more affluent communities, informing calls for reforms to ensure the 340B program serves low-income and uninsured patients.

Keywords

340B, drug margin, provider behavior, market concentration, hospital

Introduction

The 340B Drug Pricing Program aims to help eligible healthcare facilities serving low-income and uninsured patients stretch scarce resources by allowing covered entities to purchase outpatient drugs at federally mandated discounted rates while often selling them at higher rates. Eligible facilities are defined in statute and include, but are not limited to, public or private, non-profit hospitals and health systems serving a disproportionate share of low-income patients (ie, disproportionate share hospitals), children's hospitals, and critical access hospitals as well as other categories of designees and grantees, including federally qualified health centers (FQHCs) and Ryan White clinics.

Under the 340B program, drug manufacturers participating in Medicaid agree to provide outpatient drugs to covered entities at a price no greater than the 340B ceiling price, based on the average manufacturer price (AMP) and the Unit Rebate Amount (URA) of the Medicaid Drug Rebate Program. The Medicare Payment Advisory Commission has estimated that, in 2022, ceiling price costs equated to approximately a discount of 29% on aggregate.[1] Facilities may negotiate further discounts below the ceiling price; the average total discount (ie, mandated and negotiated discounts) off list prices for drugs purchased at 340B price in 2022 was

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57%.[2] Drugs purchased with 340B discounts are provided to eligible patients[3] and may be physician-administered or dispensed at in-house or contracted retail pharmacies ("contract pharmacies"). Covered entities then obtain reimbursement from insurers at higher rates, providing a source of revenue for facilities.[4]

The 340B program has grown substantially in recent years. In 2005, there were 591 hospitals enrolled as 340B covered entities;[5] this number had grown to more than 2,600 in 2023.[6] Total drug purchases under the 340B program have increased from $16.2 billion in 2015 to $66.3 billion in 2023, including a 23.4% increase from 2022 to 2023 alone, or approximately $58 billion in discounts from wholesale acquisition cost (WAC).[7-9] The number of contract pharmacies has similarly increased, with 4 in 10 retail pharmacies now having at least one 340B contract.[10]

The rapid expansion of the 340B program has garnered the attention of researchers examining the impact of the program on covered entities and underserved patients. Some covered entities report using 340B funds to expand program offerings, including increased medication access services and charity care.[11] Program participation has also been associated with increased safety net care among federally qualified health centers.[12] However, other research suggests no association between 340B participation and care to vulnerable populations[13] and that 340B revenue is often used to acquire physician practices and open sites in higher-income neighborhoods.[10] There is limited, mixed evidence on the impact of 340B participation on the quality or outcomes of care for Medicaid and uninsured patients[11,14] or patient out-of-pocket costs.[11,15]

Research on 340B entities enrolling after the 2003 Medicare Modernization Act expanded 340B eligibility suggests that entities enrolling in 2004 or later often serve wealthier communities[16] and report lower spending on uncompensated care[17] than covered entities enrolled prior to 2004. Studies on 340B entities entering the program after the further expansion of 340B eligibility under the Affordable Care Act in 2010 similarly report no net gain in uncompensated care or other services for uninsured and low-income patients after entering the program[18,19] Another study reports a heterogeneous response to 340B savings among newly participating hospitals (2012-2018), with public hospitals, but not private, nonprofit hospitals, significantly increasing total unprofitable services.[20]

Despite the increasing research focus on the expansion and impact of the 340B program, few studies have examined the profit margins associated with program participation. One peer-reviewed study reported that reimbursed prices at 340B hospitals were a median of over 3 times greater than acquisition prices.[21] Prices reimbursed by commercial insurers for new oncology drugs obtained through 340B at pediatric hospitals have also been explored, with median negotiated prices ranging from 102% to 630% of average sales price.[22] This variation in negotiated prices was similarly observed in a sample of 11 hospitals and 10 highly used drugs, with study authors noting a "particularly wide" gap between acquisition costs, as estimated by Medicare payment limits, and charges to commercial insurers for 340B entities.[23] Our objective is to add to the limited descriptive literature on 340B margins by (1) estimating facility-level margins on selected drug classes, and (2) identifying factors associated with higher 340B margins, including drug class, facility, and market-level characteristics.

Methods and Data

Study Overview

We conducted a cross-sectional regression analysis of predictors of 340B margins (margin = {reimbursed amount − acquisition cost}/acquisition cost, where reimbursements and acquisition costs were in 2021 USD) in US provider organizations that administered at least 1 of 5 drug classes. This analysis used data linked across multiple proprietary and public datasets.

Data Sources

Data were collected for the calendar year 2021 to determine drug margins for 340B covered entities across the US. For provider organizations that were 340B covered entities throughout 2021, facility-level data on non-340B acquisition costs and reimbursed amounts were obtained from IQVIA (www.iqvia.com) and included data linked across 4 datasets [IQVIA dataset name]:

- Data on individual prescribers in the U.S., including licensures and verified affiliations with provider organizations [OneKey]
- Actual non-340B acquisition costs [National Sales Perspectives, NSP]
- Actual reimbursed amounts for drugs administered [Remit Data]
- 340B and non-340B acquisition volumes for hospitals and free-standing offices, where free-standing offices included hospital-affiliated physician offices and independent, 340B eligible clinics [Drug Distribution Data, DDD]

340B acquisition costs were estimated for each facility based on the non-340B acquisition costs and accounting for the statutory 340B rebate (23.1%) and inflation rebate. The inflation rebates were estimated for each product as the difference between utilization-weighted NDC-level, inflation-adjusted launch prices and product list prices in 2021.[24-26] Facilities were also screened for IQVIA's contractual eligibility criteria and for administration of any of the 5 selected drug classes. Data on poverty,[27] Legal/Statistical Area Description (LSAD) classification,[28] and

market concentration[29] were linked by core-based statistical area (CBSA)[30] unique codes.

Model Framework

We examine drug, facility-level, and geographic market-level predictor variables associated with pricing power, facility profits, and implementation of the 340B program. The outcome variable is the overall margin that covered entities realize on drugs administered under the 340B program.

Drug prices, margins, and rebates can vary substantially by drug class. We selected a distribution of physician-administered drug classes in terms of therapy area, WAC, and rebate levels: allergic asthma; erythropoietins (EPOs), tumor necrosis factor (TNF) inhibitors, PD-1/PD-L1 checkpoint inhibitors, and wet age-related macular degeneration (AMD) treatments (Supplemental Table S1).[31] These drug classes represent a diversity of therapeutic areas, including those studied in recent research on the impact of the 340B program. Studies have reported associations between 340B and hospital-physician consolidation and shifts in site of care in hematology-oncology[11,32] as well as patterns of prescribing and administration in hematology-oncology and ophthalmology.[32] Others have hypothesized that observed differences in biosimilar uptakes in erythropoietin and TNF inhibitor biosimilars at 340B hospitals may be a result of financial incentives surrounding profit margins on originator biologics at those facilities.[33]

Prior studies have identified several common facility-level and geographic market-level factors associated with the ability to set prices and drive higher profits. There are 3 main components to overall margins under 340B: the CMS-determined unit drug discount, any additional discounts negotiated by the facility, and the amount the facility is reimbursed by payers for the drug. The second and third of these are dependent on the market power of the facility. Market concentration has been shown to be an important structural factor contributing to hospital pricing. Greater market share may lead to an ability to negotiate higher payments from private payers,[34,35] including among non-profit hospitals.[36] Pricing power similarly operates at the facility level: as the importance of a facility to a health plan in each area increases, facility reimbursement can increase substantially.[37] We capture the effects of concentration and pricing power with a measure of area-level population per federally qualified health center (FQHC) as well as a facility-level measure of drug mark-ups in non-340B markets. Further, we include a facility-level measure of non-340B drug margins as an indicator of pricing power in the negotiation of reimbursement amounts for non-340B drugs, as consolidation and market power have been linked to increasing prices for provider-administered drugs.[38] Finally, we include facility type, categorized as HOPD or free-standing offices (including hospital-affiliated physician offices and independent, 340B eligible clinics),[39-41] as well as facility size[42] based on the total number of included drug administrations during 2021.

We also capture the insight that more recent 340B participants may preferentially serve wealthier areas[16] by including a measure of the proportion of the population at or below 150% of the Federal Poverty Level (FPL). And, as there may be a difference in facility margin behavior depending on the proportions of 340B to non-340B volume, we include the mean proportion of 340B administrations across all drug classes at the facility-level. Census Division was also included to account for potential regional differences in costs and 340B program participation.

Statistical Analysis

Model variables and specifications for each are summarized in Supplemental Table S2. Generalized estimating equation (GEE) models were used to analyze the relationship between 340B margins and predictor variables, assuming a gamma distribution with a log link, with observations at the drug:site level. Robust errors were employed, and correlations were assumed to be independent across clusters with clustering at the facility level. All analyses were conducted with Stata v18.0 (College Station, TX). Results of alternative model specifications are included in the online supplement.

Results

Sample Characteristics

A total of 128 sites and 672 drug:site observations were included in the final analytic sample (Supplemental Table S3). The majority (63.8%) of drug:site observations were HOPDs (Table 1). In comparing sample characteristics by facility category, differences were observed in drugs administered and characteristics related to 340B volume, but not geographic characteristics. Specifically, differences were observed in the distribution of administrations across the 5 drug classes between HOPDs and free-standing offices ($P < .001$). This was driven primarily by the PD-1/PD-L1 inhibitors for oncology, consistent with the observed acquisition of oncology practices by hospitals.[11,32] Some differences across HOPDs and free-standing offices were found in the percentage of 340B volume (continuous: 77.8% vs 69.9%, $P < .001$; dichotomous, >90%: 40.1% vs 31.3%, $P = .023$) and the total number of units administered (213.3 units vs 452.2, $P < .001$). In this sample, there were no statistically significant unadjusted differences in market characteristics between HOPDs and free-standing offices.

Bivariate Analyses of 340B Margins

Margins on 340B drug administrations showed significant bivariate relationships with several model covariates (Figure 1). There were clear differences in 340B margins across drug categories ($P < .001$), consistent with current rebating practices, as well as across facility type, with overall mean margins in HOPDs over 3.5 times those in free-standing offices

Table 1. Sample Characteristics, Observations at Drug:Site Level, 2021.

Drug and Market Characteristics	Facility category		*P*-value
	HOPD (N = 429)	Free-standing office (N = 243)	
Drug class, N (%)			
Allergic asthma	77 (17.9%)	51 (21.0%)	<.001
EPO	23 (5.4%)	8 (3.3%)	
PD-1/PD-L1	158 (36.8%)	39 (16.0%)	
TNF	168 (39.2%)	118 (48.6%)	
Wet AMD	3 (0.7%)	27 (11.1%)	
% 340B volume, N (%)			
1%-89%	257 (59.9%)	167 (68.7%)	.023
90% to 100%	172 (40.1%)	76 (31.3%)	
% 340B volume, mean (s)	0.778 (0.217)	0.699 (0.271)	<.001
Units per Facility	213.3 (407.6)	452.2 (1347.8)	<.001
LSAD category, N (%)			
Micropolitan/Rural	29 (6.8%)	14 (5.8%)	.611
Metropolitan	400 (93.2%)	229 (94.2%)	
Pop per FQHC, mean (s)	63 338 (40 589)	63 635 (36 320)	.925
% Population < 150% of FPL	0.149 (0.040)	0.148 (0.041)	.912
Census region, N (%)			
New England	19 (4.4%)	7 (2.9%)	.252
Mid Atlantic	56 (13.1%)	34 (14.0%)	
South Atlantic	70 (16.3%)	57 (23.5%)	
E N Central	108 (25.2%)	44 (18.1%)	
E S Central	28 (6.5%)	19 (7.8%)	
W N Central	41 (9.6%)	21 (8.6%)	
W S Central	28 (6.5%)	13 (5.3%)	
Mountain	38 (8.9%)	20 (8.2%)	
Pacific	41 (9.6%)	28 (11.5%)	

Note. Kruskal-Wallis equality-of-populations rank test was used to assess within-group trends. Abbreviations used: AMD, age-related macular degeneration; EPO, erythropoietins; FPL, federal poverty level; FQHC, federally qualified health center; HOPD, hospital outpatient department; LSAD, legal/statistical area description; TNF, tumor necrosis factor.

($P < .001$). 340B margins were significantly lower in facilities with very high rates (≥90%) of total 340B volume versus those with less overall 340B volume ($P < .001$). Aside from moderately higher overall 340B margins in smaller, micropolitan markets ($P = .011$), there were few clear trends in bivariate relationships between 340B margins and total units administered ($P = .658$), market concentration ($P = .218$), nor with percent of the local population with household income below 150% of FPL ($P = .344$). There was a strong overall bivariate trend between 340B and non-340B margins ($P < .001$). The distribution of drug administrations with respect to other model covariates (Tables S4A-S4C) do not indicate that variations in drug classes drive the results shown in Figure 1; notably, the small number of EPO administrations are distributed across other covariate categories and do not appear to determine the bivariate results.

Multivariable Analyses of 340B Margins

Regression results show that drug, facility characteristics, and geographic healthcare market-level characteristics influence drug margins under the 340B program (Table 2). Adjusted 340B margins in free-standing offices remain lower than in HOPDs, though the differences found in the unadjusted results are greatly reduced. The effect of the percent of 340B volume on adjusted 340B margins is no longer statistically significant, while the adjusted effect of clinic size (measured as total units administered) remains insignificant when controlling for other factors. Covered entities in more concentrated markets – greater population per FQHC – achieve higher adjusted 340B margins than facilities in less concentrated markets; each 1% increase in the population/FQHC is associated with a 0.05% increase in 340B margins ($P < .001$). In addition, facilities in areas with a greater share living under 150% of the FPL achieve adjusted 340B margins that are lower than facilities in higher-income areas ($P < .01$). The relationship between normalized non-340B margin and 340B margins is statistically significant ($P < .001$) and is robust in models that do not include market and area-level poverty covariates (Supplemental Table S5) and in drug-class-specific models (Supplemental Table S6). In addition, key results on the effects of market concentration

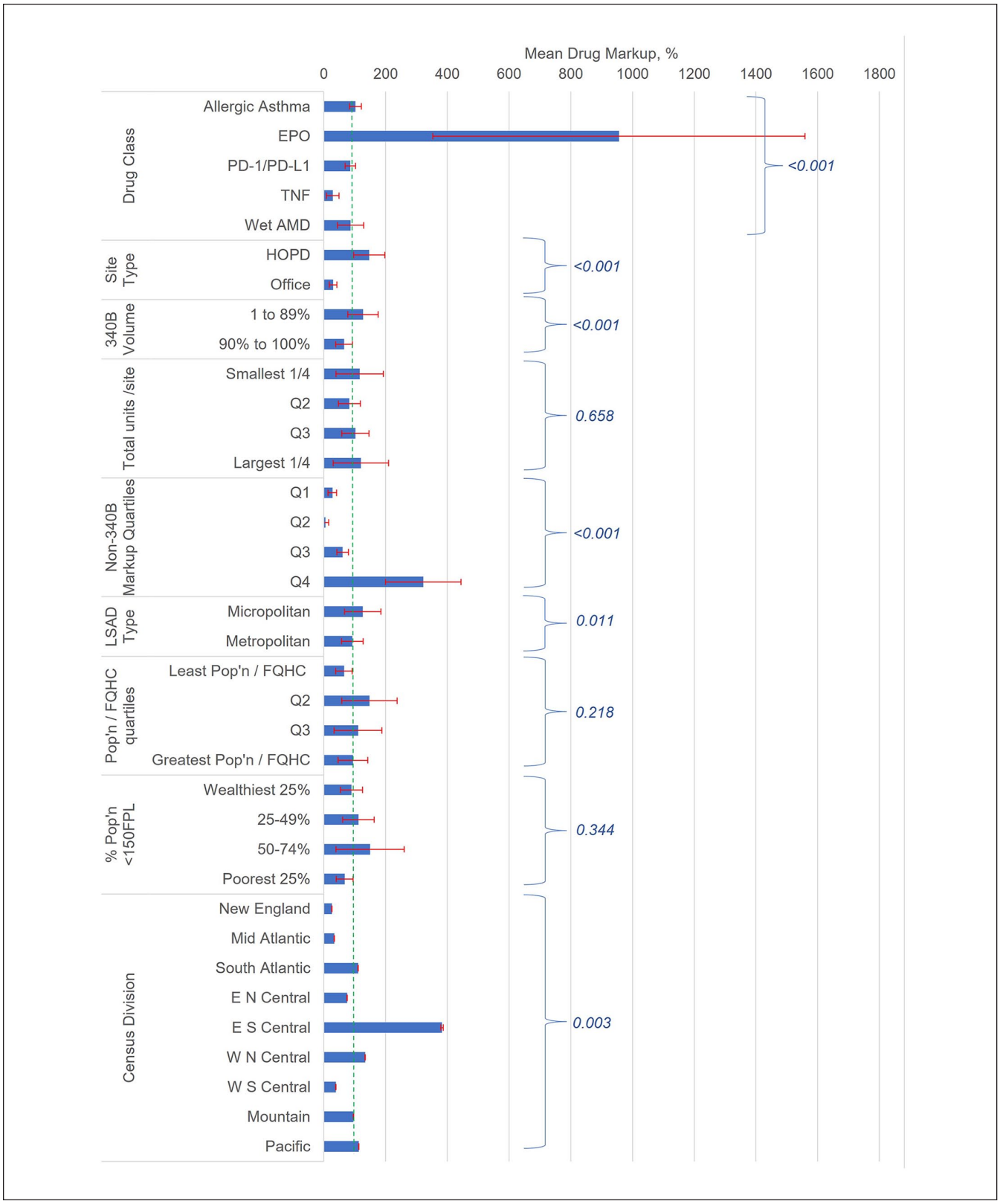

Figure 1. Bivariate relationships between 340B margins and model covariates, 2021.

Note. Overall mean (dotted line) and *P*-values (brackets) listed; Kruskal-Wallis equality-of-populations rank test was used to assess within-group trends. Abbreviations used: AMD, age-related macular degeneration; EPO, erythropoietins; FPL, federal poverty level; FQHC, federally qualified health center; HOPD, hospital outpatient department; LSAD, legal/statistical area description; PD-1, programmed death-1; PD-L1, programmed death-ligand 1; TNF, tumor necrosis factor.

Table 2. Estimated Effects of Drug, Facility, and Geographic-Level Characteristics on 340B Drug Margins, 2021 (Dependent Variable: ln(1 + 340B Margin)).

Independent variable	Coefficient	95% CI	*P*-value
Drug class (Allergic asthma ref)			
EPO	1.19	(0.833 to 1.54)	<.001
PD-1/PD-L1	−0.186	(−0.286 to −0.086)	<.001
TNF	−0.860	(−0.952 to −0.768)	<.001
Wet AMD	0.068	(−0.136 to 0.272)	.516
Site type: Office (HOPD ref)	−0.202	(−0.271 to −0.133)	<.001
340B volume: 90%-100% (1%-89% ref)	−0.067	(−0.137 to 0.002)	.053
Total units/site (ln)	0.014	(−0.008 to 0.036)	.223
Non 340B margin (norm)	7.86	(6.95 to 8.77)	<.001
LSAD Category: Micropolitan (Metropolitan ref)	−0.063	(−0.257 to 0.131)	.523
Population / FQHC (ln)	0.049	(0.024 – 0.074)	<.001
% Pop'n < 150% of FPL	−1.33	(−2.33 to −0.337)	<.01
Census Division (New England ref)			
Mid Atlantic	0.011	(−0.169 to 0.191)	.904
South Atlantic	0.101	(−0.060 to 0.262)	.221
E N Central	0.159	(−0.017 to 0.335)	.079
E S Central	0.329	(0.072 to 0.586)	<.05
W N Central	0.229	(0.041 to 0.417)	<.05
W S Central	0.191	(−0.036 to 0.418)	.099
Mountain	0.213	(0.033 to 0.393)	<.05
Pacific	0.287	(0.109 to 0.465)	<.01
N	672		
Wald c2	1424		

Abbreviations: AMD, age-related macular degeneration; EPO, erythropoietins; FPL, federal poverty level; FQHC, federally qualified health center; HOPD, hospital outpatient department; LSAD, legal/statistical area description; PD-1, programmed death-1; PD-L1, programmed death-ligand 1; TNF, tumor necrosis factor.

and area-level poverty are consistent, and statistically significant across drug classes (Supplemental Table S6).

Discussion

This analysis of predictors of 340B margins among covered entities suggests that the market power of 340B covered entities and the affluence of the area they serve are both associated with higher margins for drugs purchased under that program. The finding that facilities with higher market power in non-340B markets, or those that are in less competitive areas, are able to extract greater profits under the 340B program, is consistent with the literature on provider behavior generally[35-37] and recent work on the 340B program.[16,18] The effect of the percentage of facility-level 340B volume on 340B margin differed between the bivariate and fully adjusted models. Specifically, in bivariate analysis, facilities with higher proportions of 340B volume in the selected drug classes have lower overall margins. This relationship is no longer significant in the fully adjusted model, reflecting the importance of accounting for market power and area poverty.

The association between geographical wealth and 340B margin suggests a combination of structural constraints at the facility and market levels for covered entities in poorer geographic areas. Facilities with higher rates of Medicaid reimbursement may have lower 340B profits relative to facilities with a higher proportion of commercially insured patients, given higher negotiated reimbursement rates paid by private insurers. Higher 340B margins for drugs dispensed to more affluent, better insured patients may incentivize the expansion of contract pharmacies into wealthier areas observed by others.[43,44] This trend has been criticized as a shift away from a focus on uninsured and low income populations,[12,45] with one group of researchers observing that the program has evolved to one ". . .*that enables eligible hospitals to generate profits by providing these drugs to well-insured patients*."[46] Others have similarly noted that "*nonprofit, [disproportionate share hospitals] may be using the 340B program in margin-motivated ways.*"[47] As a response to these concerns, reforms to more narrowly define facility and patient eligibility[13] have been proposed as one way to refocus the program to safety-net providers and care to uninsured and underinsured patients.[48]

Our results are consistent with a scenario in which facilities in poor areas do provide more uncompensated care[11] despite realizing lower 340B profits, while facilities in wealthy areas would not increase levels or quality of uncompensated care despite higher 340B margins. Testing this scenario, which has similarly been posited by others,[16] would require detailed data on 340B revenues and how they are used. The Health Resources and Services Administration (HRSA) does not currently require covered entities to report this information but faces growing calls to increase

transparency requirements, including mandating reporting of 340B savings and revenue, how savings are used, and spending to expand safety net services.[12,49]

Our analysis is necessarily limited by data availability. Linking multiple datasets containing acquisition costs, drug reimbursement, and 340B program eligibility results in a sample size that is small relative to the size of the 340B program. While we selected drug classes capturing a wide distribution of drugs administered under 340B, more work will be needed to demonstrate these relationships in the bulk of 340B drugs. Data availability was limited to HOPDs and free-standing offices, therefore we could not capture the potential impact of intermediaries,[50] such as third-party administrators (TPA) and pharmacy benefit managers (PBMs), on 340B margins. Several prior studies have highlighted the importance of facility tenure in the 340B program as it relates to facility and patient outcomes.[16,18,19] We did not have access to a measure for 340B tenure, and such a measure would likely inform the discussion on whether and to what extent facility strategic choices affect profitability and care provision. In addition, our measure of market concentration essentially measures concentration in services for underserved patients as opposed to a broad measure of concentration in healthcare provider markets. The results of that measure should be interpreted in that light. In addition, the data do not indicate whether drugs are acquired directly or through a group purchasing organization (GPO, for those facilities not affected by the GPO prohibition) or Apexus, the 340B prime vendor, and do not capture any additional discounts that these organizations may be able to negotiate. Thus, our estimates of drug margins may be both somewhat underestimated and also include a component of the GPO's purchasing power.

Conclusion

Margins on 340B drugs were higher among facilities in stronger bargaining positions and those serving wealthier areas. These findings add to the growing body of literature on the expansion of the 340B program into more affluent communities, informing calls for reforms to ensure the 340B program serves low-income and uninsured patients.

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None.

Author Contributions

Concept and design: Nordyke
Acquisition of data: Nordyke
Analysis and interpretation of data: Nordyke, Motyka, Patterson
Drafting of the manuscript: Nordyke, Patterson
Critical revision of the paper for important intellectual content: Nordyke, Motyka, Patterson
Obtaining funding: Nordyke
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Supervision: Nordyke, Patterson

Data availability statement

The authors confirm that the data supporting the findings of this study are available within the article [and/or] its supplementary materials.

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Consent to Participate

Not Applicable.

Consent for Publication

Not Applicable.

Tracked Changes or Comments

Not Applicable.

Supplemental Material

Supplemental material for this article is available online.

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