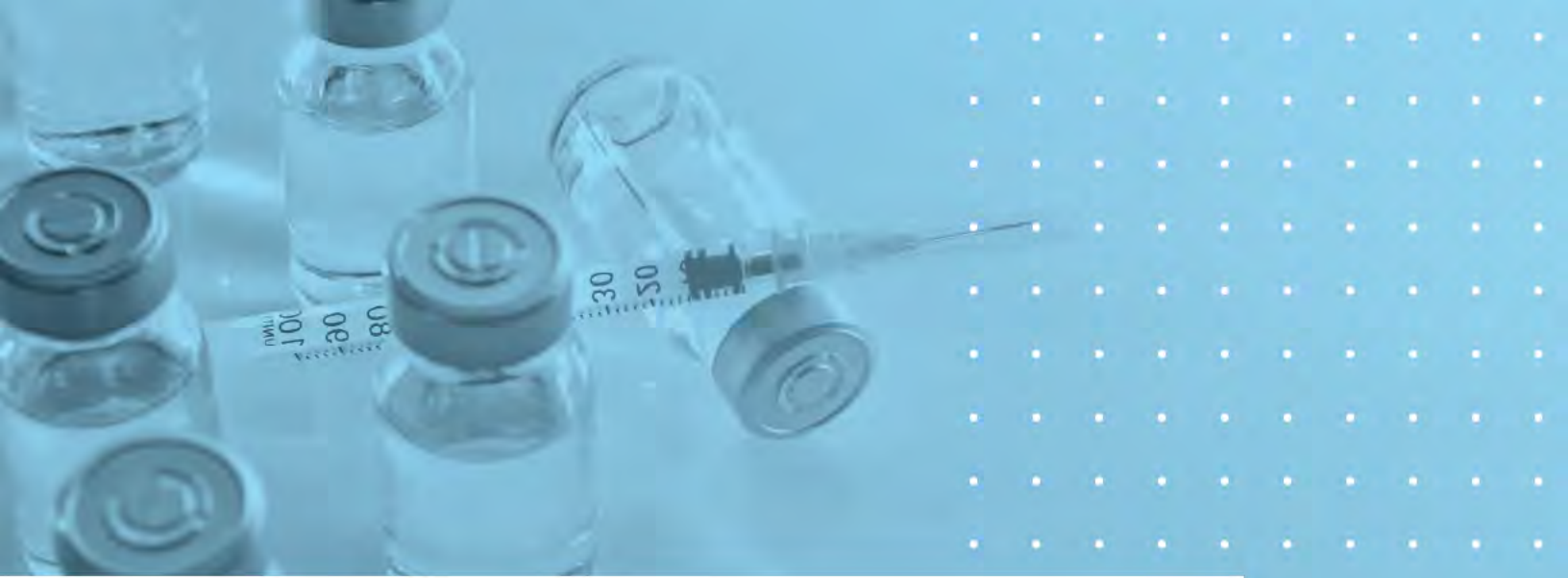




Site-of-Care Shift for Physician-Administered Drug Therapies: Update



PREPARED BY:

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INTELLIGENCE THAT WORKS

Introduction

In October 2017, BRG professionals published a white paper evaluating the breakdown in site of care for top drugs used to treat several conditions (breast cancer, rheumatoid arthritis, and multiple myeloma). The paper analyzed data on physician-administered medicines covered by Medicare Part B and found that as of 2015, nearly one-third of Medicare Part B drug reimbursement for breast cancer and multiple myeloma treatments, and nearly 19 percent for rheumatoid arthritis treatments, occurred in the 340B hospital setting. For all three conditions, historical trends indicated a significant shift in site of care since 2008.

This paper updates the prior analysis to reflect Medicare claims data through 2017 and provide a broader view of all Part B drugs. This paper also compares the total size of the 340B Drug Discount Program to the total size of Part B drug sales, both measured at wholesale acquisition cost (WAC), and provides an updated analysis of the impact of the Centers for Medicare and Medicaid Services' (CMS) cut in reimbursement for most 340B-purchased Part B drugs.

Background on 340B Program and Shift in Site of Care

The 340B Drug Discount Program allows certain qualifying clinics and hospitals access to discounted prices for outpatient drugs covered by Medicaid (these drugs include both retail and physician-administered drugs). Many 340B hospitals also access the discount for their off-campus hospital outpatient departments (HOPDs) under US Health Resources and Services Administration (HRSA) guidance and CMS cost-reporting rules. These HOPDs may include previously independent physician offices that have since been acquired by a hospital. Such purchases of independent physician offices by hospitals, in addition to less formal arrangements such as referral networks, have contributed to the documented shift in site of care from the physician office setting to the hospital outpatient department setting.

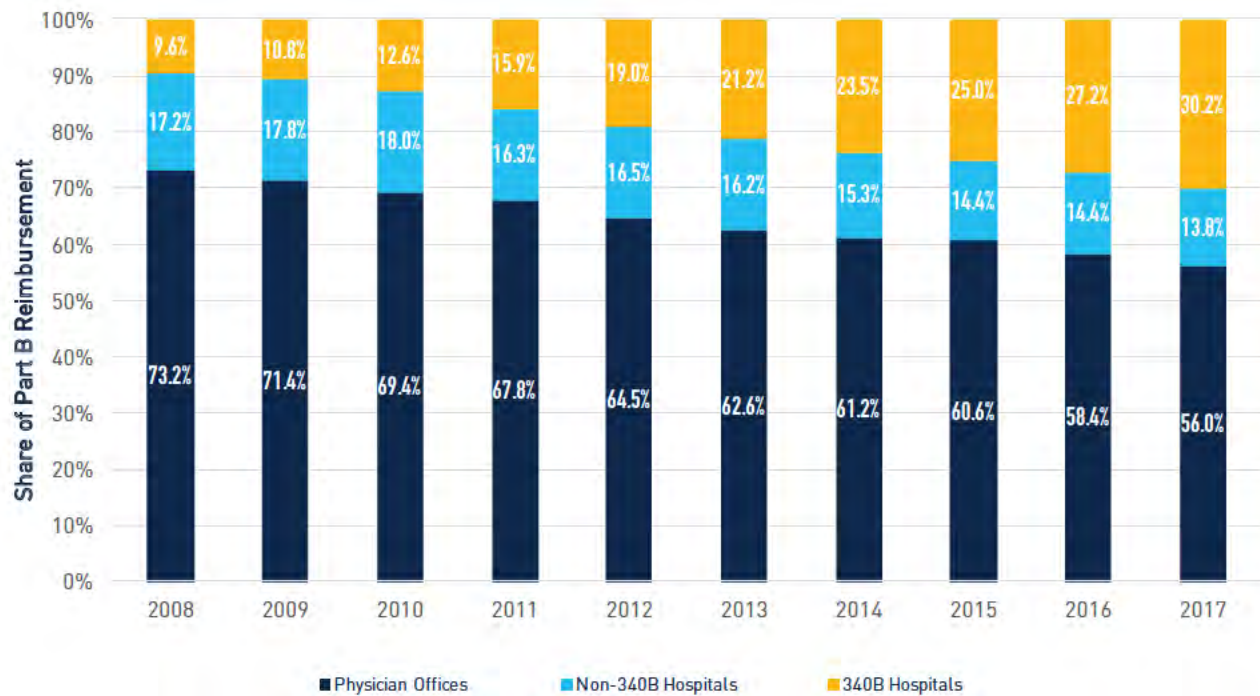
Shift in Site of Care for Common Drug Therapies

We analyzed Medicare Part B drug claims across the period from 2008 to 2017 using 340B program enrollment data from the HRSA Office of Pharmacy Affairs (OPA) to identify claims occurring at a 340B-enrolled hospital. We then calculated the share of reimbursement for those claims (payments from Medicare and beneficiaries) occurring in the 340B hospital setting, the non-340B hospital setting, and the physician office setting. Across all Part B drugs, more than 30 percent of reimbursement occurred in the 340B hospital setting in 2017, as compared to less than 10 percent in 2008.¹

¹ Metrics developed using: Medicare Outpatient Research Identifiable Files (RIF) for 2008 to 2017; Medicare Carrier Limited Data Sets (LDS) for 2008 to 2017; HRSA OPA 340B Covered Entity Database.

FIGURE 1

Site of Care for All Drug Therapies Reimbursed in Medicare Part B (2008-2017)

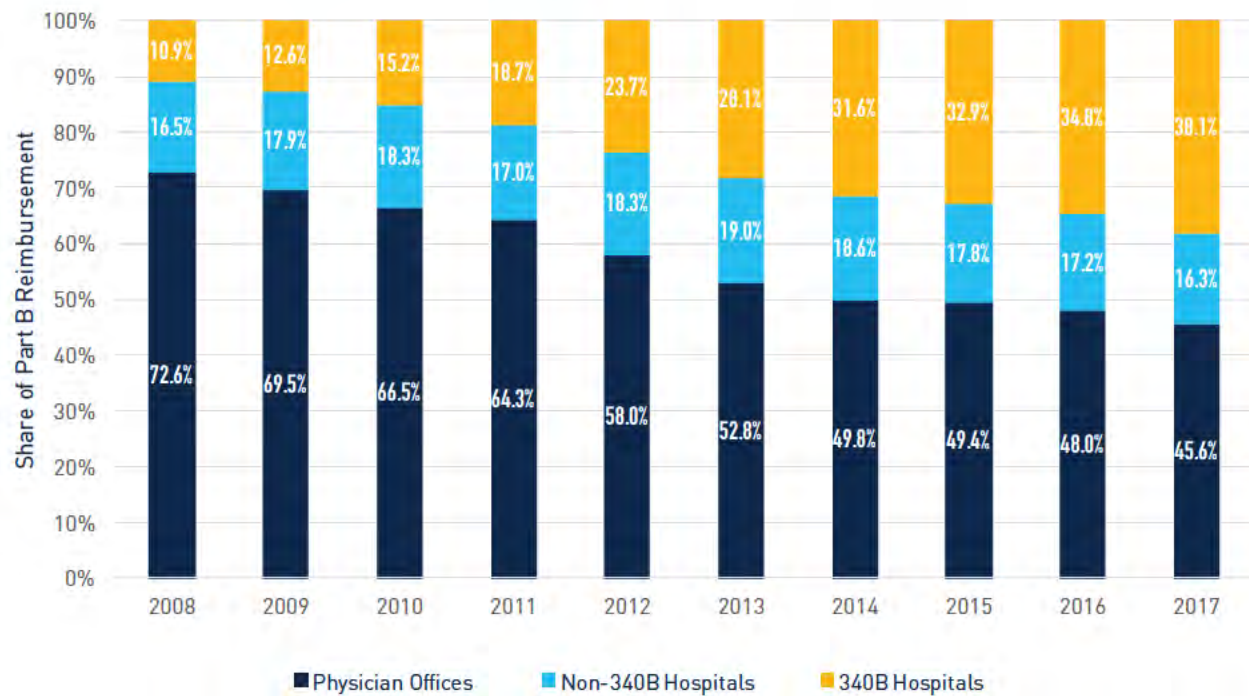


In a similar manner, we broke down reimbursement for the top ten drugs, as measured by Part B drug reimbursement, indicated for treatment of breast cancer, rheumatoid arthritis, and multiple myeloma.²

² Metrics developed using: Medicare Outpatient RIF for 2008 to 2017; Medicare Carrier (LDS for 2008 to 2017; HRSA OPA 340B Covered Entity Database.

FIGURE 2

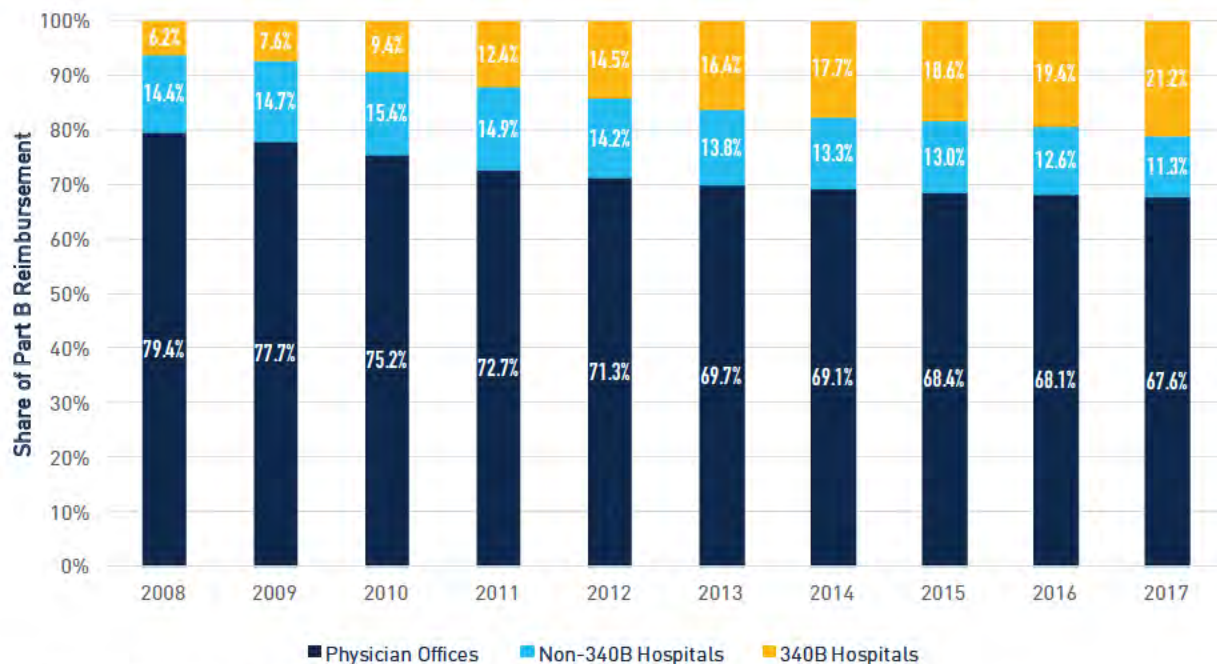
Site of Care for Breast Cancer Drug Therapies Reimbursed in Medicare Part B (2008-2017)



Note: Analysis includes top ten drugs reimbursed under Part B and used for breast cancer treatments.

FIGURE 3

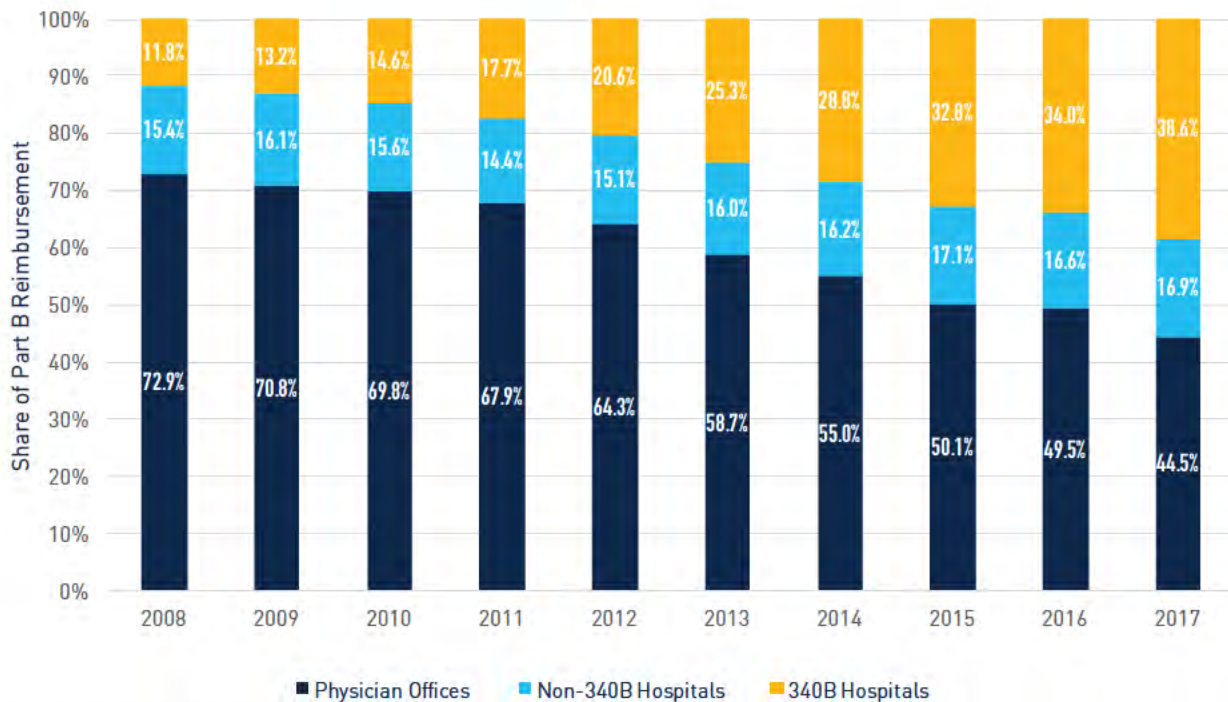
Site of Care for Rheumatoid Arthritis Drug Therapies Reimbursed in Medicare Part B (2008-2017)



Note: Analysis includes top ten drugs reimbursed under Part B and used for rheumatoid arthritis treatments.

FIGURE 4

Site of Care for Multiple Myeloma Drug Therapies Reimbursed in Medicare Part B (2008-2017)



Note: Analysis includes top ten drugs reimbursed under Part B and used for multiple myeloma treatments.

The shift in site-of-care trend continued into 2016 and 2017 for treatments related to all three conditions. The 340B HOPD setting share of the total of Part B reimbursement increased to more than 38 percent for both breast cancer and multiple myeloma treatments, and now exceeds 21 percent for rheumatoid arthritis treatments.

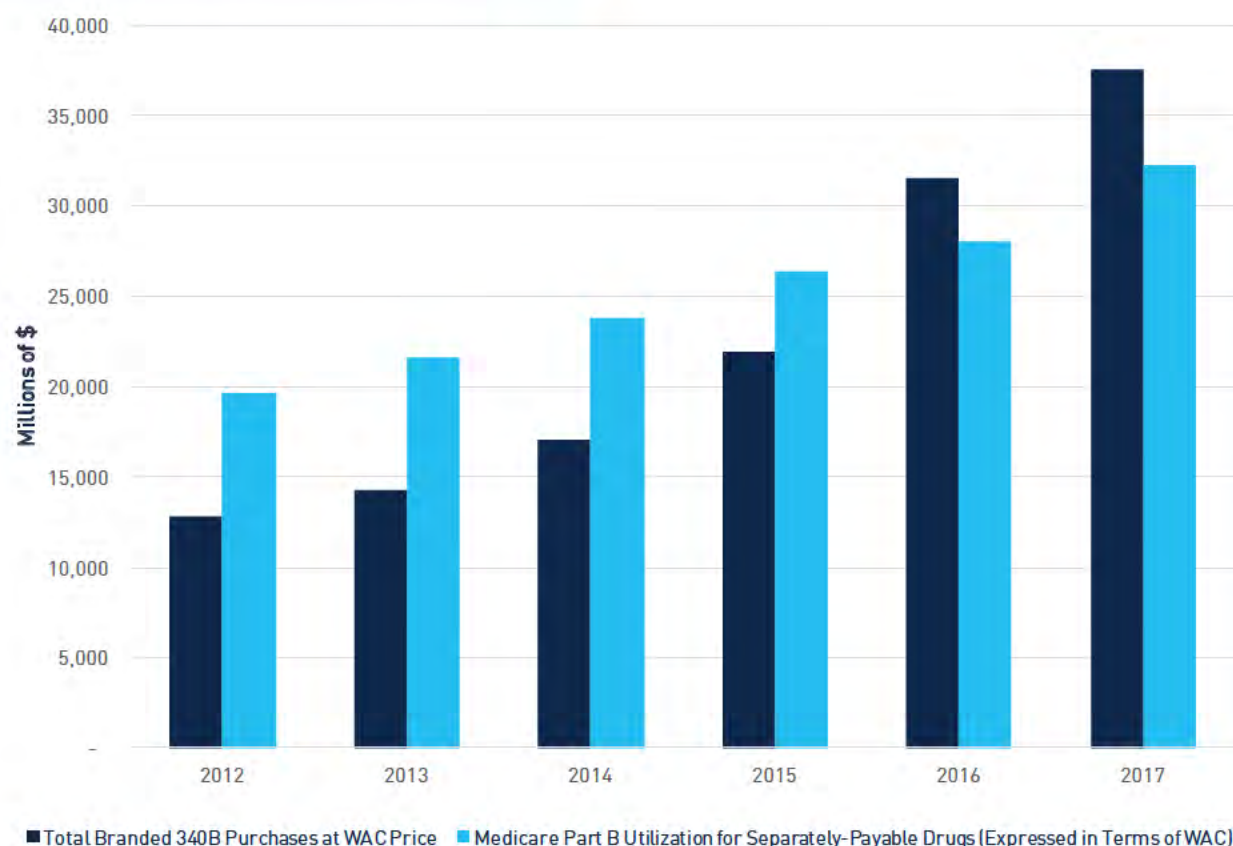
The shift in site of care into the 340B hospital setting has contributed to the rapid growth in the size of the 340B program, particularly over the last few years. In July 2018, BRG professionals published an estimate that total branded 340B purchases at the WAC price accounted for 10.1 percent of the addressable market in 2017.³ Below, we compare the size of the 340B program (defined in the same manner) to total Part B drug utilization (expressed in terms of WAC) over time. Beginning in 2016, the 340B program sales exceeded the size of total Part B drug utilization.⁴

³ Aaron Vandervelde and Eleanor Blalock, *Measuring the Relative Size of the 340B Program: 2017 Update*, BRG white paper (July 2018), available at: <https://www.thinkbrg.com/newsroom-publications-340b-size-2017-update.html>

⁴ Part B drug spending metrics for 2012-2016 developed based on the Medicare Part B Drug Spending Dashboard; Part B drug spending metric for 2017 developed using: Medicare Outpatient RIF for 2017 and Medicare Carrier LDS for 2017; 340B metric developed based on BRG analysis of Apexus/HRSA reporting of 340B drug sales.

FIGURE 5

Size of 340B Program Compared to Medicare Part B Drug Utilization



Analysis of Potential Impact of Regulatory Response

In 2018, CMS reduced Medicare Part B reimbursement for drugs purchased by hospitals at the 340B price from the Average Sales Price (ASP) plus 6 percent to ASP minus 22.5 percent, acknowledging that hospital participation in the 340B program appears to be correlated with “drug spending increases.”⁵ The payment reduction was subsequently litigated, and in December 2018, the District Court for the District of Columbia held that the 340B drug payment cuts were outside the authority of the Secretary of Health and Human Services.⁶ Specific implications for affected hospitals’ 2018 340B drug reimbursement are unclear at this time as the court further considers the hospitals’ remedies. While the recent court ruling does not apply to CMS’ 2019 340B drug reimbursement cut, the 2019 cut will likely be litigated in the future.

In our 2017 report, we noted that the ASP payment cut would result in only a 13 percent reduction in Disproportionate Share Hospital (DSH) hospital margin earned on 340B purchased drugs, as it does not affect reimbursement for patients covered under Medicare Advantage, commercial insurance, or Medicaid, nor does it eliminate all hospital margin opportunity under Medicare Part B for heavily discounted drugs.

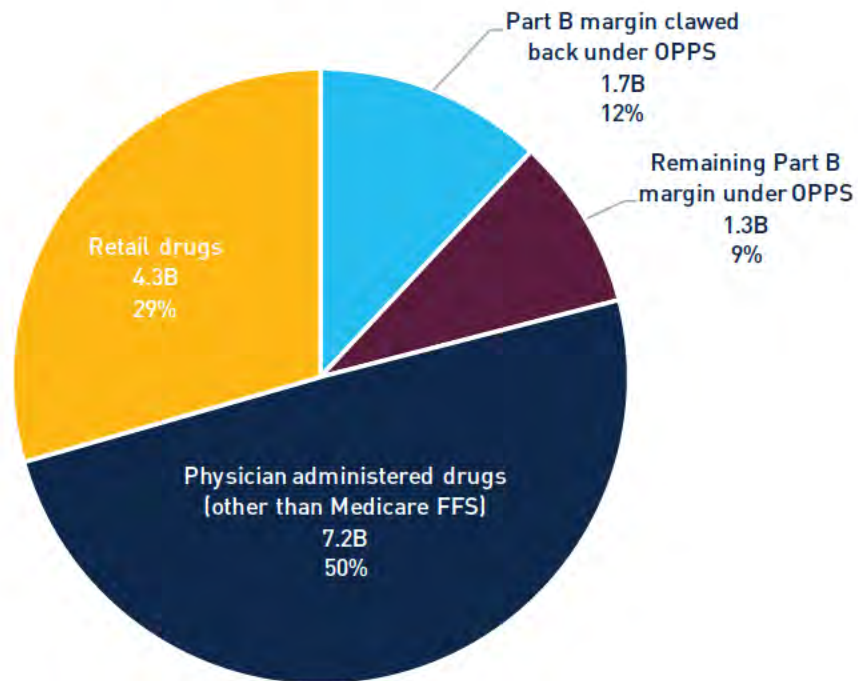
In this report, we have updated this calculation to reflect the latest data on total 340B sales and typical discounts off of the WAC. Our updated findings are that the reimbursement cut results in a 12 percent (\$1.7 billion) reduction in DSH hospital 340B margin.

5 “Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs,” 42 CFR Parts 414, 416, and 419, Federal Register 82:239 (December 14, 2017), available at: <https://www.govinfo.gov/content/pkg/FR-2017-12-14/pdf/R1-2017-23932.pdf>

6 *Am. Hosp. Ass’n v. Azar*, No. 18-2084, “Memorandum Opinion Denying Defendants’ Motion to Dismiss; Granting Plaintiffs’ Motion for a Permanent Injunction; Denying as Moot Plaintiffs’ Motion for a Preliminary Injunction” (DDC Dec. 27, 2018), available at: https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2018cv2084-25

FIGURE 6

2017 DSH Hospital Margins for Medicines Purchased through the 340B Program



Total DSH Hospital Margins = \$14.5 B

Source: BRG analysis of Apexus disclosures of 2017 total sales at the 340B price; analysis of the typical 340B discount off of Wholesale Acquisition Cost (WAC), and analysis of typical payer reimbursement as a percentage of WAC.

Conclusion

Our latest analysis indicates that the shift in site of care to the 340B HOPD setting continued into 2016 and 2017. The trend has impacted Part B drug therapies broadly, with a greater impact on drugs that treat certain conditions (breast cancer and multiple myeloma, for example). One driver of this shift is the financial incentive created by the 340B program, in which hospitals have historically been able to retain the difference between standard drug reimbursement and the discounted 340B acquisition cost. It is unclear at this time whether CMS' reimbursement cut for 340B-purchased drugs will be reversed or continue in some form into the future. Either way, significant margin opportunity remains for 340B hospitals on drugs, and as a result we expect the consolidation trend to continue in the future.

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About the Author

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New HRSA Data: 340B Program Reached \$29.9 Billion in 2019; Now Over 8% of Drug Sales

 drugchannels.net/2020/06/new-hrsa-data-340b-program-reached-299.html



The 340B Drug Pricing Program has logged another year of incredible growth.

According to data provided to *Drug Channels* by the Health Resources and Services Administration (HRSA), discounted 340B purchases were at least \$29.9 billion in 2019. That figure is an astonishing 23% higher than its 2018 counterpart.

Since 2014, purchases under the 340B program have tripled. Over the same period, manufacturers' net drug revenues have grown at an average rate that's below 5%. Consequently, the 340B program has grown to account for more than 8% of the total U.S. drug market and about 16% of the total rebates and discounts that manufacturers provide.

What's more, the 340B program is now almost as large as the Medicaid program's outpatient drug sales. However, 340B lacks Medicaid's regulatory infrastructure and controls. Medicaid rebates directly and transparently lower drug costs for the government, while 340B discounts disappear into providers' financial statements. It's troubling and hard to defend.

Read on for our latest details on the 340B program's ongoing and startling growth.

340B BACKGROUND

The 340B program mandates that pharmaceutical manufacturers provide outpatient drugs to certain healthcare entities—known as eligible covered entities—at significant discounts. In 2019, more than 2,500 hospitals participated in the program. Since 2010, 340B covered entities have also been able to access 340B pricing through multiple external pharmacies. More than 25,000 pharmacies contracted with 340B covered entities in 2019.

Hospitals and other 340B covered entities profit from the difference between a drug's third-party reimbursement and the covered entity's 340B acquisition cost, a.k.a., the 340B ceiling price.

The 340B ceiling price is equivalent to the Medicaid net price. More technically, the 340B discount as a percentage of the average manufacturer price (AMP) equals the Medicaid rebate as a percentage of AMP. [Click here to read my explanation of how to compute the 340B ceiling price.](#)

Consequently, hospitals and other 340B covered entities can acquire many brand-name specialty pharmaceuticals for as little as \$0.01, a practice known as **penny pricing**. This can occur when the calculation for a 340B price yields zero, which means that a drug has hit its 100% Medicaid rebate cap. For instance, AbbVie disclosed that Humira, the top-selling drug in the U.S., hit the rebate cap starting in early 2016. ([source](#)) Since then, both 340B hospitals and the Medicaid program have been able to buy Humira for \$0.01.

For broader background on 340B's role in the pharmacy and PBM industries, see section 11.5 of our [2020 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers](#).

I have been covering the 340B program on *Drug Channels* for eight years now. [Click here to read my more than 80 articles about the program.](#)

340BOOM

In recent years, the Health Resources and Services Administration (HRSA) has provided *Drug Channels* with data measuring the 340B program. Apexus, the HRSA-designated Prime Vendor, reports these data to HRSA. A little-known fact: Apexus is owned by [Vizient](#), one the largest hospital group purchasing organizations.

The following chart summarizes the ongoing surge in covered entities' purchases made under the 340B Drug Pricing Program. It also includes our estimates of the value of those purchases at undiscounted, non-340B prices.

[Click to Enlarge]

340B Drug Pricing Program, Purchases by Covered Entities, 2014 to 2019



Here's a summary of our latest findings:

Discounted purchases made under the program totaled \$29.9 billion in 2019—an increase of 23% from the \$24.3 billion in 2018.

The compound average growth rate (CAGR) of 340B purchases was an incredible 27.1% from 2014 through 2019.

Manufacturers' net revenues (per IQVIA) grew at a CAGR of only 4.7% from 2014 to 2019.

Two important comments on these data:

The chart above includes DCI's estimated invoice value of these purchases. The undiscounted invoice figure is based on average Medicaid drug rebate rates, as reported by MACSTATS. For 2018, MACSATS reported that rebates reduced Medicaid's gross spending on outpatients prescriptions by 59%. We have adjusted these rebate figures to account for pharmacy dispensing and PBM administration costs included in the Medicaid gross spending data. The figures above therefore differ slightly from our previous estimates. The actual undiscounted figures are unknown.

The data from Apexus include only indirect sales made via wholesalers. The \$29.9 billion figure is therefore less than the actual total of 340B purchases at discounted prices. That's because the Apexus data exclude an unknown amount of manufacturer sales made directly to healthcare institutions and some sales by specialty distributors.

340BIG

Many partisan supporters try to minimize 340B's share of the total U.S. market. In reality, the 340B program is a significant and growing part of the industry.

Here are three computation approaches that portray the size of today's 340B program:

1) 340B as a share of net drug sales = 8.3%

The discounted HRSA figures above include purchases at or below the deeply discounted 340B ceiling prices. An appropriate comparison must therefore also be discounted sales, i.e., manufacturers' net revenues after rebates and discounts.

According to IQVIA, manufacturers' net revenues were projected to be \$360 billion in 2019.

Using net revenues, 340B's share in 2019 was **8.3%**, or \$29.9 billion ÷ \$360 billion.

This overall average also hides wide variation. Specialty drugs have a higher-than-average share of sales made at 340B discount prices. For example, Merck recently disclosed that one-third of Keytruda's sales come from 340B covered entities.

FYI, 340B's 2019 share is 120 basis points higher than our 7.1% computation for 2018.

2) 340B as a share of gross-to-net discounts for brand-name drugs = 16%

The 340B program has become a significant and growing part of the total discounts that manufacturers provide.

For 2019, the total value of gross-to-net reductions for brand-name drugs was \$175 billion. (See Section 9.2.2. of our 2020 pharmacy/PBM report.) This figure measures the gap between: (1) manufacturers' gross revenues of brand-name drugs at the wholesale acquisition cost (WAC) list price, minus (2) manufacturers' actual revenues at drugs' net prices after rebates, off-invoice discounts, copay assistance, price concessions, and such other reductions as distribution fees, product returns, the 340B Drug Pricing Program, and more. Rebates constitute about two-thirds of gross-to-net reductions.

Based on the chart above, the total value of gross-to-net reductions from the 340B program was \$31.1 billion (= \$61.0 - \$29.9). We estimate that brand-name drugs account for 90% of 340B discounts, or \$28 billion.

Therefore, 340B's share of total gross-to-net discounts for brand-name drugs in 2019 was **16%**, or \$28 billion ÷ \$175 billion.

3) Drug sales under the 340B program now almost equal drug sales under the Medicaid program.

For a final comparison, consider the Medicaid Drug Rebate Program (MDRP). Pharmaceutical manufacturers that participate in the MDRP must also agree to offer a 340B ceiling price to covered entities.

The Centers for Medicare & Medicaid Services (CMS) projects that net sales of outpatient drugs paid by Medicaid were \$34.9 billion in 2019. See The Latest CMS Outlook for Drug Spending—And How COVID-19 Will Change It.

Therefore, the 340B program is now **85%** (= \$29.9 ÷ \$34.9) as large as the Medicaid program.

For an alternative estimate, I recommend Measuring the Relative Size of the 340B Program: 2018 Update. Using different assumptions about 340B discounts, Berkeley Research Group concluded that 340B accounted for 14.0% of brand-name drug sales.

340BETTER

340B Health, which lobbies for hospitals that participate in the 340B program, continues to claim falsely that 340B is "just 1% of the total U.S. drug market." LOL. (As of this morning, this figure appeared on the [340B Infographics page of 340B Health's website.](#))

BTW, 340B Health always launches an annual *ad hominem* attack on me to distract us from the uncomfortable facts about the program's true size. Can't wait.

Longtime readers know that I believe that the 340B program is long overdue for reform, especially in light of the many abuses and problems that have been uncovered by the U.S. Government Accountability Office (GAO) and the Office of the Inspector General (OIG). Substantial evidence suggests that 340B savings are not always shared with patients and their insurance providers, including Medicare.

Unlike the highly regulated Medicaid program, the 340B program is managed via a tangle of sub-regulatory guidance, private letters, and "Frequently Asked Questions" posted to the HRSA website.

There is also no transparency into how 340B discounts are spent, because hospitals and their lobbyists fight any call for them to disclose or account for how they use their 340B profits. There is compelling evidence that [hospitals are double-counting 340B savings against their fundamental legal and statutory community benefit obligations as non-profit organizations.](#)

By contrast, detailed Medicaid data are available from nonpartisan government agencies. Meanwhile, the 340B program's advocates and regulators consistently misrepresent the program's size and growth.

In our current environment, there's little chance for reform. Consider this year's update to be my annual reminder that the 340B program is not fine.

The Federal Program That Keeps Insulin Prices High

The Wall Street Journal

September 11, 2020 Friday

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Body

Perhaps the biggest flashpoint in the political debate about prescription drug prices is the cost of insulin. This summer an executive order from President Trump required low prices for some patients, and Eli Lilly last week announced new measures to make insulin more affordable for diabetics. Yet many aren't aware that a federal program is goosing the price of insulin and other treatments, and keeping the prices high for patients who need these drugs.

Over the past few months the little-known 340B Drug Pricing Program has become the source of intense jockeying over who should benefit from the deep drug discounts -- sometimes as much as 100% -- that manufacturers provide to hospitals and their pharmacy partners. Drug manufacturers Sanofi, Merck and Novartis are demanding transparency to ensure that their discounts aren't diverted.

Congress created the 340B Drug Pricing Program in 1992 with the vague goal of helping providers "stretch scarce federal resources" by requiring manufacturers to offer steep drug discounts to certain "safety net" hospitals. But the program includes no clear mandate on how the rebates should be spent. Good intentions have been swamped by middlemen that pocket discounts while forcing patients, employers and the Medicare program to pay more for prescription drugs.

For 18 years, 340B remained a minor, generally uncontroversial part of the U.S. health-care system. But shortly after the Affordable Care Act passed in 2010, the Obama administration announced an expansion: Hospitals could purchase and dispense discounted drugs through an unlimited number of external (or contract) commercial pharmacies.

For years I've been studying the economics of the complex and opaque intersection of the 340B program and the pharmacy industry. My analysis has found that since 2010 the 340B program has grown by almost 500% and is approaching the size of the nation's Medicaid outpatient drug market. The number of external pharmacies in the 340B program has also skyrocketed, from fewer than 1,300 in 2010 to 28,000 in 2020. That means almost half the U.S. pharmacy industry now profits from the 340B program, which was designed as a narrow support to certain hospitals.

The Federal Program That Keeps Insulin Prices High

Profit margins of up to 100% allow hospitals to pay inflated fees to their pharmacy partners, which can earn margins well above what the patient's insurance company usually pays. Public companies such as Walgreens, CVS, Walmart, Cigna, UnitedHealth Group, and Kroger have rushed into the 340B business. A booming industry of consultants and technology companies helps hospitals and commercial pharmacies profit from this aspect of the 340B program.

Patients don't benefit from these discounts. Instead, they are expected to pay their health plans' full out-of-pocket costs. A patient with a high-deductible health plan must pay the full list price for his medicine. The same sad math applies to seniors in the Medicare Part D program. Seniors taking many expensive specialty therapies must pay 5% of their prescription's price without discounts -- even when the manufacturer has practically given the product away.

Unlike Medicaid, the pharmacy component of 340B doesn't have -- and has never had -- a regulatory infrastructure. That's because the Obama administration's 2010 notice bypassed the usual rule-making and comment procedures. Consequently, there's no requirement that hospitals appropriately use the billions in 340B pharmacy discounts, no fair-market-value standards for pharmacies' fees, and zero transparency around the profits earned by the billion-dollar public companies that dominate 340B pharmacy networks.

Even worse, multiple government watchdogs have found that hospitals often don't provide discounted drug prices to uninsured low-income patients who filled prescriptions at a hospital's 340B contract pharmacy. The Government Accountability Office discovered that in a sample of 28 hospitals, 16 (57%) didn't provide discounted drug prices to needy patients at 340B pharmacies.

Manufacturers can find themselves paying a Medicaid rebate and a 340B discounts for the same prescription. Such double dipping occurs because there is a lack of transparency into claims data that would allow states and manufacturers to apply payment policies correctly. Health and Human Service's Inspector General in a report last month identified this lack of transparency as one of its top unimplemented recommendations to the agency.

Manufacturers understandably oppose paying 200% in discounts while others in the system make money. Hospitals and pharmacies have fought requests for data that manufacturers need to verify or track 340B discounts.

Congress needs to clean up this mess. The health-care system has changed a lot in the 28 years since the discount program was introduced. The 340B program needs to be modernized so that it benefits seniors and other patients -- while supporting the genuine safety-net services of health-care providers. In the absence of sensible regulations, manufacturers will struggle to make sure that patients benefit from discounts on prescription drugs.

Mr. Fein is CEO of Drug Channels Institute.

(See related letters: "Letters to the Editor: Cheaper Insulin Via 340B Helps Poor People" -- WSJ Sept. 19, 2020)

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Notes

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Walgreens and CVS Top the 28,000 Pharmacies Profiting from the 340B Program. Will the Unregulated Party End?

 drugchannels.net/2020/07/walgreens-and-cvs-top-28000-pharmacies.html



It's time for our annual look at the 340B Drug Pricing Program's booming pharmacy component.

Our exclusive analysis of government data finds that 28,000 pharmacy locations—almost half of the U.S. industry—now act as contract pharmacies for the hospitals and other healthcare providers that participate in the 340B program. Over the past 12 months, the number of pharmacies in the program has grown by more than 3,300 locations.

As you will see below, multi-billion-dollar, for-profit, publicly traded pharmacy chains—Walgreens, CVS, Walmart, Rite Aid, Kroger, and Albertsons—continue their unchecked 340B expansion.

Despite this astonishing growth, the contract pharmacy component does not have—and has never had—a regulatory infrastructure. That's because the subregulatory notice that created contract pharmacies wasn't subject to any rulemaking procedures. Eli Lilly recently challenged this notice, which forced the government to concede that its own pharmacy guidance is “not legally enforceable.”

As you review our analysis, ponder why manufacturers still comply with HRSA's non-binding guidance—and why investors remain unconcerned with the risks of public companies' participation in the out-of-control 340B program.

340B BACKGROUND

The 340B program mandates that pharmaceutical manufacturers provide outpatient drugs to certain healthcare entities—known as eligible covered entities—at significant discounts. The Health Resources and Services Administration (HRSA), an agency of the U.S. Department of Health and Human Services, oversees the program through its Office of Pharmacy Affairs (OPA).

A covered entity can purchase and dispense 340B drugs through internal or external (contract) pharmacies. In 2010, HRSA decided that eligible entities (including those that have an in-house pharmacy) could access 340B pricing through an unlimited number of

contract pharmacies. There was no rulemaking or public comment on the agency's unilateral decision. As far as I know, there is no evidence that HRSA contemplated the predictable explosion in contract pharmacy arrangements.

Pharmacies profit by trading their third-party prescription margins for a share of the 340B discounts earned by covered entities. These profits can come at the expense of low-income, uninsured patients, per [GAO Confirms It: 340B Hospitals and Contract Pharmacies Profit from Low-Income, Uninsured Patients](#). A huge ecosystem of technology vendors and consultants enables the extraction and sharing of 340B discounts.

The contract pharmacy process is complex and confusing. For more details, see Section 11.5 of our [2020 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers](#).

In profiling the 340B contract pharmacy market, Drug Channels Institute examined HRSA's *Contract Pharmacy Daily Report*, as published on July 1, 2020. We screened out all contracts that had been terminated before that date. Using our proprietary database, we classified all contract pharmacy locations by parent organization. Most chains and many PBM-owned pharmacies are listed with multiple alternate names.

340BOOM CONTINUES

Since HRSA's 2010 change in guidance, the number of pharmacies in the 340B program has skyrocketed:

In January 2010, fewer than 1,300 unique locations acted as 340B contract pharmacies.

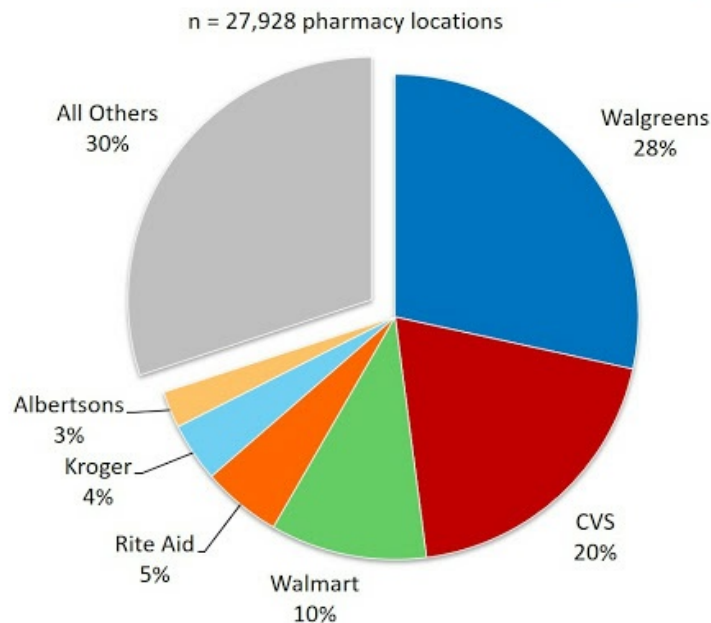
As of July 2020, DCI found 27,928 unique locations acting as 340B contract pharmacies. Since [our July 2019 analysis](#), the number of 340B contract pharmacies has grown by 3,357 locations (+14%).

These pharmacies have more than 112,000 contractual relationships with more than 8,000 340B covered entities. About three-quarters of these covered entities are disproportionate share and children's hospitals.

Four large retail chains account for about 6 out of 10 of the program's contract pharmacy locations. [These companies are among the largest U.S. pharmacies.](#)

[Click to Enlarge]

340B Contract Pharmacy Locations, by Company, 2020



Source: Drug Channels Institute analysis of OPA Daily Contract Pharmacy Database. Data show number of unique contract pharmacy locations as of July 1, 2020. Company totals are computed from combined banners (store names) in the database.

Published on Drug Channels (www.DrugChannels.net) on July 14, 2020.



For the past few years, these companies have dominated contract pharmacies.

Walgreens remains the dominant 340B contract pharmacy participant. Nearly 8,000 Walgreens locations act as 340B contract pharmacies. The chain therefore accounts for more than one-quarter of all locations. More than 80% of all Walgreens locations are now 340B contract pharmacies.

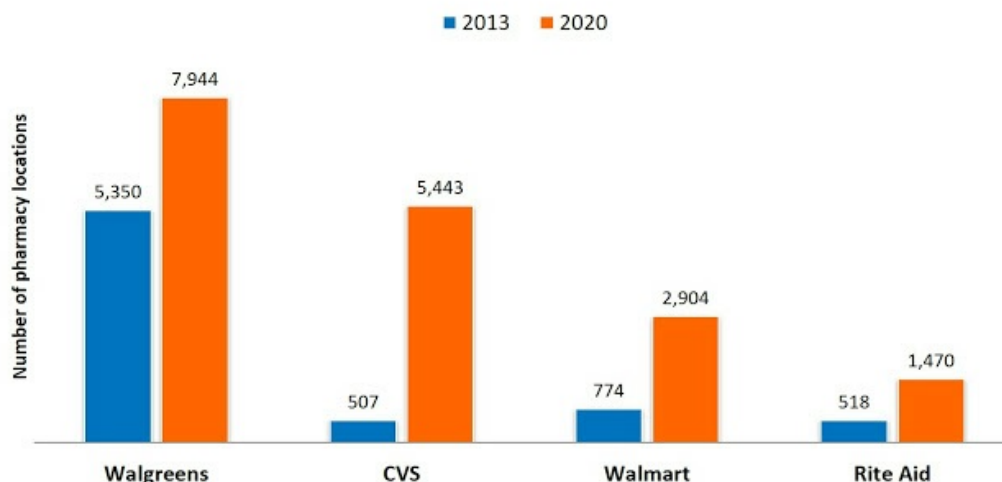
CVS continues to increase its participation in the 340B program. The company has added more than 1,900 locations over the past 12 months. This means that half of all CVS locations are now 340B contract pharmacies. The company's growth has been facilitated by CVS Health's acquisition of Wellpartner, a provider of 340B contract pharmacy services.

The other major retail chains—Walmart, Rite Aid, Kroger, and Albertsons—account for more than 6,000 additional 340B contract pharmacy locations. Thousands of independent pharmacies and small chains participate, too.

The chart below shows the growth in 340B participation for the four largest chains since our first analysis, in 2013. In line with overall program growth, the largest chains have dramatically increased the number of locations acting as 340B contract pharmacies.

[Click to Enlarge]

340B Contract Pharmacy Locations, by Chain, 2013 vs. 2020



Source: Drug Channels Institute analysis of OPA Daily Contract Pharmacy Database. Data show number of unique contract pharmacy locations as of July 1, 2020. Company totals are computed from combined banners (store names) in the database.

Published on Drug Channels (www.DrugChannels.net) on July 14, 2020.



In upcoming articles, I'll examine pharmacy benefit manager (PBM) and specialty pharmacy participation in 340B. I'll also delve into how hospitals are using their in-house specialty pharmacies to increase 340B profits.

SUBREGULATORY MISCHIEF

The 340B program's sales have grown to become almost as large as the Medicaid program's outpatient drug sales. According to data provided to *Drug Channels* by HRSA, purchases under the 340B program have tripled since 2014. Details here: [New HRSA Data: 340B Program Reached \\$29.9 Billion in 2019; Now Over 8% of Drug Sales.](#)

However, 340B lacks Medicaid's regulatory infrastructure and controls. There's no requirement that the discounts provided under the 340B program be utilized appropriately, no fair market value standards for pharmacies' fees, no limit to the size of a contract pharmacy network, and zero transparency into the profits earned by billion-dollar, public companies.

That's right. HRSA hasn't bothered to issue guidance or notices on these and other crucial topics. Its inaction has enabled profiteering by public pharmacy and PBMs.

What's more, HRSA has effectively conceded that it can't enforce its guidance. The recently launched [HHS Guidance Repository](#) contains numerous guidance notices from HRSA. However, the repository contains disclaimers stating that the documents "do not have the force and effect of law and are not meant to bind the public in any way."

Perhaps that's why Lilly recently began limiting distribution of certain Cialis formulations. ([Click here to read the notice.](#)) External 340B contract pharmacies will no longer be able to dispense brand-name Cialis on behalf of covered entities. This move makes sense given that there are more than a dozen generic versions of Cialis on the market.

Lilly's actions forced HRSA to acknowledge that its contract pharmacy guidance is "not legally enforceable." D'oh!

The 340B program continues its unbridled takeover of the pharmacy industry. Considering the dollars involved, I'm skeptical about the prospects for appropriate legislative and regulatory reform of the 340B program. Only a direct legal challenge to HRSA's irresponsible and incomplete oversight will get 340B on track.

EXCLUSIVE: 340B Program Purchases Reach \$24.3 Billion—7%+ of the Pharma Market—As Hospitals' Charity Care Flatlines

 drugchannels.net/2019/05/exclusive-340b-program-purchases-reach.html



The 340B Drug Pricing Program continues to expand at double-digit rates. According to our government contacts, discounted 340B purchases hit a record \$24.3 billion in 2018. That figure is an astonishing 26% higher than its 2017 counterpart.

What's more, we have found that since 2014, purchases under the program have grown at an average rate of 28% per year. By comparison, manufacturers' net drug revenues have grown at an average rate of below 5% over the same period. Consequently, the 340B program has grown to account for at least 7% to 8% of the total U.S. drug market.

Nearly all of the billions in 340B discounts have accrued to hospitals. Yet hospitals' charity care has dropped amid the 340B program's growth. The charts have the details.

So where did the money go? We have no idea, because hospitals and their lobbyists fight any call for them to disclose or account for how they use their 340B profits—while consistently misrepresenting the program's size and growth. Be skeptical when you read random stories about the generosity of a 340B covered entity. As always, the plural of anecdote is not data.

Read on for the latest details and ponder who really benefits from the 340B program's size—and how much longer this shocking growth can continue.

UNSTOPPABLE

For the past few years, the Health Resources and Services Administration (HRSA) has provided *Drug Channels* with data measuring the 340B program. For general background on the program, see Section 11.5 of our [2019 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers](#). I also highlight a few other resources below.

The following chart shows the ongoing surge in covered entities' purchases made under the 340B Drug Pricing Program.

[Click to Enlarge]

Purchases by Covered Entities Made Under the 340B Drug Pricing Program, 2012 to 2018



We include the estimated invoice value of these purchases. The undiscounted invoice figure is our highly conservative guess based on HRSA estimates of total savings in 2015 by covered entities. We believe that this savings rate underestimates actual discount rates, so the figures above differ slightly from our previous estimates. The actual undiscounted figures are unknown, but are likely larger.

Here's a summary of our latest findings:

Discounted purchases made under the program via Apexus, the HRSA-designated Prime Vendor, totaled \$24.3 billion in 2018—an increase of 25.9% from \$19.3 billion in 2017.

The compound average growth rate (CAGR) of 340B purchases was 28.1% from 2014 through 2018. Wow.

Manufacturers' net revenues (per the latest IQVIA report) grew at a CAGR of only 4.4% from 2014 to 2018.

340B ACCOUNTED FOR 7% to 8% OF THE MARKET IN 2018

Many partisan supporters try to minimize 340B's share of the total U.S. market. In reality, the 340B program is a significant and growing part of the industry. Here are two computation approaches that yield comparable results:

1) 340B as a share of discounted purchases

The discounted HRSA figures above include purchases at or below the deeply discounted 340B ceiling prices. An appropriate comparison must therefore also be discounted purchases.

According to IQVIA's *Medicine Use and Spending in the U.S.: A Review of 2018 and Outlook to 2023*, manufacturers' net revenues were \$344 billion in 2018.

Using net revenues, 340B's share in 2018 was **7.1%**, or \$24.3 billion ÷ \$344 billion.

2) 340B as a share of undiscounted purchases

An alternative method compares estimated undiscounted 340B purchases at invoice prices with IQVIA's *invoice-price spending* market size. This figure was \$482 billion in 2018. It represents the amounts paid to wholesalers and distributors by their pharmacy or hospital customers, including prompt-payment and volume discounts but excluding such off-invoice discounts as 340B discounts and PBM rebates.

Using invoice-price spending, 340B's share in 2018 was **8.1%**, or \$39.2 billion ÷ \$482 billion.

These are very rough estimates that understate 340B's actual share of the market. That's because the data from Apexus includes only indirect sales made via wholesalers. The \$24.3 billion figure is therefore less than the actual total of 340B purchases at discounted prices, because it excludes an unknown amount of manufacturer sales made directly to healthcare institutions.

For an alternative estimate, I recommend Measuring the Relative Size of the 340B Program: 2017 Update. Using different assumptions about 340B discounts, Berkeley Research Group concluded that 340B was 10.1% of the U.S. market in 2017.

Note that 340B Health, which lobbies for hospitals that participate in the 340B program, continues to falsely claim that 340B was "less than 2% of total drug company revenues" in 2015. It wasn't true then and is certainly not true today.

HOSPITAL CHARITY CARE HAS NOT KEPT PACE WITH 340B

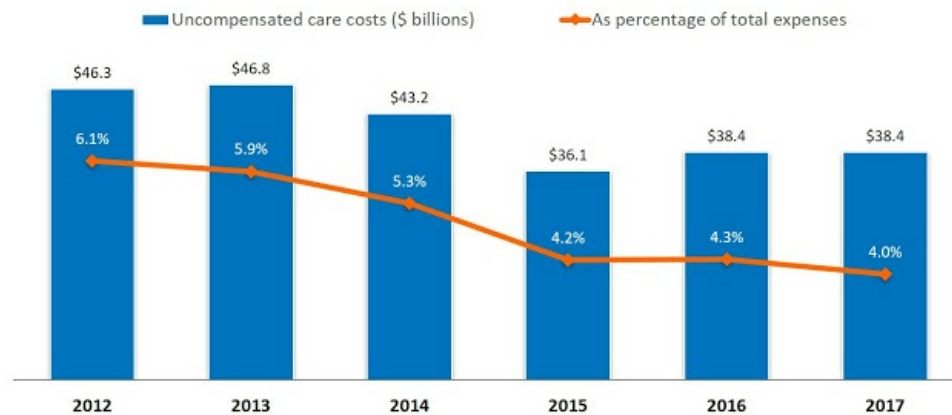
The 340B program is highly controversial, in part because its founding legislation did not specify or restrict how covered entities should utilize the funds that the program generates. Here are some complementary data that raise additional questions.

Most 340B purchases are made by hospitals. The 340B program's defenders usually argue that hospitals provide charity care that justifies the amazing growth shown above.

An embarrassing point of comparison: The total value of hospitals' uncompensated care has declined, from \$46.8 billion in 2013 to \$38.4 billion in 2017 (the most recent year available). These data come from the American Hospital Association. Uncompensated care as a percentage of hospitals' total expenses has also declined, from 5.9% in 2013 to 4.0% in 2017.

[Click to Enlarge]

U.S. Hospitals, Uncompensated Care Costs, Total Value and Share of Expenses, 2012 to 2017



Source: Drug Channels Institute analysis of American Hospital Association (AHA) data

Published on Drug Channels (www.DrugChannels.net) on May 14 2019.



BTW, uncompensated care has hit a historic low as a percentage of expenses. This figure remained unchanged from 2016 to 2017, despite a 7% increase in community hospital operating expenses.

My simple observation is consistent with data from the U.S. Government Accountability Office (GAO). In a June 2018 report, the GAO found that more than 20% of 340B hospitals provide minimal amounts of charity care. Links and my discussion appear in [our July 2018 news roundup](#).

Hospitals have many non-340B, government-granted incentives to subsidize charity care. The majority of hospitals in the United States operate as nonprofit organizations and, as such, are exempt from most federal, state, and local taxes. In exchange, they are expected to provide various "community benefits" to maintain this non-profit status. (See [Nonprofit Hospitals' Community Benefit Requirements](#) from the Robert Wood Johnson Foundation.) Much of the uncompensated care reported in the chart above is tied to these requirements—and not to the 340B program.

LEARN MORE

Long time readers know that I think the 340B program is long overdue for reform, especially in light of the many abuses and problems that have been uncovered. Substantial evidence suggests that 340B savings are not always shared with patients and their insurance providers, including Medicare.

To learn more about the 340B program, consider these useful articles:

- [340B DRUG DISCOUNT PROGRAM: The Issues Spurring Discussion, Stakeholder Stances and Possible Resolutions](#), The Community Access National Network (highlighted in [our March 2019 news roundup](#))

[GAO Confirms It: 340B Hospitals and Contract Pharmacies Profit from Low-Income, Uninsured Patients](#) (our writeup of a highly troubling GAO report)

[Challenges for Managed Care from 340B Contract Pharmacies](#), *Journal of Managed Care & Specialty Pharmacy*

[Click here to read all *Drug Channels* articles about the 340B Drug Pricing Program.](#)

A Primer on 340B Contract Pharmacies and Medicaid Duplicate Discounts (video)

 drugchannels.net/2020/10/a-primer-on-340b-contract-pharmacies.html



Below is a brief video primer on a hot *Drug Channels* topic. I review:

- The growth of the 340B Drug Pricing Program

- The role and expansion of 340B contract pharmacies

- How 340B intersects with the Medicaid drug rebate program

- Challenges with duplicate discounts

This 10 minute video provides a quick and efficient primer on the key issues. Grab some popcorn and enjoy!

The video below is an excerpt from Drug Channels Institute's September 2020 video webinar **Evolving 340B: Moving From Discounts to Rebates**. The original webinar was sponsored by Kalderos.

[Click here if you can't see the video below.](#) Since it was a Zoom webinar, the replay puts the speaker (me) in a tiny box during the video.

340B Contract Pharmacies and Medicaid

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Evolving 340B: Moving from Discounts to Rebates
September 11, 2020

 DRUG CHANNELS
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Watch Video At: <https://youtu.be/cAPiyoTRILg>



For-Profit Pharmacy Participation in the 340B Program

OCTOBER 2020



PREPARED BY:

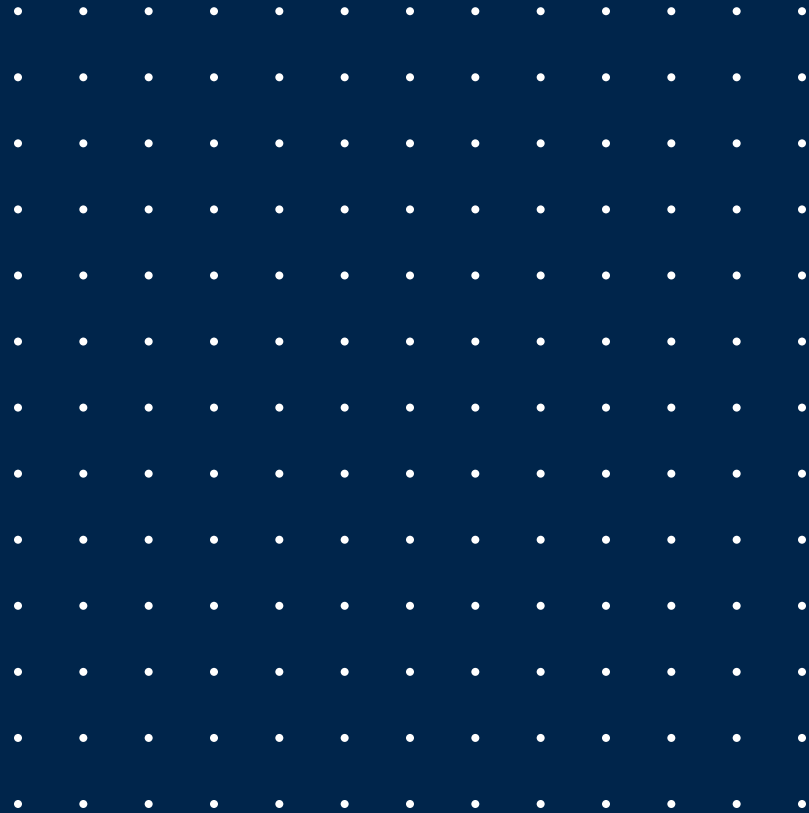
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INTELLIGENCE THAT WORKS





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Executive Summary

In March 2010, the Health Resources and Services Administration (HRSA) expanded guidance allowing 340B covered entities to establish contract pharmacy arrangements with an unlimited number of pharmacies.¹

What started as a well-intentioned effort to provide safety-net providers free or discounted drugs to treat uninsured and vulnerable patients appears to have evolved into a profit-centric corporate initiative that has fundamentally altered the 340B program. Today, half of the twenty largest for-profit corporations in the United States—including Walgreens, Cigna, CVS Health, and Walmart—are active participants in the 340B program through contract pharmacy arrangements.² Using vertically integrated supply chains consisting of pharmacies, pharmaceutical benefit managers (PBMs), and health plans, these corporations can leverage their market power to drive growth in the 340B program and capture profits related to 340B sales.

In light of this evolution in the 340B program, BRG professionals conducted this analysis to better understand historical trends in 340B contract pharmacy arrangements, the increased participation of for-profit corporations in the 340B program, average profit margins on 340B purchased medicines dispensed through contract pharmacies, and the potential impact of growth in 340B contract pharmacy participation. Key findings include:

1. Following HRSA's expansion of the contract pharmacy program in March 2010, contract pharmacy participation grew 4,228 percent between April 2010 and April 2020.
2. While over 27,000 distinct pharmacies participate in the 340B program today, we estimate over half of the 340B profits retained by contract pharmacies are concentrated in just three pharmacy chains (Walgreens, Walmart, CVS Health) and Cigna's Accredo specialty pharmacy.
3. The average profit margin on 340B medicines commonly dispensed through contract pharmacies is an estimated 72 percent, compared with just 22 percent for non-340B medicines dispensed through independent pharmacies.
4. 340B covered entities and their contract pharmacies generated an estimated \$13 billion in gross profits on 340B purchased medicines in 2018, which represents over 25 percent of the total gross profits on brand medicines realized by all providers that dispense or administer medicines.

1 Federal Register, "Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services," Vol. 75, No. 43 (March 5, 2010), available at: <https://www.govinfo.gov/content/pkg/FR-2010-03-05/pdf/2010-4755.pdf>

2 Based on BRG analysis of the 340B contract pharmacy database.

History of 340B Contract Pharmacies

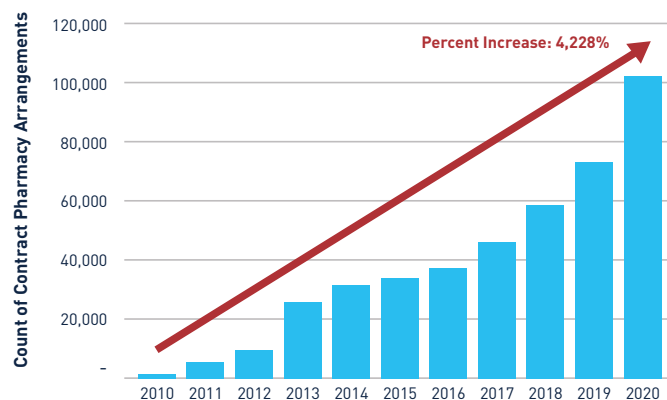
Congress created the 340B program in 1992 to provide recipients of HRSA grants (known as “grantees”) and safety-net hospitals access to the voluntary discounts pharmaceutical manufacturers had provided before the enactment of the Medicaid rebate statute. These voluntary discounts had declined due to the Best Price provision in the Medicaid rebate statute for these covered entities. To assist the covered entities, Congress made qualifying hospitals and safety-net clinics eligible for steep discounts on medicines under the 340B program.

340B contract pharmacies were first permitted through guidance issued by HRSA in 1996.³ At the time, grantees (e.g., community health centers, Ryan White clinics, black lung clinics) that did not have a pharmacy license were unable to dispense 340B purchased medicines to the indigent populations they served on site. Through the 1996 guidance, HRSA enabled any 340B covered entity that did not operate its own pharmacy to contract with a single third-party pharmacy to dispense 340B purchased medicines to eligible patients on its behalf. These are referred to as contract pharmacy arrangements and were predominantly established with independently owned community pharmacies located near the 340B covered entity. In 2000, 98 percent of all contract pharmacy arrangements were with independent pharmacies, and 80 percent of these pharmacies were within ten miles of the 340B covered entity. Of the forty-nine total contract pharmacy arrangements, 98 percent were established by grantees as opposed to safety net hospitals.⁴

In 2001, in response to requests by 340B covered entities to expand the 340B contract pharmacy program, HRSA initiated a demonstration project that allowed a small number of 340B covered entities to contract with multiple third-party pharmacies. This demonstration project enabled 340B covered entities that served patients in a geographically broad area to provide 340B purchased medicines in the communities where their patients lived.⁵ The profile of these multiple contract pharmacy networks looked different from the original program in that there was greater participation by national pharmacy chains (54 percent overall) and less than half of the contract pharmacies were within ten miles of the 340B covered entity.⁶

Figure 1

Contract Pharmacy Arrangements April 1, 2010 - April 1, 2020



“The average gross margin on 340B purchased medicines dispensed through contract pharmacies is an estimated 72%...

For some products, 340B contract pharmacies dispense a medicine that was purchased by the 340B covered entity for a penny, but still receive full reimbursement for the medicine from private insurance and Medicare Part D plans.”

In March 2010, HRSA issued additional guidance allowing all 340B covered entities, even those with their own outpatient pharmacies, to contract with an unlimited number of third-party pharmacies. This guidance fundamentally opened the doors for all covered entities to generate additional profits on 340B purchased drugs. Subsequently, for-profit pharmacies rushed to capitalize on the outsized profit margins available on 340B purchased medicines. Between April 1, 2010, and April 1, 2020, the number of contract pharmacy arrangements increased from 2,321 to 100,451—a 4,228 percent increase (see Figure 1).

Today, more than 27,000 individual pharmacies (almost one out of every three pharmacies) participate in the 340B program as contract pharmacies, including virtually all the major national and regional chains, such as Walgreens, Walmart, CVS, Rite-Aid, Kroger, Albertsons, Costco, and many more. Hospitals enrolled in the 340B program contract on average with twenty-two distinct pharmacies, and the largest contract pharmacy networks include over 250 pharmacies, some of which are thousands of miles away from the 340B covered entity (see Case Study 1). Hospitals now account for over 44 percent of all contract pharmacy arrangements, up from 2 percent in 2000.

The enormous growth in 340B contract pharmacy arrangements seems to boil down to a single factor: outsized profit margins. The National Community Pharmacists Association (NCPA) issues an annual report on independent pharmacy financials. Between 2013 and 2018, NCPA reported that the average gross margin on all prescription medicines ranged between 22 percent and 23 percent. As we will discuss in more detail later in this report, the average gross margin on 340B purchased medicines dispensed through contract pharmacies is an estimated 72 percent. For some products, 340B contract pharmacies dispense a medicine that was purchased by the 340B covered entity for a penny but still receive full reimbursement for the medicine from private insurance and Medicare Part D plans. That reimbursement can exceed \$1,000 for many specialty medicines. The profit potential inherent in the 340B program appears to have attracted the largest for-profit corporations in the world and altered the hierarchy of 340B program stakeholders.

3 Federal Register, Vol. 61, No. 165 / Friday, August 23, 1996 / Notices [August 23, 1996], available at: <https://www.govinfo.gov/content/pkg/FR-1996-08-23/pdf/96-21485.pdf>

4 Based on BRG analysis of 340B covered entity and contract pharmacy data published by HRSA.

5 Federal Register, “Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services,” notice by HRSA [January 12, 2007], accessed at: <https://www.federalregister.gov/documents/2007/01/12/E7-334/notice-regarding-340b-drug-pricing-program-contract-pharmacy-services>

6 Based on BRG analysis of the 340B covered entity and contract pharmacy data published by HRSA.

Evolution of For-Profit Pharmacy Participation

The 340B program was originally created for non-profit healthcare providers viewed as the backbone of the “safety net” of the US healthcare system.⁷ The first participants in the 340B program included not-for-profit hospitals that served large indigent populations and small healthcare clinics that relied on federal grants, because many of their patients were uninsured and could not afford basic healthcare services. Between 2004 and 2010, the 340B program grew substantially driven primarily by new enrollments of disproportionate share hospitals. By 2010, 16 percent of covered entities had established contract pharmacy arrangements, and over 85 percent of those contract pharmacy arrangements were with independent community pharmacies.

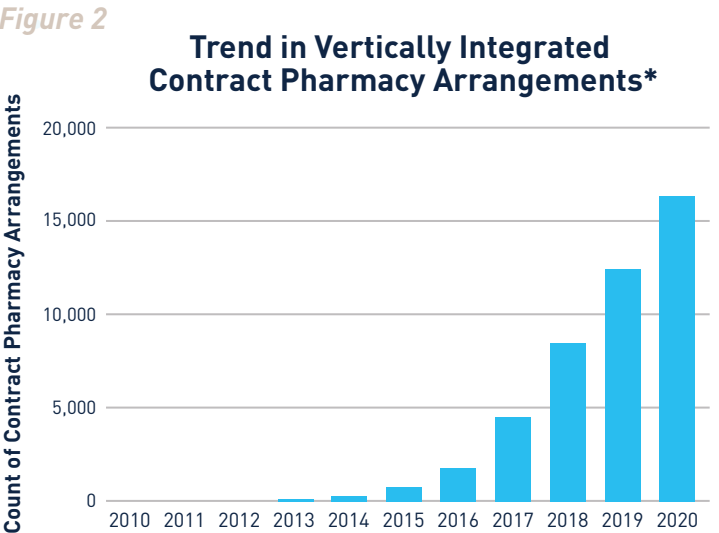
That changed following the March 2010 expansion of the contract pharmacy program and the lack of oversight over how for-profit entities can benefit from the 340B program. The 2010 guidance created an opportunity for sophisticated, for-profit pharmacy chains to realize larger margins than they otherwise could. Between 2010 and 2015, large national and regional pharmacy chains established tens of thousands of contract pharmacy arrangements. By 2015, these chain pharmacies represented over 66 percent of all contract pharmacy arrangements, up from just 15 percent at the beginning of 2010. Instead of maintaining close relationships with covered entities, as had been the practice for independent pharmacies before 2010, large national and regional chains turned to sophisticated software algorithms to identify 340B prescriptions and maximize the revenue generated from these discounted fills.

Starting in 2016, a new pattern of vertically integrated specialty pharmacy enrollments emerged. Specialty pharmacies dispense expensive medications that may require special handling or patient support services. Operations for these pharmacies are typically concentrated in a small number of locations distributed throughout the US, and medicines are shipped directly to patients.

Over the past two decades, PBMs, the organizations that establish pharmacy reimbursement rates, make formulary decisions, and set cost-sharing amounts, have built large national specialty pharmacies that primarily serve the beneficiaries of the PBM that owns the specialty pharmacy. In January 2016, there were 1,473 contract pharmacy arrangements between 340B covered entities and these vertically integrated specialty pharmacies. By April 2020, this count had grown to 16,293—a 1,006 percent increase in four years (see Figure 2).

The evolution in for-profit pharmacy participation in the 340B program encompasses both the types of pharmacies participating and the structure of the contracts themselves. Based on our primary research, we understand that most contract pharmacy arrangements established prior to 2010 provided for an enhanced dispensing fee paid to the contract pharmacy. This contracting structure reflected the more complex service the contract pharmacy provided (i.e., dispensing a 340B purchased medicine to a 340B patient, managing 340B eligibility, and potentially maintaining separate inventories) and the increased compensation for that service. Any profit associated with the reimbursement of the medicine (less the enhanced dispensing fee) went to the 340B covered entity as the primary stakeholder in the 340B program.

A 2018 Government Accountability Office (GAO) report based on data collected between 2014 and 2016 found that the types of contracting arrangements had evolved to include pharmacies retaining a percentage of 340B profits or overall reimbursement.⁸ This shift toward 340B profit sharing by contract pharmacies suggests that for-profit pharmacies are also a primary stakeholder in the 340B program, despite this never having been conceived of nor explicitly included in the program by Congress when it passed the 340B statute. Current guidance makes no recommendations on how profit-sharing agreements between covered entities and contract pharmacies should be structured. As a result, covered entities freely negotiate the terms of agreements with contract pharmacies. Although large, sophisticated academic medical centers may have enough leverage to negotiate favorable terms with an organization wielding the combined market power of a national pharmacy, PBM, and health plan, small grantees carry little leverage when negotiating with these entities.⁹



*Excludes certain Walgreens mail order pharmacies that disenrolled en masse in 2015/2016

340B Profit Margins for Retail and Specialty Medicines

Outsized profit margins on 340B purchased medicines dispensed through a retail or specialty pharmacy has attracted for-profit national pharmacies that are vertically integrated with PBMs and health plans. For nearly all contract pharmacy arrangements, the determination of whether a medicine is eligible for a 340B discount is made after the medicine is dispensed to and paid for by the patient and his or her health plan. For brand medicines, this reimbursement amount is roughly equivalent to the list price or wholesale acquisition cost (WAC) of the medicine. To determine the profit margin on a 340B purchased medicine dispensed through a 340B contract pharmacy, we must also estimate the 340B discounted price of the medicine.

7 HRSA, Sec. 340B Public Health Service Act, available at: <https://www.hrsa.gov/sites/default/files/opa/programrequirements/phsactsection340b.pdf>
8 Government Accountability Office, *Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* (June 2018).
9 *Cares Community Health v. Department of Health and Human Services*, No. 18-5319, slip. op. at 10 (D.C. Cir. Dec. 20, 2019).

The 340B price is calculated using a statutory formula derived from two pricing metrics incorporated in the Medicaid Drug Rebate Program. At a high level, these pricing metrics for brand medicines are:

Basic Medicaid Rebate: Equal to the greater of 1) 23.1 percent of average manufacturer's price (AMP) or 2) the largest discount available in the commercial market (referred to as "Best Price").

Consumer Price Index (CPI) Penalty: A price inflation penalty that grows as increases in AMP for a medicine exceed the rate of inflation.

Using these two primary components, the 340B price is equal to AMP less the Basic Medicaid rebate less the price inflation penalty (see Figure 3). Depending on the competitive dynamics that exist in any therapeutic category, the 340B price could fall below \$0.00. In these instances, the price is reset to \$0.01 and is referred to as "penny pricing."

Table 1: 340B Price Calculation Examples

	Pricing Component	Formula	Diabetes Example	Oncology Example
[A]	AMP		\$500.00	\$1,000.00
[B]	Medicaid Rebate	Greater of [C] or [D]	250.00	231.00
[C]	Base Rebate	[A] * 23.1%	115.00	231.00
[D]	Best Price	Largest Discount	250.00	100.00
[E]	CPI Penalty	Price Increase Above CPI	225.00	200.00
[F]	340B Discounted Price	[A] - [B] - [E]	\$25.00	\$569.00

As discussed further in Appendix A, we developed a methodology for estimating the 340B price using publicly available data and applied this methodology to the eighty-six largest retail and specialty brand medicines that are commonly dispensed through a 340B contract pharmacy based on 2018 sales volume. Our methodology incorporates both concepts discussed above. Where public statements on 340B pricing are available, we have compared our results against actual 340B prices. Based on these comparisons and the structural design of our methodology, we believe that our 340B price estimates, and therefore the 340B profit margins these prices are used to calculate, are conservative.

When comparing our 340B price estimate to the WAC price for the same medicine, our analysis found the average 340B discount from WAC across the eighty-six retail and specialty brand medicines examined was 72 percent in 2018. By comparison, most non-340B pharmacies typically purchase a brand medicine at a 2 percent to 3 percent discount off of WAC.¹⁰ For certain therapeutic categories with steep commercial discounts attributable to competition in the category, the average 340B discount exceeded 80 percent (see Figure 4). Twenty-seven of the medicines in our analysis had an average discount in 2018 of at least 90 percent, and we identified six medicines with a 340B price equal to \$0.01.

Table 2: Average 340B Discounts by Therapeutic Class

Average 340B Discounts by Therapeutic Class						
Therapeutic Class*	Avg. Discount	# Medicines in Class	Medicines with a Discount of at Least:			
			72%	80%	90%	95%
Anti-infective agent	44%	11				
Antineoplastic agent	50%	8	1			
Blood modifier agent	58%	4				
Cardiovascular agent	71%	3	1	1		
Central nervous system agent	58%	13	2			
Anti-diabetes agent	90%	23	18	17	10	10
Gastrointestinal agent	90%	7	6	5	2	1
Immunological agent	47%	4				
Respiratory agent	67%	11	5	3		
Top 86 Products	72%	86	35	27	12	11

*Excludes Therapeutic Classes with one product

10 Based on BRG analysis of National Average Drug Acquisition Cost (NADAC) data.

FAST FACTS: Contract Pharmacy Growth

General Statistics	Hospitals		Grantees	
	2010	2020	2010	2020
Total Contract Pharmacy Arrangements	193	43,217	2,128	58,252
% of Total Contract Pharmacy Arrangements	8%	43%	92%	57%
Average Contract Pharmacies per Entity	1	22	1	11
Average Distance b/w Contract Pharmacy & Entity (miles)	34	334	36	198

Penetration Rate				
Count of Entities w/ Contract Pharmacies	116	1,999	1,803	5,195
% of Entities w/ Contract Pharmacies	13%	78%	16%	27%

Because reimbursement by Medicaid, commercial, and Medicare Part D insurance plans is approximately equal to WAC for brand medicines, 340B covered entities and their contract pharmacies realized an average 72 percent profit margin on 340B purchased brand medicines. This margin is more than three times greater than the average margin realized by independent pharmacies and contributes to the rapid growth of 340B contract pharmacy arrangements. We estimate that 340B covered entities and their contract pharmacies generated over \$13 billion in profits from 340B purchased medicines in 2018, which represents over 25 percent of the total \$48 billion in profits realized by all providers that dispensed or administered brand medicines in 2018.¹¹ These profits are highly concentrated in 340B hospitals and the pharmacies they contract with, which account for almost 90 percent of all 340B purchases.¹²

There is little information on how profits are shared between 340B covered entities and their contract pharmacies. A 2018 GAO report¹³ found a variety of contracting designs, but the underlying data was collected between 2014 and 2016, and 340B contract pharmacy arrangements have evolved rapidly since then. Although we don't know what share of the \$13 billion in profits generated through 340B contract pharmacies are retained by for-profit pharmacies, we can estimate their relative shares of profits. To do this, we considered the total number of contract pharmacy arrangements by chain, the type of pharmacy (retail versus specialty), and the size of the 340B covered entity contracted with each pharmacy. Our analysis found that more than half of all profits realized by the 27,000 340B contract pharmacies participating in the 340B program today are concentrated in just four companies: Walgreens, CVS, Walmart, and Cigna's Accredo specialty pharmacy.

More than half of all profits realized by 340B contract pharmacies are concentrated in just four companies.

Implications of For-Profit Pharmacy Participation in the 340B Program

As the prevalence of contract pharmacy arrangements has grown and the contracting design between 340B covered entities and contract pharmacies has evolved, the implications of these arrangements are becoming clear. First, profits on 340B purchased medicines are now distributed across a vertically integrated supply chain that includes not just the covered entities but also pharmacies, contract pharmacy administrators, PBMs, health plans, and employer groups. The 340B program was originally intended to provide healthcare services to indigent populations but income from the program is now being captured by some of the largest corporations in the world.

Second, 340B covered entities are often in competition with the very pharmacies with which they contract. This occurs because the vertically integrated healthcare companies implement cost-sharing models that create incentives for 340B patients to fill their prescriptions in the contract pharmacy instead of the 340B covered entity's own pharmacy. Given the choice between a \$35 copayment at the preferred contract pharmacy or a \$250 coinsurance payment at the 340B covered entity's own hospital outpatient pharmacy, most patients will fill their prescriptions at the contract pharmacy. Based on our work with 340B purchase data, we estimate that almost two-thirds of all retail and specialty drugs purchased at a 340B price are dispensed by contract pharmacies. Separately, the covered entity also enters into contracts with the vertically integrated PBM, which establishes reimbursement rates for the pharmacies owned and operated by the covered entity. When PBMs reduce reimbursement rates to the covered entities' owned pharmacies, the margins at the vertically integrated contract pharmacies may exceed those at the covered entities' owned pharmacies. This creates further incentives for utilization through the vertically integrated contract pharmacy.

11 Aaron Vandervelde and Andrew Brownlee, *Revisiting the Pharmaceutical Supply Chain: 2013-2018*, BRG white paper (January 2020), available at: <https://ecomunications.thinkbrg.com/44/1613/uploads/vandervelde-pharmaceutical-supply-chain-2020-final-cleaned.pdf>

12 Hatwig, Christopher, *The 340B Prime Vendor Program; Supporting All 340B Stakeholders*, Apexus PPT presentation (2014).

13 Government Accountability Office, "DRUG DISCOUNT PROGRAM: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement" (June 21, 2018), available at: <https://www.gao.gov/products/GAO-18-480>

Vertical Integration of National Pharmacies				
Health Plan	Aetna	Cigna HealthSpring		United Healthcare
PBM	CVS Caremark	Express Scripts		OptumRX
Pharmacy <i>(retail, mail order and/or specialty pharmacy)</i>	CVS Caremark	Accredo	Walgreens	OptumSpecialty
Third Party 340B Services Firm	Wellpartner	Verity Solutions	340B Complete Shields Health Solutions	

Third, the outsized profit margins on 340B purchased medicines may contribute to additional consolidation and vertical integration in the healthcare marketplace. Three of the largest pharmacy chains participating in the 340B program (Walgreens, CVS Health, and Accredo), have developed or acquired 340B contract pharmacy administrators (see Figure 5). Contract pharmacy administrators develop and operate the software algorithms that determine 340B eligibility and enable the for-profit pharmacies to influence which prescriptions are classified as 340B. Walgreens recently announced an equity investment in Shields Health Solutions,¹⁴ which operates 340B hospital outpatient pharmacies on an outsourced basis; and Optum recently completed a series of 340B contract pharmacy acquisitions to create Optum Specialty (Optum acquired Diplomat¹⁵ and Avella). As consolidation and vertical integration in the 340B contract pharmacy space continues, 340B covered entities will likely be forced to give up a growing share of 340B program income to these for-profit entities.

Conclusion

The role of contract pharmacies has evolved extensively since HRSA allowed 340B covered entities to contract with an unlimited number of for-profit pharmacies in 2010. What began as a close alignment between 340B covered entities serving indigent populations and independent community pharmacies has morphed into a sophisticated network of vertically integrated for-profit national pharmacies with enormous power. This evolution has fundamentally altered the 340B program and resulted in for-profit entities earning substantial profits through complex profit-sharing agreements with the 340B covered entities. Fueled by margins that are three times greater than the average non-340B medicine, the 340B contract pharmacy channel has grown dramatically over the last ten years and now accounts for over 25 percent of all margins realized by pharmacies and providers in the United States. The growing prevalence of these arrangements is taking the 340B program farther away from its original intended goal of helping safety-net entities provide care to vulnerable patients.



14 Walgreens, "Shields Health Solutions Receives Equity Investments from Welsh, Carson, Anderson & Stowe and Walgreen Co.," press release (July 30, 2019), available at: <https://news.walgreens.com/press-releases/general-news/shields-health-solutions-receives-equity-investments-from-welsh-carson-anderson-stowe-and-walgreen-co.htm>

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Case Study #1

Description: Academic medical center that is part of a Midwestern health system
Covered Entity Type: Disproportionate Share Hospital (DSH)
Total Contract Pharmacy (CP) Arrangements: 250+

Category	Year of First Registration	Date of Most Recent Registration	Percent of Total Active CP Network	Average Distance from Parent Site (mi)
Independent Pharmacies	2011	1/1/2020	22%	80.868
Chain Retail Pharmacies	2012	4/1/2020	64%	55.092
Specialty Pharmacies	2011	4/1/2020	14%	611.212

Case Study #2

Description: Grantee community health center located in the Northeast
Covered Entity Type: Community Health Center (CH)
Total Contract Pharmacy (CP) Arrangements: 9

Category	Year of First Registration	Date of Most Recent Registration	Percent of Total Active CP Network	Average Distance from Parent Site (mi)
Independent Pharmacies	2015	7/1/2019	100%	8.394
Chain Retail Pharmacies	N/A	N/A	0%	N/A
Specialty Pharmacies	N/A	N/A	0%	N/A

These are meant for illustrative examples. Actual contract pharmacy arrangements may vary

Appendix A: Methodology

The analysis in this paper encompasses all 340B covered entities and their respective contract pharmacies registered with Health Resources and Services Administrations (HRSA) since the inception of the program in 1992. Figures related to 340B discounts and contract pharmacy profit margins are estimates, as exact calculations would require data proprietary to the parties involved, such as detailed gross sales figures and rebate data. Therefore, these estimates rely primarily upon publicly available data or data that can be purchased through third-party vendors. In some instances, certain figures in the analysis have been estimated, conservatively, based on the authors' direct and extensive industry experience. These instances are noted below.

To understand the growing prevalence of contract pharmacies in the 340B channel as well as overall program growth, we rely upon information obtained directly from HRSA reports. Current and historical registrations for both covered entities and contract pharmacies can be obtained directly from HRSA's Office of Pharmacy Affairs (340B OPAIS) website. After acquiring data from HRSA, additional analysis and research was required for the following:

- Identification of pharmacy chains/ownership (parent corporate entities).
- Classification of pharmacy channel:
 - > Most pharmacies can be classified as retail (brick and mortar) or specialty/mail pharmacies. Specialty/mail pharmacies generally focus on dispensing higher-cost medicines that may require special handling, such as cold storage. These medicines are frequently used in therapeutic areas such as immunology, oncology, or virology.
- Identification of exact geographical location (latitude and longitude) of covered entities and contract pharmacies.
- Association of demographic information based on geographic location.
- Association of Hospital Cost Report data (HCRIS).

To estimate the average 340B discount for contract pharmacy dispensed medicines, we identified a market basket of medicines representative of those medicines dispensed at contract pharmacies. First, we identified the top two hundred medicines by gross sales in the US, then limited our analysis to self-administered brand medicines with enough gross volume to be material to our calculations. Although generic medicines are included in the 340B program, margins associated with these medicines are often too small to support the fees associated with contract pharmacy utilization and were therefore excluded in our analysis. Physician-administered medicines are rarely dispensed through contract pharmacies and were also excluded from

the analysis. Though our methodology does not include the full universe of 340B eligible products, our market basket is highly representative of the products that drive 340B contract pharmacy margins.

After identifying our market basket of eighty-six medicines, we estimated the two components of the 340B price for each medicine as outlined above—*2018 CPI Penalty* and *Basic Medicaid Rebate*—and calculated the 340B discount by comparing the estimated 340B price with the WAC for each medicine. Our final estimated 340B discount of 72 percent reflects the average of these discounts weighted by each medicine's gross sales.

2018 CPI Penalty: We relied on Elsevier Gold Standard pricing data to determine the WAC for each medicine at launch and in 2018. We assumed the average manufacturer's price (AMP) to be 98 percent of WAC both at launch and in 2018. Inflation data was collected from the Bureau of Labor and Statistics and used to establish the allowable increase in AMP for each product. The CPI penalty was calculated as the difference between the allowable AMP in 2018 versus the estimated 2018 AMP derived from the Gold Standard pricing data.

Basic Medicaid Rebate: As discussed in this study, this is the greater of the base Medicaid rebate (23.1 percent of AMP) or the Best Price, which represents the discount from AMP of the lowest available commercial price offered by the pharmaceutical manufacturer. The lowest available commercial price is typically the difference between the WAC and the largest rebate offered to commercial health plans. As rebate data is proprietary, we relied upon public disclosures and MACPAC estimates of Medicaid rebate amounts by therapeutic class as a proxy for the Best Price. Because the MACPAC data represents an average rebate amount for a therapeutic category (as opposed to the largest rebate), we believe the proxy rebate amount to be below the Best Price for each medicine, and therefore consider our discount estimate and the resulting profit margin calculations to be conservative.

To estimate contract pharmacies' share of 340B profit margins, we first calculate contract pharmacies' share of all 340B sales. We estimate that in 2018, 25 percent of all sales for medical-benefit medicines (physician-administered) and 6 percent of pharmaceutical-benefit medicines (self-administered) were dispensed in a 340B setting—whether at an outpatient or contract pharmacy. These estimates were informed by our experience working directly with a broad group of manufacturers participating in the 340B program and analysis of Medicare Part B and Part D claims data. Using this information in conjunction with IQVIA estimates¹⁶ of the breakout between self-administered and physician-administered branded medicines and our estimate of the average branded discount in for 340B self-administered medicines in 2018 (72 percent), we approximate that 21 percent of all 340B sales are for self-administered medicines. Our final calculation is outlined in Table 3:

Table 3: Methodology to Estimate 340B Profit Margin

Step	Calculation	Estimated Value
A	Total Indirect Sales at 340B Price	\$24.3 B
B	% of 340B Sales for Retail Medicines	21%
C = A x B	Total Retail Sales at 340B Price	\$5.2 B
D	Avg. 340B Retail Discount	72%
E = C / (1-D) x 1.1	Gross 340B Retail Sales (Direct & Indirect)	\$18.6B
F = E-C	340B Profit Margin on Retail Sales	\$13.2

16 IQVIA, "2018 Medicine Use and Spending in the US" (May 2019), available at: https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us--a-review-of-2018-outlook-to-2023.pdf?_=1573048662823

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By Rena M. Conti and Peter B. Bach

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The 340B Drug Discount Program: Hospitals Generate Profits By Expanding To Reach More Affluent Communities

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ABSTRACT The federal 340B program gives participating hospitals and other medical providers deep discounts on outpatient drugs. Named for a section of the Veterans Health Care Act of 1992, the program's original intent was to help low-income and uninsured patients. But the program has come under scrutiny by critics who contend that some hospitals exploit the drug discounts to generate profits instead of either investing in programs for the poor or passing the discounts along to patients and insurers. We examined whether the program is expanding in ways that could maximize hospitals' ability to generate profits from the 340B drug discounts. We matched data for 960 hospitals and 3,964 affiliated clinics registered with the 340B program in 2012 with the socioeconomic characteristics of their communities from the US Census Bureau's American Community Survey. We found that hospital-affiliated clinics that registered for the 340B program in 2004 or later served communities that were wealthier and had higher rates of health insurance compared to communities served by hospitals and clinics that registered for the program before 2004. Our findings support the criticism that the 340B program is being converted from one that serves vulnerable patient populations to one that enriches hospitals and their affiliated clinics.

Section 340B of the Veterans Health Care Act of 1992 was intended to give assistance to low-income and uninsured patients.¹ The 340B program gives registered “340B entities” such as hospitals and other medical care providers—including federally qualified health centers and state AIDS Drug Assistance Programs—access to deep discounts on outpatient drugs similar to those offered through the Medicaid Drug Rebate Program, which was created by the Omnibus Budget Reconciliation Act of 1990.

Participation in the 340B program has increased substantially in recent years. In 2011 there were 16,500 340B entity sites that were affiliated with approximately 3,200 unique

340B entities. That is roughly double the number of sites reported in 2001.¹

As the number of sites qualifying for the 340B discounts has grown, the program has come under increased scrutiny. Critics contend that this growth is largely driven by hospitals seeking to exploit the availability of 340B drug discounts to generate profits.

340B hospitals can generate profits by prescribing drugs to patients who have private insurance or Medicare.² Other participating medical providers are required to pass along the discounts to patients and to provide annual reports about their service to vulnerable populations to the Health Resources and Services Administration (HRSA), which oversees the 340B

program. However, 340B hospitals are not required to pass along their discounts to patients or insurers or to demonstrate their investments in outpatient programs for the poor. Consequently, these providers can generate 340B profits by pocketing the difference between the discounted price that they paid for the drugs and the higher reimbursement paid by insurers and patients.

“Hospitals can elect to sell all of their 340B drugs to only fully insured patients while not passing any of the deeply discounted prices to the most vulnerable, the uninsured. This is contrary to the purpose of the 340B program since much of the benefit of the discounted drugs flows to the covered entity rather than to the vulnerable patients that the program was designed to help,” Sen. Charles Grassley (R-IA) wrote in a 2013 letter to Mary Wakefield, administrator of HRSA.³

In 2012 one 340B entity, Duke University Hospital, reported five-year profits of \$282 million accrued through its outpatient departments and affiliated clinics as a result of its participation in the 340B program.⁴ Another report suggested that profits generated through the prescribing of a single medical oncologist who practices at an outpatient clinic affiliated with a 340B hospital could reach \$1 million per year, when the oncologist administered drugs obtained at 340B discounted prices to treat fully insured patients.⁵

It is logical to assume that as 340B hospitals consider the pros and cons of expansion, the potential profit might lead them to expand into areas that serve more affluent and better insured patients, even if this is counter to the 340B program’s goals of improving care and access for low-income and uninsured patients. Strategic behavior by these hospitals could take one of three forms: A hospital could decide to provide outpatient service to new communities where patients have higher incomes and greater access to insurance, compared to communities served by the hospital in earlier years; to pursue affiliations with outpatient clinics or open outpatient clinics in such new communities; or both. The wide implementation of these strategies would enhance the profitability of participating 340B hospitals without advancing the core goals of the program.

We conducted an empirical analysis to determine whether the expansion of the 340B program has been associated with a shift away from its core focus on low-income and underinsured communities and toward communities whose residents generally have higher incomes and greater access to insurance. Specifically, we focused on 340B hospitals that also participated in Medicare’s disproportionate-share hospital

(DSH) program. This program provides hospitals with increased payments for services based on a formula that takes into account the proportion of low-income and uninsured patients treated as inpatients at those facilities.

If, compared to previously registered 340B hospitals, newly registered hospitals served similar or more vulnerable communities, newly affiliated clinics cared for similar or more vulnerable communities, or both, that would be evidence that the program’s expansions have been consistent with Congress’s original intent.

Study Data And Methods

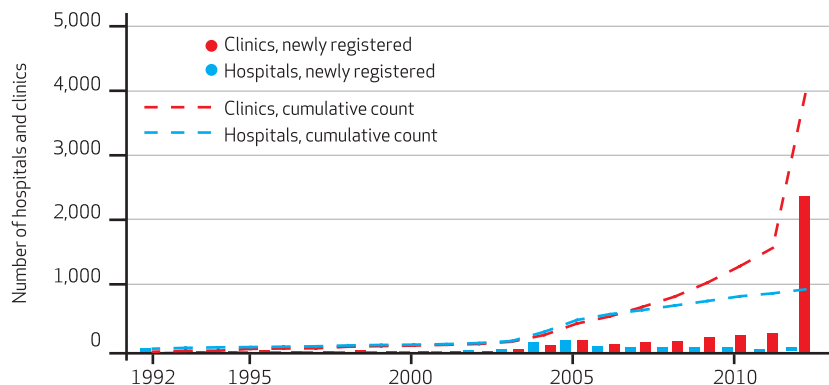
This is an observational study that used nationally representative data on 340B program participants matched to data from the US Census Bureau⁶ on communities’ socioeconomic characteristics. We employed a cross-sectional intertemporal design. This allowed us to assess the 2012 socioeconomic characteristics of the communities served by 340B hospital entities that received DSH payments (which we refer to below as 340B DSH hospitals) and their affiliated clinics in relation to the year when these providers first registered for the 340B program. The study design also allowed us to determine if expansions of the program at the level of the hospital, affiliated clinic, or both were trending toward serving more affluent communities of patients instead of the low-income populations that the program was intended to help.

Using a single year to assess the socioeconomic characteristics of all of the communities in our study has strengths and limitations. Specifically, the cross-sectional analytic approach ensures that our results are not an artifact of the passing of time or of shifting socioeconomic characteristics in particular communities. The approach also takes advantage of a specific program requirement: Every year, each 340B entity must be recertified for the program. For a hospital participating in Medicare’s DSH program, certification requires that the current patient population served by its inpatient service meet 340B program requirements based on data reported in the hospital’s Medicare cost reports. Hospitals that do not meet these requirements annually are terminated from the program, along with their affiliated clinics.

However, using area-level measures of a community’s socioeconomic characteristics limited our ability to determine the makeup of the population that a 340B entity serves. This limitation is a classic form of mismeasurement: It weakened our ability to detect the patterns of 340B program registrations and clinic affiliations that we hypothesized existed over time, without in-

EXHIBIT 1

Numbers Of Disproportionate-Share Hospitals And Their Affiliated Outpatient Clinics In The 340B Program, 1992-2012



SOURCE Authors' analysis of data from the 340B provider list maintained by the Office of Pharmacy Affairs in the Health Resources and Services Administration.

roducing directional bias.

The online Appendix⁷ provides details about the data sources that we employed, our outcome variable definitions, the empirical methods that we used, and the sensitivity analyses that we performed.

Study Results

In 2012 there were 960 340B DSH hospitals (Exhibit 1). The number of newly registered 340B DSH hospitals has steadily increased since the 340B program's inception in 1992. However,

the number began to increase at a higher rate starting in 2003. In 2012 there were 3,964 outpatient clinics affiliated with the 340B DSH hospitals. The number of clinics newly registered with the 340B program has increased exponentially since 1993, numbering 3,964 in 2012. In 2007 the number of affiliated clinics in the program (689) surpassed the number of DSH hospitals in the program (641).

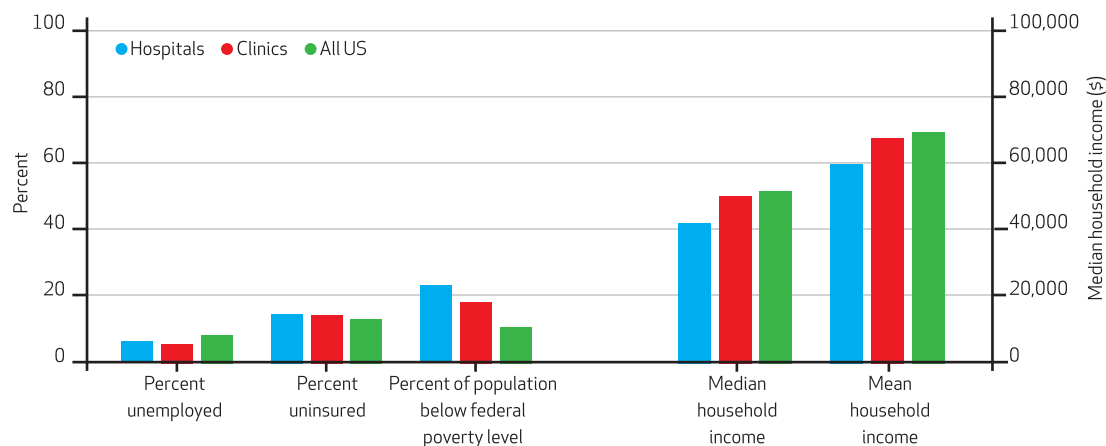
Fifty-three percent of 340B DSH hospitals (510 out of 960) had at least one affiliated clinic in 2012 (data not shown). On average, these 510 hospitals had nine affiliated clinics each (median: 4; range: 1-140).

In 2012 health uninsurance rates were lower ($p < 0.0001$) in communities with affiliated clinics, compared to communities with 340B DSH hospitals (Exhibit 2). Communities with 340B DSH hospitals had significantly higher poverty rates and lower unemployment and mean and median household incomes, compared to national averages ($p < 0.01$). The socioeconomic characteristics of communities with affiliated clinics were significantly more similar to national averages ($p < 0.01$). The differences between communities with 340B DSH hospitals and those with affiliated clinics were also significant ($p < 0.01$).

Generally, DSH hospitals that registered for the 340B program in 2004 or later served communities with fewer low-income people ($p < 0.05$), compared to DSH hospitals that registered before 2004 (Exhibit 3). Communities with hospitals that registered before 2004 and

EXHIBIT 2

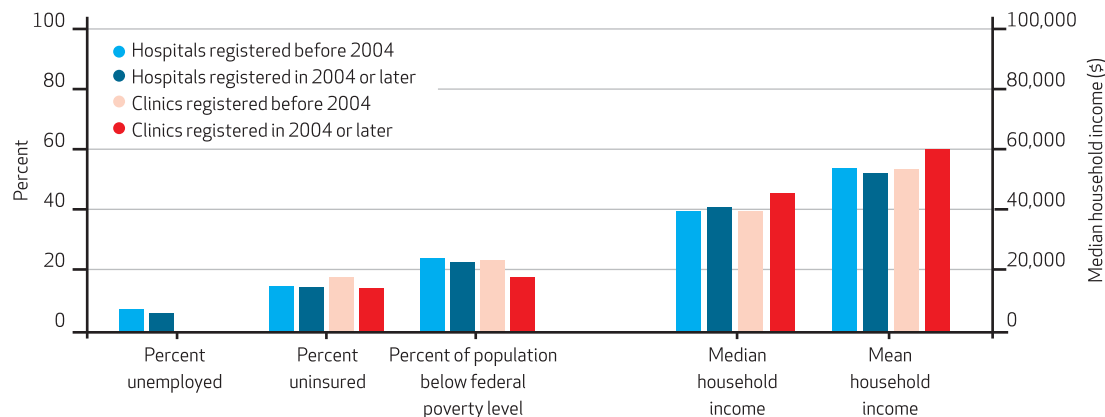
Socioeconomic Characteristics Of Communities Served By 340B Disproportionate-Share Hospitals And Served By Hospital-Affiliated Outpatient Clinics Compared To Communities In All US ZIP Code Tabulation Areas



SOURCE Authors' analysis of data from the 340B provider list maintained by the Office of Pharmacy Affairs in the Health Resources and Service Administration; US Census Bureau's American Community Survey demographic and housing estimates, 2012; and US Census Bureau's Small Area Health Insurance Program, August 2013. **NOTES** Percent unemployed, uninsured, and below federal poverty level relate to the left-hand y axis. Household income relates to the right-hand y axis.

EXHIBIT 3

Socioeconomic Characteristics Of Communities Served By Disproportionate-Share Hospitals And By Hospital-Affiliated Outpatient Clinics, By Time Of Registration For The 340B Program



SOURCE Authors' analysis of data from the 340B provider list maintained by the Office of Pharmacy Affairs in the Health Resources and Service Administration; US Census Bureau's American Community Survey demographic and housing estimates, 2012; and US Census Bureau's Small Area Health Insurance Program, August 2013. **NOTES** Percent unemployed, uninsured, and below federal poverty level relate to the left-hand y axis. Household income relates to the right-hand y axis. Communities with clinics that registered for the 340B program both before 2004 and later had unemployment rates of less than 1 percent.

those with hospitals that registered in later years did not differ significantly in terms of uninsurance rates or mean and median household incomes. Clinics affiliated with 340B entities that registered for the 340B program in 2004 or later served wealthier communities with higher levels of insurance ($p < 0.01$), compared to clinics that registered before 2004.

Furthermore, when we compared communities served by hospitals and those served by clinics, we found that facilities registering in 2004 or later differed from those registering before 2004 (Exhibit 4). Relative to communities served by hospitals registering in the later time period, communities served by clinics had lower rates of uninsurance, for example, but the opposite was true with facilities registering in the earlier time period. In general, hospitals that registered in 2003 or before had clinics that served significantly poorer communities than their parent institutions, compared to facilities that registered after 2004 ($p < 0.01$).

These findings were robust in regressions that employed continuous time measures and alternative years as the cutoff point. Notably, differences with clinics' parent 340B hospitals in terms of socioeconomic characteristics of the communities served were increasingly stark for clinics that joined the 340B program in 2011 and 2012, compared to those that joined before 2004 ($p < 0.01$; for percentage differences in community socioeconomic characteristics between affiliated clinics and DSH hospitals by year of 340B registration, see Appendix Exhibit A1).⁷

In addition, our results were robust in regressions that used the Primary Care Service Area as an alternative geographic unit of analysis (results available upon request from the corresponding author). Our findings were also consistent with an additional comparison of variables reported on each 340B hospital's 2012 Medicare cost report, which HRSA uses to determine the hospitals' registration and annual certification for the 340B program (for a comparison of hospital characteristics reported on Medicare cost reports from hospitals that qualified for the 340B program before 2004 and those that qualified later, see Appendix Exhibit A2).⁷

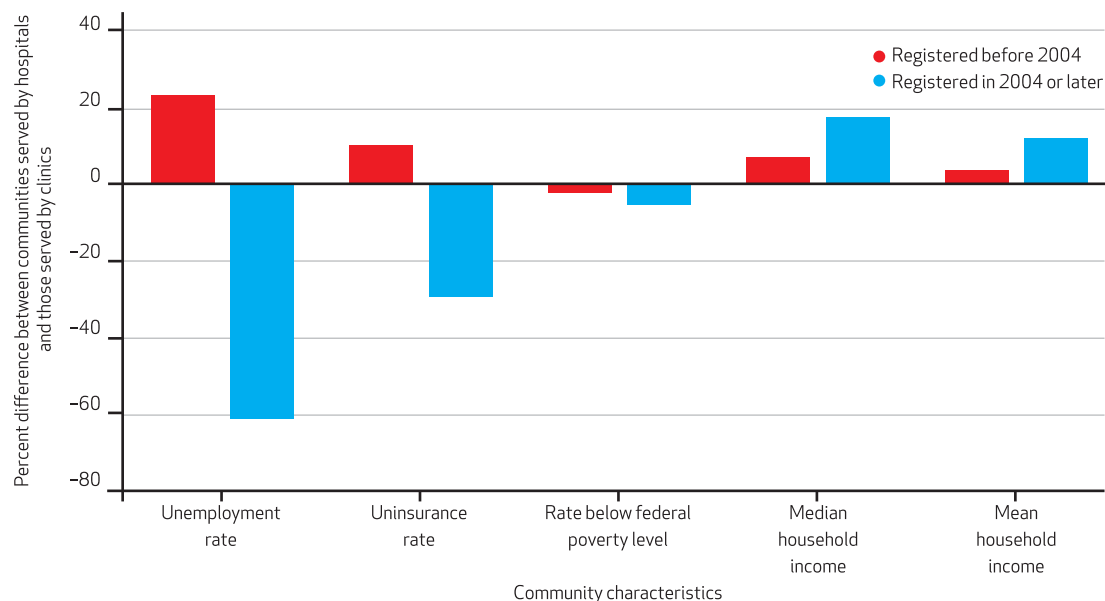
Discussion

The primary purpose of the 340B program was to give assistance to low-income and uninsured patients.¹ Since its inception, the program has experienced expansions. However, we observed significant growth in the number of newly registered 340B DSH hospitals and exponential growth in the number of outpatient clinics affiliated with them since 2004.

We focused on whether these expansions have been associated with a shift away from the program's core focus on low-income and uninsured populations. We found that 340B DSH hospitals serve communities that are poorer and have higher uninsurance rates than the average US community. However, beginning around 2004, newly registered 340B DSH hospitals have

EXHIBIT 4

Socioeconomic Characteristics Of Communities Served By Hospital-Affiliated Clinics In Comparison To Characteristics Of Communities Served By Disproportionate-Share Hospitals, By Time Of Registration For The 340B Program



SOURCE Authors' analysis of data from the 340B provider list maintained by the Office of Pharmacy Affairs in the Health Resources and Service Administration; US Census Bureau's American Community Survey demographic and housing estimates, 2012; and US Census Bureau's Small Area Health Insurance Program, August 2013. **NOTES** The figure shows how communities served by clinics compared to those served by hospitals. For example, the unemployment rate in communities served by clinics that registered before 2004 was 23 percent greater than the unemployment rate in communities served by hospitals that registered before 2004. In contrast, the rate in communities served by clinics that registered later was 61 percent less than the rate in communities served by hospitals that registered later.

tended to be in higher-income communities, compared to hospitals that joined the 340B program earlier.

We also found that, compared to 340B DSH hospitals, their affiliated clinics 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 hospital parents did. These results suggest that the expansions among 340B DSH hospitals run counter to the program's original intention.

Our findings are consistent with recent complaints by stakeholders and media reports suggesting that the 340B program is being converted from one that serves vulnerable communities to one that enriches participating hospitals and the clinics affiliated with them.³⁻⁵ Other recent analyses have suggested that hospitals receiving DSH payments are shifting some specialty care from the inpatient to the outpatient setting, where drug discounts gained from participation in the 340B program may generate increased profits.⁸⁻¹⁰

Our results are consistent with another examination of the recent geographical patterns of

merger and acquisition activities occurring between hospitals and clinics in twelve US communities. Emily Carrier and coauthors report that hospitals are increasingly pursuing targeted, geographic service expansion to "capture" well-insured patients.¹¹ An important future empirical analysis would examine whether 340B DSH hospitals are pursuing such activities at a different rate, are targeting different patient populations, or both, compared to hospitals that do not participate in the 340B program.

More broadly, our findings suggest that gaining access to 340B drug discounts may act as one motivating rationale for the affiliations and mergers among hospitals and outpatient physician practices that are becoming increasingly common in the United States.¹²⁻¹⁴ There are likely multiple reasons for such mergers, acquisitions, and affiliations that linked hospitals and outpatient clinics during this period.

From the hospitals' perspective,¹⁵ the goals of these activities may include improving payer mix, becoming better able to compete with other hospitals, and avoiding competition from specialist-owned ambulatory surgery centers;¹⁶ co-operating on quality improvement measures;¹⁷ and increasing leverage with health plans.¹⁸

Physicians may also wish to pursue these relationships to improve their working hours or referral patterns and to reduce significant financial risks.

In this context, the potential for profit derived from 340B drug purchases should be most concentrated among specialty outpatient practices—including those in oncology, neurology, and ophthalmology—that heavily use costly prescription drugs to care for their patients. It is beyond the scope of our analysis to test this hypothesis empirically. However, we surveyed the trade literature on documented shifts in care and in merger and acquisition activities among outpatient specialty care providers. We found evidence that supported the hypothesis for oncologists.^{19–22} A 2012 report by Elaine Towle and coauthors suggests that the share of physician-owned private practices in oncology declined 10 percentage points between 2010 and 2011, while merger and acquisition activities between

community oncology practices and hospitals increased substantially.²²

Conclusion

Few data are available to systematically assess the impact that the expansion of 340B-qualified hospitals may be having on medical care spending, access, and quality. Most previous literature on these effects has drawn on news reports or government audits that featured selected institutions.²³ In previous work we argued that these expansions are likely raising chemotherapy spending and prices for patients and insurers, and providing limited gain to the poor and uninsured.² The pursuit of timely, transparent, and national assessments of whether and how the activities of 340B hospitals and their affiliated clinics are benefiting the populations originally targeted by the Veterans Health Care Act is an important policy goal. ■

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authors and not that of the University of Chicago, Memorial Sloan Kettering Cancer Center, or the National Cancer Institute. The authors thank Ernst R.

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SPECIAL ARTICLE

Consequences of the 340B Drug Pricing Program

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ABSTRACT

BACKGROUND

The 340B Drug Pricing Program entitles qualifying hospitals to discounts on outpatient drugs, increasing the profitability of drug administration. By tying the program eligibility of hospitals to their Disproportionate Share Hospital (DSH) adjustment percentage, which reflects the proportion of hospitalized patients who are low-income, the program is intended to expand resources for underserved populations but provides no direct incentives for hospitals to use financial gains to enhance care for low-income patients.

METHODS

We used Medicare claims and a regression-discontinuity design, taking advantage of the threshold for program eligibility among general acute care hospitals (DSH percentage, >11.75%), to isolate the effects of the program on hospital–physician consolidation (i.e., acquisition of physician practices or employment of physicians by hospitals) and on the outpatient administration of parenteral drugs by hospital-owned facilities in three specialties in which parenteral drugs are frequently used. For low-income patients, we also assessed the effects of the program on the provision of care by hospitals and on mortality.

RESULTS

Hospital eligibility for the 340B Program was associated with 2.3 more hematologist–oncologists practicing in facilities owned by the hospital, or 230% more hematologist–oncologists than expected in the absence of the program ($P=0.02$), and with 0.9 (or 900%) more ophthalmologists per hospital ($P=0.08$) and 0.1 (or 33%) more rheumatologists per hospital ($P=0.84$). Program eligibility was associated with significantly higher numbers of parenteral drug claims billed by hospitals for Medicare patients in hematology–oncology (90% higher, $P=0.001$) and ophthalmology (177% higher, $P=0.03$) but not rheumatology (77% higher, $P=0.12$). Program eligibility was associated with lower proportions of low-income patients in hematology–oncology and ophthalmology and with no significant differences in hospital provision of safety-net or inpatient care for low-income groups or in mortality among low-income residents of the hospitals' local service areas.

CONCLUSIONS

The 340B Program has been associated with hospital–physician consolidation in hematology–oncology and with more hospital-based administration of parenteral drugs in hematology–oncology and ophthalmology. Financial gains for hospitals have not been associated with clear evidence of expanded care or lower mortality among low-income patients. (Funded by the Agency for Healthcare Research and Quality and others.)

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THE FEDERAL 340B DRUG PRICING PROGRAM allows qualifying hospitals to purchase outpatient drugs at substantial discounts and to dispense or administer them to patients while receiving standard reimbursements from insurers.^{1,2} The program was created in 1992, but few hospitals participated until eligibility was expanded for general acute care hospitals in 2003 and for other categories of hospitals in 2010. After 2003, the program grew rapidly, with 42% of general acute care hospitals participating by 2012.

The program is explicitly intended to encourage hospitals to dedicate resources generated from the discounts to expanding or improving care for vulnerable populations, particularly those served by safety-net providers.³⁻⁵ Accordingly, in assessing eligibility, the program favors hospitals that disproportionately serve low-income patients, but it does not require or provide incentives for hospitals to repurpose financial gains to enhance care for underserved patients. Rather, the discounts — which range from 20% to 50% — only strengthen the incentives for hospitals to supply drugs to patients who have generous insurance coverage.^{5,6} The extent to which hospitals support the mission of the program is subject to minimal oversight.⁷

Thus, the program may not elicit the intended responses from hospitals — such as providing more care to low-income communities, investing in safety-net providers, or reducing health disparities — and may even have unintended consequences.⁸ In particular, the program may have induced provider consolidation. Particularly in the case of parenteral drugs that are infused or injected in clinical facilities (i.e., drugs reimbursed by Part B in Medicare), hospitals qualifying for the program have incentives to employ physicians and acquire or open practices with physicians who frequently order parenteral drugs, in order to increase referrals and expand capacity for outpatient drug administration. Hospitals are reimbursed for parenteral drugs when they are administered in hospital-owned facilities, including off-campus practices owned by hospitals.⁹⁻¹¹

The primary objective of this study was to assess the extent to which hospitals have followed program incentives by acquiring practices or employing more physicians in parenteral drug-intensive specialties, treating more patients in these specialties, and favoring high-income groups with more generous insurance when treating ad-

ditional patients. The secondary objective was to test whether the program has been associated with expanded care or decreased mortality in low-income groups.

METHODS

STUDY DESIGN

To isolate the effects of the program, we used a regression-discontinuity design^{12,13} that took advantage of the eligibility rules of the 340B Program for general acute care hospitals, which establish eligibility above a threshold of 11.75% in the Disproportionate Share Hospital adjustment percentage (DSH percentage) of each hospital. The DSH percentage, a federally defined measure that determines additional payments for uncompensated care, is largely based on the percentage of admissions at a hospital that are for Medicaid patients and low-income Medicare patients (see the Supplementary Appendix, available with the full text of this article at NEJM.org).¹⁴

In the context of our study, a regression-discontinuity approach assumes that all determinants of hospital behavior for hospitals just above or just below the eligibility threshold were similar with the exception of exposure to the program. Equivalently, hospitals with minimally different DSH percentages within a sufficiently narrow range around the threshold are considered to be quasi-randomly assigned to program eligibility. In accordance with standard practice when there may be too few observations within such a range, we included hospitals from a broader range of DSH percentages and used regression to estimate threshold-related discontinuities (level shifts) in the cross-sectional relationship between hospital DSH percentages and each study outcome. This approach assumes that the relationship would have continued uninterrupted across the threshold in the absence of the program. Unlike comparisons of longitudinal changes (e.g., a difference-in-differences approach), our cross-sectional regression-discontinuity approach did not require hard-to-justify assumptions about how hospitals would have evolved in the absence of the program during a period of rapid hospital-physician consolidation.

STUDY DATA AND POPULATION

Our study included general acute care hospitals with 50 or more beds. We excluded for-profit hospitals because they are not eligible for the

340B Program and other categories of hospitals because they are subject to different eligibility criteria or payment systems.¹⁵ We further limited our analysis to hospitals with a DSH percentage within 10 percentage points of the 11.75% eligibility thresholds (i.e., 1.75% to 21.75%) and assessed the robustness of our results to narrower ranges in sensitivity analyses (see the Supplementary Appendix).

For hospital-level analyses, we constructed hospital-level variables for each year from 2008 through 2012 using Medicare claims and enrollment data for a random 20% sample of fee-for-service beneficiaries and data from the Centers for Medicare and Medicaid Services Hospital Cost Report Information System (HCRIS). For patient-level analyses of mortality in communities served by the hospitals in our study, we restricted the sample of fee-for-service Medicare beneficiaries to those living in ZIP Codes occupied by a single hospital (75% of the study hospitals fit this description).

STUDY VARIABLES

340B Program Participation and Eligibility

Using data from the Health Resources and Services Administration, we categorized a hospital as a 340B Program participant in a given year if it was a registered participant at any point during the year.¹⁶ To assess the program eligibility of each hospital, we used the DSH percentage of the hospital from the previous year, as reported in the HCRIS, because eligibility is determined prospectively (see the Supplementary Appendix).

Dependent Variables

Our primary hospital-level analyses included several prespecified and closely related outcome measures, which are described in more detail in the Supplementary Appendix. For each hospital in each year, we adapted previously described methods, using Medicare outpatient and carrier claims to determine the number of physicians in hematology–oncology, ophthalmology, or rheumatology who were practicing in a facility owned by the hospital.¹⁷ We prespecified these three specialties because they account for the most Part B drug spending in Medicare and have the highest proportions of revenue attributable to parenteral drugs among all specialties.^{15,18} We focused on these specialties because of the emphasis of our study on parenteral drugs. However, the 340B Program may have accelerated

hospital–physician integration in other specialties, too, because the discounts also apply to prescription drugs and may have encouraged hospital acquisitions of multispecialty groups.¹⁹

For each of the three specialties in each year and each hospital (including all outpatient practices and facilities owned by the hospital), we used Medicare claims and enrollment data to determine the number of Medicare patients served in outpatient facilities of the hospital by a physician in the specialty (see the Supplementary Appendix), the number of these patients receiving Part B drugs from the hospital, the number of reimbursed Part B drug claims billed by the hospital for these patients (and associated Medicare revenue), and the proportion of these patients who were dually enrolled in Medicaid and Medicare or received state assistance for Medicare cost-sharing. These dually eligible beneficiaries have less generous coverage or coverage that reimburses hospitals at lower rates for Part B drugs and other services than do persons with private supplemental insurance.

For secondary hospital-level analyses assessing hospital investments in the safety net, we used HCRIS data to assess the following variables yearly for federally qualified health centers (FQHCs) integrated with each hospital: the number of health care professionals employed, the number of patient encounters, and Medicare spending for FQHC care. We also assessed from claims the number of inpatient admissions for low-income groups. For secondary patient-level analyses of Medicare beneficiaries in the ZIP Codes of the hospitals, we assessed annual mortality from Master Beneficiary Summary files.

Covariates

As covariates for hospital-level and patient-level analyses, we assessed hospital teaching status, urban or rural classification, and Census region. As covariates for patient-level analyses of mortality, we additionally assessed the following patient characteristics: age, sex, race and ethnic group, whether disability was the original reason for Medicare enrollment, presence of end-stage renal disease, chronic conditions from the Chronic Conditions Data Warehouse, and the Hierarchical Condition Category score.

STATISTICAL ANALYSIS

For each hospital-level dependent variable, we fit the following model to estimate the eligibility

threshold–related discontinuity in the relationship between the variable and the hospital DSH percentage:

$$E(Y_{it}) = \beta_0 + \beta_1 340B\text{Eligible}_{it} + \beta_2 DSH_{it} + \beta_3 (340B\text{Eligible}_{it} \times DSH_{it}) + \gamma X_{it} + \alpha_t,$$

where $E(Y_{it})$ denotes the expected value of the outcome for hospital i in year t , $340B\text{Eligible}_{it}$ indicates whether the DSH percentage of the hospital exceeded the eligibility threshold, DSH_{it} is the DSH percentage of the hospital, X_{it} is a set of hospital-year level characteristics, and α_t denotes fixed effects for year. The terms DSH_{it} and $(340B\text{Eligible}_{it} \times DSH_{it})$ allow the slopes of the linear relationship between the hospital DSH percentage and outcome to differ on either side of the eligibility threshold.

The coefficient of interest, β_1 , is the adjusted discontinuity, or the difference in the outcome between hospitals above versus below the program eligibility threshold after adjustment for covariates and the relationship between hospital DSH percentage and the outcome. This quantity represents the estimated effect of 340B eligibility on the outcome variable. Because some eligible hospitals do not enroll in the 340B Program, we used instrumental-variables methods to estimate discontinuities associated with program participation. To aid interpretation of the multiple tests in our primary analyses, we conducted post hoc significance tests using a modified Hochberg procedure²⁰ that accounted for the multiplicity of outcomes and the high degree of correlation among them. Additional details about these analyses are provided in the Supplementary Appendix.

For analyses of mortality in the local communities of hospitals, we estimated similar models at the patient level after restricting the sample to Medicare beneficiaries living in ZIP Codes occupied by a single hospital and assigning the DSH percentage of that hospital to all beneficiaries residing in its ZIP Code. In a supplemental analysis, we used a similar strategy to examine overall Part B drug use and spending among beneficiaries in the local communities of hospitals (see the Supplementary Appendix).

In all analyses, we excluded hospitals with DSH percentages that were within 1 percentage point of the eligibility threshold in order to reduce measurement error introduced by misclas-

sification of hospital eligibility among hospitals that were close to the threshold.²¹ This misclassification resulted from misalignment for some hospitals between annual periods for DSH reporting in the HCRIS and calendar-year periods used for determining eligibility. In hospital-level analyses, hospitals were weighted by their number of beds. All analyses used robust variance estimators to account for clustering at the hospital level.²²

In sensitivity analyses, we tested the robustness of our estimates to adjustment for different specifications of the relationship between DSH percentage and outcomes. We also tested for eligibility-related discontinuities in hospital characteristics that should not be affected by the program and, for mortality analyses, in patient characteristics to test the assumption that potential confounders trended continuously across the eligibility threshold. We conducted additional analyses to assess the extent to which hospitals might have manipulated their DSH percentage to become eligible for the program, including analyses using the DSH percentages and hypothetical eligibility of hospitals in 2002 (before program expansion). In falsification tests, we repeated our hospital-level analyses among for-profit hospitals (which are not 340B-eligible) and among study hospitals in 2002 (when few were eligible), and we reestimated models using a range of alternate hypothetical eligibility thresholds.

RESULTS

340B PROGRAM ELIGIBILITY AND PARTICIPATION

Hospital participation in the 340B Program increased sharply at the DSH percentage threshold for eligibility, with some misclassification of program eligibility among hospitals close to the threshold, as expected (Fig. S1 in the Supplementary Appendix). The eligibility of hospitals for the 340B Program was stable over short and long periods (Figs. S2 and S3 in the Supplementary Appendix). For example, hospitals that were eligible in 2008 and met inclusion criteria for analysis were eligible for 4.7 years of the 5-year study period, on average.

HOSPITAL RESPONSE TO 340B PROGRAM INCENTIVES IN DRUG-INTENSIVE SPECIALTIES

Hospitals with DSH percentages that exceeded the program eligibility threshold had significant-

ly more hematologist–oncologists practicing in hospital-owned facilities than did hospitals with percentages below the threshold (Table 1 and Fig. 1). Specifically, the difference in the number of hematologist–oncologists between eligible and ineligible hospitals after adjustment for its relationship with hospital DSH percentage and hospital covariates (the adjusted discontinuity estimate) was 2.3 hematologist–oncologists per hospital ($P=0.02$). This translates to 230% more hematologist–oncologists per hospital than the expected mean in the absence of a discontinuity at the threshold (1.0 per hospital). Program eligibility was associated with an adjusted discontinuity of 0.9 (or 900%) more ophthalmologists per hospital ($P=0.08$) and 0.1 (or 33%) more rheumatologists per hospital ($P=0.84$). Program eligibility was also associated with significantly more patients receiving parenteral drugs and with significantly more Part B drug claims billed per year in hospital-owned facilities in hematology–oncology (90% more drug claims than the expected mean, $P=0.001$) and ophthalmology (177% more, $P=0.03$) but not in rheumatology (77% more, $P=0.12$). (Table 1 and Fig. 1). In hospital-owned hematology–oncology and ophthalmology practices, program eligibility was associated with significantly lower percentages of patients who were dually eligible for Medicare and Medicaid (Table 1, and Fig. S4 in the Supplementary Appendix).

Instrumental-variables estimates of discontinuities associated with program participation (rather than eligibility) were substantially larger. We found no significant eligibility-related discontinuities in hospital characteristics. All significant estimates remained so after multiple outcomes were accounted for. Additional details of these analyses are provided in Tables S1, S2, and S3 in the Supplementary Appendix.

CARE AND MORTALITY IN LOW-INCOME GROUPS

In hospital-level analyses, program eligibility was not associated with significant discontinuities in the number of health care professionals employed or patient encounters in integrated FQHCs or in the annual number of inpatient admissions for dually eligible Medicare beneficiaries, beneficiaries living in high-poverty areas, or beneficiaries served by safety-net providers (Table 2). In patient-level analyses involving beneficiaries who were residing in ZIP Codes that had a single study hospital, program eligibility of the local

hospital was associated with substantial discontinuities in shares of admissions and hospital outpatient spending attributable to 340B-eligible hospitals but was not associated with significant discontinuities in mortality for beneficiaries in the local communities of the hospitals (defined by hospital ZIP Codes), either overall or for low-income subgroups (Table 2, and Fig. S5 in the Supplementary Appendix). Discontinuities in observed patient characteristics also were minimal (Table S4 in the Supplementary Appendix).

SENSITIVITY AND SUPPLEMENTAL ANALYSES

The results of all sensitivity analyses and falsification tests supported the conclusions of our main analyses, including analyses that were restricted to hospitals with DSH percentages that were within 3 percentage points of the eligibility threshold, which produced estimates that were similar to those from our main analyses and remained significant in all cases (Tables S5 through S14 and Fig. S7 in the Supplementary Appendix). In a supplemental patient-level discontinuity analysis examining whether the greater provision of parenteral drugs by hospitals that was associated with program eligibility was accompanied by higher total Part B drug spending in local communities for patients served by parenteral drug-intensive specialties, program exposure was associated with 10.2% higher spending on Part B drugs in hospital-owned settings ($P=0.03$) but with lower drug spending in the independent office setting. The net discontinuity in total drug spending (in either setting) was positive but not significant (Tables S15, S16, and S17 in the Supplementary Appendix).

DISCUSSION

Our findings suggest that in hematology–oncology and ophthalmology but not in rheumatology, hospitals that are eligible for the 340B Drug Pricing Program have responded to program incentives by increasing the outpatient provision of parenteral drugs and, in the case of hematology–oncology, by employing physicians or acquiring physician practices. Our findings also suggest the program prompted eligible hospitals to treat more Medicare patients who are more likely to have private supplemental insurance to cover the 20% of Part B drug costs that is not covered by Medicare.²³ The finding that patients served

Table 1. Hospital—Physician Consolidation, Additional Patients Served in Hospital-Owned Settings, and Additional Hospital Drug Provision Associated with Eligibility for the 340B Program, According to Specialty.

Hospital-Level Measure ^{*,‡}	Hematology—Oncology			Ophthalmology			Rheumatology		
	Expected Mean†	Adjusted Discontinuity (95% CI)‡	P Value	Expected Mean†	Adjusted Discontinuity (95% CI)‡	P Value	Expected Mean†	Adjusted Discontinuity (95% CI)‡	P Value
Physicians in outpatient practices or facilities owned by hospital — no.§	1.0	2.3 (0.3 to 4.3)	0.02	0.1	0.9 (−0.1 to 2.0)	0.08	0.3	0.1 (−0.6 to 0.8)	0.84
Medicare patients served per year in outpatient practices or facilities owned by hospital — no.¶	149.8	60.2 (−0.8 to 121.2)	0.05	45.5	77.3 (7.7 to 146.8)	0.03	30.4	9.7 (−15.3 to 34.8)	0.45
Medicare patients served who were dually eligible for Medicaid or state assistance — %	16.0	−1.6 (−3.1 to 0.0)	0.05	18.2	−3.8 (−6.7 to −0.8)	0.01	19.4	−2.0 (−5.1 to 1.0)	0.19
Medicare patients per year receiving Part B drugs from outpatient practices or facilities owned by the hospital — no.	76.6	41.7 (14.1 to 69.2)	0.003	28.3	33.2 (3.2 to 63.2)	0.03	10.4	6.4 (−3.1 to 15.9)	0.19
Part B drug claims billed per year by outpatient practices or facilities owned by hospital — no.**	247.8	223.1 (88.8 to 357.3)	0.001	43.5	76.9 (9.6 to 144.3)	0.03	27.2	21.0 (−5.1 to 47.1)	0.12
Hospital annual Medicare revenue for Part B drugs — dollars††	436,668	360,243 (119,713 to 600,774)	0.003	75,708	98,639 (−25,876 to 22,315)	0.12	43,771	34,643 (−1586 to 70,871)	0.06

* A total of 4503 hospital-years was available for the assessment of hospital-level measures.

† Data are the expected mean at the eligibility threshold for ineligible hospitals based on the relationship between the Disproportionate Share Hospital (DSH) adjustment percentage and the outcome. Since this mean represented the expected level of each outcome in the absence of a discontinuity, the adjusted discontinuity estimates can be divided by these means to obtain an estimate of program effects in relative percentage terms.

‡ Adjusted discontinuities are estimates of the difference in each outcome above versus below the DSH percentage threshold for 340B Program eligibility after adjustment for the relationship between DSH percentage and the outcome and for hospital covariates (and patient-level covariates in the analyses of mortality) and can be interpreted as the average effect of 340B Program eligibility on the outcome. For example, the results suggest that eligibility was associated with 2.3 additional hematologist–oncologists working in practices owned by the hospitals.

§ Details on the methods used to assess the number of physicians in each specialty practicing in outpatient practices or facilities owned by each hospital are provided in the Supplementary Appendix. Among eligible hospitals, 32% had at least one hematologist–oncologist in a hospital-owned practice, 13% had at least one ophthalmologist, and 13% had at least one rheumatologist. Thus, the average estimates of program-related hospital–physician consolidation would be much larger among hospitals that added physicians or practices in response to the program.

¶ Data are the number of Medicare beneficiaries with at least one claim for a service from a physician in the specialty of interest in a practice or outpatient facility owned by the hospital. The adjusted discontinuities for percentages are given as percentage points.

|| Data are the total number of Part B drug claims billed by the hospital for patients served in the outpatient practices or facilities owned by the hospital.

†† Data are the total Medicare spending for Part B drugs administered by the hospital to patients served in outpatient practices or facilities owned by the hospital.

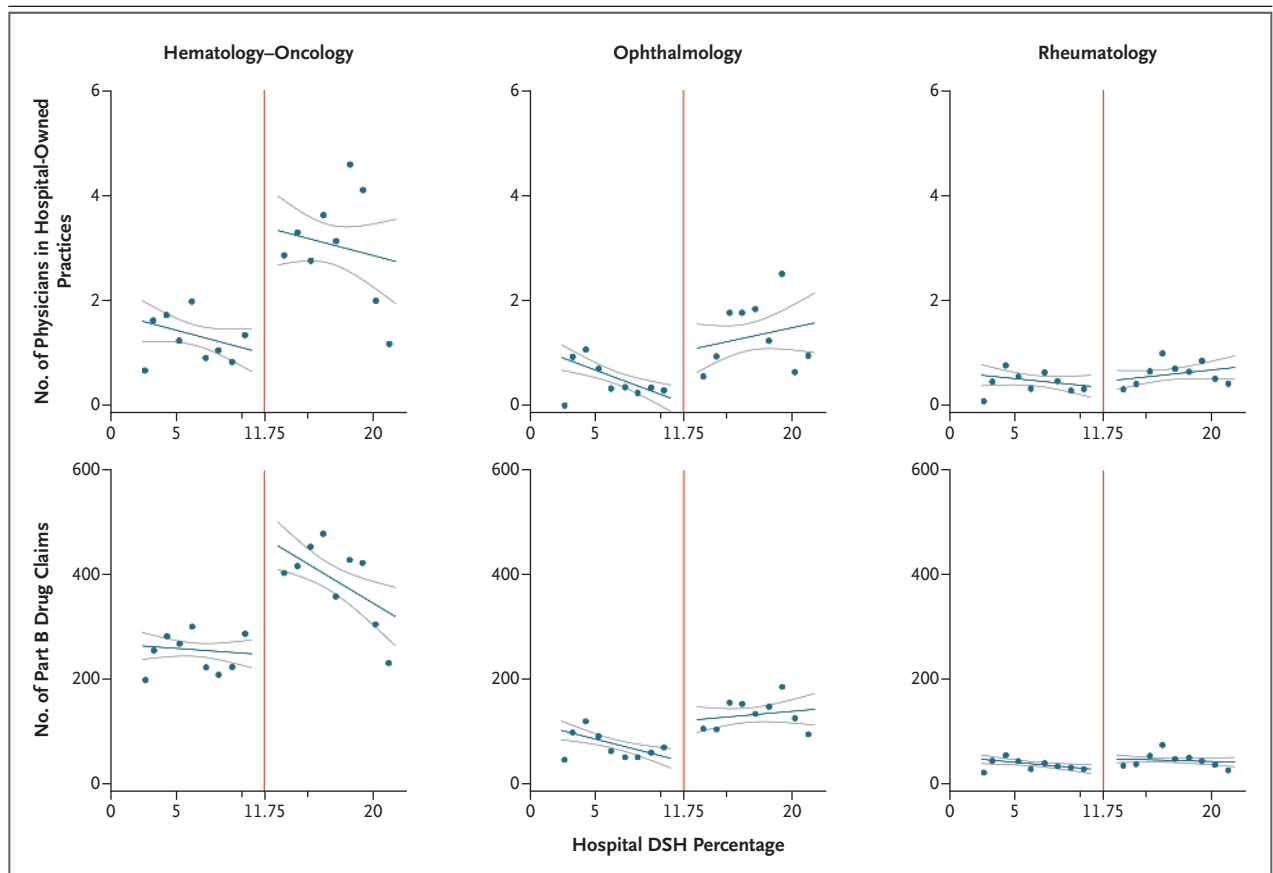


Figure 1. 340B Program–Related Discontinuities in Hospital Ownership of Physician Practices and Part B Drug Administration per Year, According to Specialty.

For each specialty, the number of physicians in hospital-owned practices and the number of hospital Part B drug claims per year are plotted according to the Disproportionate Share Hospital (DSH) adjustment percentage in the previous year, which determines 340B Program eligibility. Hospitals were categorized on the basis of their DSH percentage into 1-percentage-point bins, excluding hospitals within 1 percentage point of the eligibility threshold of 11.75%. Unadjusted bin means were calculated and plotted, with hospital size (in beds) used to weight hospital contributions to the mean. For illustrative purposes, a line of best fit to the bin means (darker blue lines) is shown to either side of the threshold, with 95% confidence intervals (lighter blue lines). The red vertical line denotes the threshold for 340B Program eligibility at a DSH percentage of 11.75%. Similar scatter plots of the numbers of patients served in hospital-owned practices and the proportion of patients served who were dually eligible by specialty across hospital DSH percentages are shown in Figure S4 in the Supplementary Appendix.

by eligible hospitals were less likely to have Medicaid, which reimburses hospitals less generously than other forms of supplemental coverage, is consistent with the financial incentives of hospitals and with evidence that 340B-participating hospitals have increasingly affiliated with hematology–oncology practices serving affluent communities.⁶

The discontinuous increases in the provision of drugs in hospital-owned settings that were found in association with program eligibility in hospital-level analyses were evident in analyses of local communities of Medicare patients. How-

ever, local increases in the total use of Part B drugs that also included provision of drugs in independent office settings (and not just in hospital-owned settings) were not significant. These findings suggest that much of the increase in the use of hospital-provided drugs resulted from a shift in setting, a finding consistent with hospital acquisitions of physician practices and more frequent referrals to hospital-owned specialty practices and infusion sites. We could not reject, however, the possibility of a meaningful effect of the program on total parenteral drug use in communities served by eligible hospitals

Table 2. Discontinuities in Hospital Care for Low-Income Groups and Mortality in Local Communities Associated with Eligibility for the 340B Program.

Measure	Expected Mean*	Adjusted Discontinuity (95% CI)†	P Value
Hospital-level analyses‡			
Hospital provision of safety-net care§			
No. of visits per year to FQHCs integrated with hospital	101.1	2.9 (–141.4 to 147.2)	0.97
Medicare spending per year for care at FQHCs integrated with hospital — dollars/hospital	1487	–1455 (–5121 to 2211)	0.44
Health care professionals employed in the FQHCs integrated with hospital — full-time equivalents	0.05	–0.04 (–0.11 to 0.03)	0.29
Hospital provision of inpatient care to Medicare patients			
No. of total admissions per year	1217.5	147.3 (–95.3 to 390.0)	0.23
No. of admissions per year for dually eligible beneficiaries	338.0	8.2 (–58.9 to 75.2)	0.81
No. of admissions per year for beneficiaries served by safety-net providers¶	79.1	13.6 (–25.0 to 52.2)	0.49
No. admissions per year for beneficiaries in low-income areas	422.2	25.2 (–79.2 to 129.6)	0.64
Patient-level analyses of Medicare beneficiaries in hospital ZIP Codes 			
Exposure to 340B Program			
Share of admissions in ZIP Code attributable to 340B-eligible hospitals — %**	17.1	48.4 (45.0 to 51.9)	<0.001
Share of hospital outpatient spending in ZIP Code attributable to 340B-eligible hospitals — %	20.8	48.0 (44.0 to 51.9)	<0.001
Annual mortality rate — %			
All beneficiaries living in hospital ZIP Code	5.1	0.1 (–0.1 to 0.3)	0.27
Dually eligible beneficiaries	6.3	0.0 (–0.4 to 0.4)	0.97
Beneficiaries served by safety-net providers¶	4.1	–0.1 (–0.9 to 0.7)	0.73
Beneficiaries in low-income areas††	5.1	0.2 (–0.1 to 0.6)	0.15

* Data are the expected mean at the eligibility threshold for ineligible hospitals based on the relationship between DSH percentage and the outcome. Since this mean represented the expected level of each outcome in the absence of a discontinuity, the adjusted discontinuity estimates can be divided by these means to obtain an estimate of program effects in relative percentage terms.

† Adjusted discontinuities are estimates of the difference in each outcome above (vs. below) the DSH percentage threshold for 340B eligibility after adjustment for the relationship between DSH percentage and the outcome and for hospital covariates (and patient-level covariates in the analyses on mortality) and can be interpreted as the average effect of 340B Program eligibility on the outcome.

‡ A total of 4503 hospital-years was available for the assessment of hospital-level measures.

§ Data are from the Hospital Cost Report Information System. The professionals employed in the federally qualified health centers (FQHCs) include physicians, nurses, physician assistants, social workers, and psychiatrists.

¶ Beneficiaries served by safety-net providers are those with at least one claim for a service provided by an FQHC, community mental health center, rural health clinic, or other provider types that typically serve low-income populations (see the Supplementary Appendix).

|| The sample included a total of 1,989,633 fee-for-service beneficiaries from the 20% sample residing in the same ZIP Code as a study hospital that was the only hospital located in its ZIP Code. The adjusted discontinuities for percentages are given as percentage points.

** The adjusted discontinuity for this variable indicates a 48.4-percentage-point absolute increase in the share of admissions in a ZIP Code that were admissions to 340B-eligible hospitals.

†† Beneficiaries in low-income areas were defined as beneficiaries residing in a ZIP Code tabulation area in which the percentage of the elderly population living below the federal poverty level exceeded 10%, the 75th percentile in our study sample, based on 2010 U.S. Census data.

that our analysis was not adequately powered to detect.

We found no evidence of hospitals using the surplus monetary resources generated from administering discounted drugs to invest in safety-net providers, provide more inpatient care to low-income patients, or enhance care for low-income groups in ways that would reduce mor-

tality. These results suggest hospital responses that are contrary to the goals of the program and have a number of important policy implications. In general, policies that are intended to improve or expand care for medically underserved populations may be ineffective if they rely on indirect mechanisms with weak incentives, such as the cross-subsidization that the

340B Program intends for hospitals to implement.⁵

Our findings suggest that the recent decision by the Department of Health and Human Services to lower drug reimbursements to hospitals participating in the 340B Program²⁴ could slow hospital–physician consolidation while not adversely affecting care for low-income patients served by general acute hospitals. This form of consolidation has increased prices and spending without ostensibly improving quality.^{17,25–28} Building on previous evidence,^{29,30} our study more generally underscores the importance of differences in profitability between hospital-owned and independent outpatient settings in encouraging hospital–physician consolidation. Thus, our findings support broader proposals to make payments and discounts for care delivery setting-neutral.³¹

Our study had several limitations. First, we relied largely on Medicare data. We would expect, however, that major investments in clinical resources for low-income groups outside of Medicare, such as the uninsured, would also affect care for low-income Medicare beneficiaries. Moreover, we found no evidence of enhanced care for a subgroup of Medicare patients with supplemental insurance that is less generous or reimburses hospitals at lower rates than private supplemental insurance. In addition, measures of hospital investments in FQHCs were not specific to Medicare.

Second, program-related increases in hospital

ownership of physician practices could have been overstated if practices owned by hospitals merely changed place-of-service codes to allow administration of discounted drugs. However, hospitals have strong incentives to encourage such coding practices, regardless of the program, because Medicare pays for services in hospital-owned settings at higher rates than in independent office settings. Third, our regression-discontinuity approach supported inferences about hospitals just above the eligibility thresholds. Hospitals with higher DSH percentages could have responded differently to program discounts. Fourth, our conclusions may not apply to categories of eligible hospitals we did not study, such as critical access hospitals.

In conclusion, the 340B Drug Pricing Program has been associated with hospital–physician consolidation in hematology–oncology and with more hospital-based administration of parenteral drugs in hematology–oncology and ophthalmology without clear evidence of expanded care or lower mortality among low-income patients.

The content of this article is solely the responsibility of the authors and does not necessarily represent the official views of the Agency for Healthcare Research and Quality or the Robert Wood Johnson Foundation.

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Physician's Office and Hospital Outpatient Setting in Oncology: It's About Prices, Not Use

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In an article accompanying this editorial, Fisher et al¹ enrich the discussion regarding costs for patients with cancer cared for in the physician's office versus the hospital outpatient setting. Using a large data set of commercial insurance claims from multiple plans, the authors note spending differences between the two settings. Given that spending is a product of both prices and quantities of health care services, the authors note that the reason for the spending difference lies in price differences for these services, rather than in differences in the quantity of services. In other words, the study suggests that when a patient is treated in a physician's office rather than in a hospital outpatient department, he or she does not receive more or less aggressive care, or more or less redundant care. The payment rates are just lower for the services.

The finding that spending differences seem to be a product of price differences in commercial insurance is not a surprise. Previous research has shown similar results.² It is also not surprising because the alternative explanation is improbable. Large and consistent differences in resource use levels overall would mean consistent differences across various types of care, and this is usually not seen in the fairly vast literature on practice variations. Such a pattern would suggest either a strong cross-services culture of over- or underuse, or aligned incentives across types of services. Neither has been documented in oncology thus far.

This issue, however, still should be addressed, because the topic of how much

care costs in the physician's office compared with in the hospital outpatient department has important policy resonance. Currently, there is a thick fog around this question. My research group recently identified and reviewed four lengthy reports on practice setting cost differences and found a wide array of different analyses targeting fundamentally different questions. Some reports examined commercial insurance, others Medicare payments. Some sought to match patient populations, whereas others did not. Some disaggregated spending into prices and quantities of services, whereas others did not.

A common theme did emerge. For matched populations, spending is higher in the hospital than in physician's office for commercial insurance; this is nearly identical in Medicare. The difference in each case has to do with payment formulas, because commercial insurance has higher payment rates in the hospital outpatient department than in the physician's office. But Medicare pays at essentially the same level in each setting even though the payment types are different. The first finding, which echoes the finding of Fisher et al¹ that the overall cost of care is higher for commercial insurance in the hospital outpatient department than in the physician's office, is troubling, given the ongoing trend toward consolidation of physicians' offices into hospitals. Many forces have been credited (or blamed) for this trend. One is the arbitrage from the differential payment rates themselves;

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another is an aging population of physician practitioners who do not want to run their own practices any longer. The 340B drug discount program has created a wider arbitrage opportunity for hospitals that obtain discounted drugs but then charge insurers the contracted (or retail) rate.³ Policymakers should note that the trend toward consolidation will continue to drive up the cost of commercial health insurance unless price concessions or equivalence can be achieved between settings.

The finding regarding Medicare is another matter and is particularly important given the ongoing discussion around the Part B pilot that the Centers for Medicare & Medicaid Services have proposed recently.⁴ (On December 15, CMS announced that it would not be finalizing the Medicare Part B Drug Payment Model during this Administration.) In opposing the pilot, physician trade associations such as ASCO and the Community Oncology Alliance have stated that the consolidation of physicians' offices into the hospital outpatient department would be exacerbated by the pilot. Our group conducted an analysis demonstrating that there is no empirical basis for this prediction and that, in fact, the pilot reduces the arbitrage between the two settings.⁵ More important, these same groups have stated that under Medicare, care costs more in the hospital outpatient setting than in the physician's office.⁶ An editorial from ASCO, for instance, reported that Medicare payment rates were 38% higher in the hospital than in the physician's office.

However, the reports we reviewed make it clear that this is not the case and that there are only minimal differences overall. Physicians' offices receive a separate payment for every infused drug, whereas hospital outpatient departments receive payment for only the more expensive drugs (those that cost more than \$95 per day). The infusion payments are based on different systems, with some higher in the physician's office, and others higher in the hospital. The Moran report, the only one that has mapped these payment differences, concluded that at most there was a 2% difference between the settings in terms of Medicare payments, when the same drug and infusion were billed in each setting.⁷

In the report by Fisher et al,¹ the authors do indicate some differences in resource use worth noting. Physicians practicing in their own offices generally have more incentives to prescribe profitable drugs than do physicians practicing in a hospital outpatient setting. Most notably, biologic drugs, which are only marginally beneficial, and white cell growth factors,

which are profitable to use but are frequently overused in the choosing wisely campaign, are both used more often in physicians' offices.⁸ The same is true for outpatient visits. The authors state that there is greater use of these drugs in patients treated in the hospital outpatient department for cancer-related hospitalizations, but the data are not included, and the methods used for this part of the analysis are unclear.

All of these findings could have been better summarized in the title, because readers may miss the narrow focus on commercial insurance payments in the study. In addition, readers may conclude incorrectly that the authors saw health care use differences between the two settings when in fact it seems that use is essentially matched. Regardless, the study does enrich our understanding of this important issue in multiple ways. **JOP**

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST**Physician's Office and Hospital Outpatient Setting in Oncology: It's About Prices, Not Use**

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