340B Drug Pricing Program: Analysis Reveals $40 Billion in Profits in 2019

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Research supported by Exelixis, Inc.

Pricing data provided by SSR Health, LLC, **www.SSRhealth.com**

AIR 340B Alliance for Integrity & Reform

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The 340B Drug Pricing Program has experienced extraordinary growth over the past 10 years, propelled by a potent mixture of regulatory, legislative, and technology changes. There is strong bipartisan support for 340B and recognition that for better or worse, 340B has become a critical source of income for many rural hospitals, community clinics, and other eligible providers. By definition, at its most basic level, the program is an income transfer from pharmaceutical firms and possibly others—including insurers and patients—to covered entities.

We have obtained data on the 340B program through a FOIA request that sheds unique light on how the program has grown over the past five years. Total 340B sales at the 340B price approached $30 billion in 2019 and continue to grow rapidly. We estimate that in 2019, 340B created over $40 billion in profits which were shared between covered entities, contract pharmacies, and possibly patients (in the form of reduced-price medicines). Oncology drugs dominate the 340B program, accounting for a large and growing share of total program profits. We estimate that

self-administered oncology drugs contribute the fastest-growing and largest share of 340B profits.

We estimate that, in total across all medicines, contract pharmacies retained at least $5 billion in annual profits from 340B sales, up from $2 billion in 2015. While the bulk of these profits are financed by drug companies in the form of foregone revenues (we estimate $25 billion, or 63% of the profits), the remaining $15 billion likely comes from higher insurance premiums and/or higher prices paid by cash customers at the drugstore.

340B Program Expansion

The 340B statute prohibits covered entities from selling or transferring a 340B drug to an individual who is not a "patient" of the covered entity. However, the definition of a 340B patient is set out in the Health Resources and Services Administration's decades-old guidance that has been criticized as overly vague. The guidance does not reflect the significant changes to the 340B program, including the expansion of for-profit pharmacies and middlemen like pharmacy benefit managers. Covered entities often use sophisticated software algorithms that identify 340B-eligible patients after their prescriptions are filled. Because these algorithms are run after an individual fills a prescription, patients are often unaware that they have participated in the 340B program at all. While 340B spending may not "cost" the government anything or generate any government revenue, we speculate that there may be indirect costs, due in part to higher health insurance premiums caused by the

incentives 340B creates to prescribe brand drugs where the potential profit from 340B is greater than for generic drugs.

The Affordable Care Act expanded the categories of hospitals eligible to participate in 340B and also sharply increased Medicaid's role in health coverage. One important way hospitals can qualify as a 340B covered entity is by treating a certain proportion of Medicaid and low-income Medicare in patients. There has also been dramatic growth in the number and types of federal grantees (e.g., Ryan White AIDS Clinics, community health centers) participating in 340B.

Until 2010, covered entities that did not have an in-house pharmacy were permitted to contract with a single contract pharmacy to enable them to benefit from 340B. In 2010 HRSA issued final administrative **guidance** allowing covered entities to contract with an unlimited number of third-party pharmacies to dispense 340B drugs. Contract pharmacy arrangements have increased **exponentially**, jumping from 2,321 in 2010 to just above 100,000 in 2020. The average 340B hospital has contracts with over 20 pharmacies, each with technology designed to maximize the chance of discovering (or "capturing") 340B-eligible patients once their prescriptions are filled. There are no data or studies to suggest that uninsured patients typically benefit directly from 340B discounts when they fill prescriptions. In fact, there is **some evidence** that uninsured patients often pay the full price for their 340B prescriptions even when they are patients of a 340B hospital.

Measuring 340B Sales Growth and Estimating Implied Profits

The Drug Channels Institute and other sources have **estimated** overall 340B sales at roughly $29.9 billion in 2019, growing at an annual rate of over 27%. Concrete evidence on the profits generated by 340B has been limited because there is no comprehensive information about which types of drugs are sold through 340B or their purchase prices and reimbursement rates. Existing research on 340B profitability either guesses at the therapeutic area distribution or takes a snapshot of sales within particular covered entities at a point in time.

We submitted a FOIA request for 340B sales data to HRSA, which provided therapeutic area (TA) level 340B sales data for years 2015 through 2019. These data provide aggregate TA sales at the 340B purchase price along with information on unit volumes. The HRSA data covers roughly $25 billion in 340B sales in 2019 for the TAs included in our analysis. Estimating the profits generated by those sales requires us to estimate a) product market shares within TAs, b) acquisition costs, and c) reimbursement levels.

We obtained pricing data from **SSR Health, LLC** covering product-level data on minimum Medicaid discounts, average non-Medicaid discounts, list prices, and overall sales for 2015-2019. We included products accounting for 90% of overall annual sales for each year. Our sample includes 330 products categorized into 88

TAs characterized by the **AHFS Classification system** (matching the categories provided by HRSA). The data cover the vast majority of physician- and self-administered branded US drug sales.

SSR Health calculates a conservative estimated Medicaid rebate for every product by combining the minimum 23.1% statutory rebate with the relevant inflation penalty. In some cases, this may underestimate the Medicaid rebate because it is missing deeper discounts required by the Medicaid rebate statute's best price provision. We used the estimated net Medicaid price as a proxy for the 340B acquisition price for each product, ensuring our profit estimates are conservative because the 340B acquisition cost cannot be higher than the net Medicaid price.

We computed a weighted average Medicaid rebate within each therapeutic class for each year based on the products' Medicaid rebates and net branded sales weights. We applied the weighted average Medicaid rebate to the TA-level HRSA 340B data to estimate the WAC value for each TA's 340B sales. Finally, we allocated 340B retail sales to individual products based on the products' net sales weights within each class.

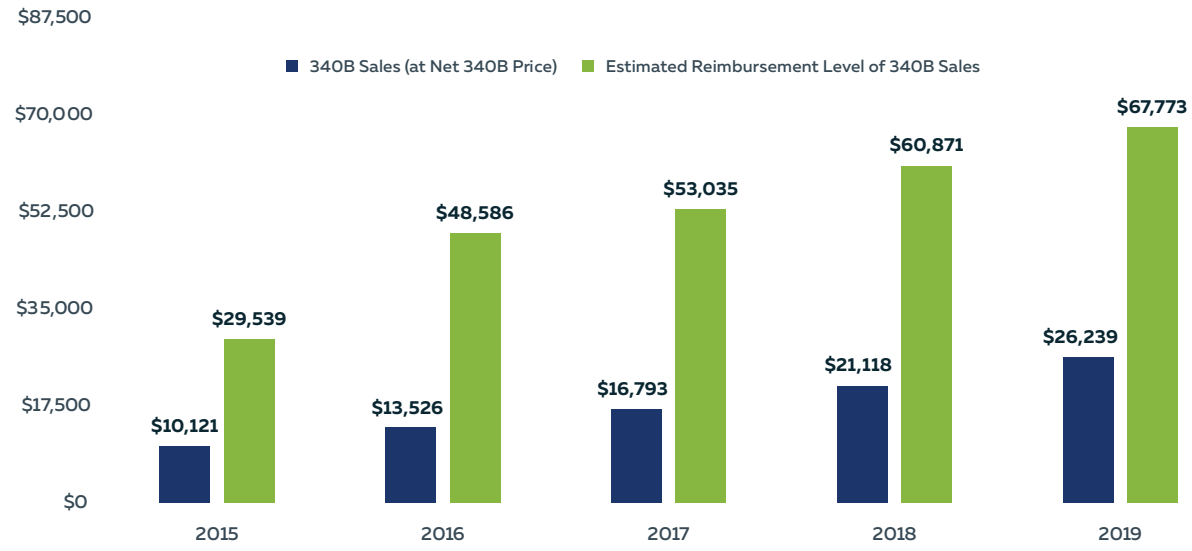
We used the estimated WAC values for each 340B product to estimate reimbursement rates assuming, based on evidence, that providers are **fully reimbursed** at market prices by commercial and public payers for dispensing and administering 340B drugs. We made separate assumptions for self-administered and physician-administered drugs and adjusted for changes in how Medicare reimbursed Part B drugs dispensed under 340B in 2018 and 2019.

According to the U.S. Government Accountability Office, commercial payers generally reimburse physician-administered drugs at a somewhat higher rate than Medicare's Average Sales Price plus 4.3% rate, and for top-selling physician-administered drugs ASP, in general, is **10-15% lower** than WAC. Overall, Medicare represents **roughly 37.5%** of total reimbursements for the physician-administered market. For 2015 to 2017 we assume commercial payers reimbursed at the same rates as Medicare, and transform ASP + 4.3% to WAC – 10%. This is a conservative assumption that understates the profit from the 340B program since **recent analysis** has shown that hospitals are typically reimbursed for physician-administered drugs at rates far above ASP. For 2018-2019 we applied the Medicare reimbursement reduction for 340B drugs to the presumed 37.5% Medicare market share, reducing the overall weighted average reimbursement for physician-administered drugs to WAC - 19%. For self-administered drugs, we assume that the average reimbursement is at WAC + 4%, consistent with the typical industry **average**. Applying all of these adjustments gives us estimates for 340B acquisition and reimbursement values by product. To calculate provider profit at the product level we took the difference between these numbers and finally aggregated product profit to calculate profits by TA and type of drug.

Sales and Profits in 340B

Figure 1 provides a summary of overall branded 340B sales growth (based on the HRSA data) and our estimate of the reimbursement value of those sales. We estimate that provider profits have more than doubled, from $20.2 billion in 2015 to $40.5 billion in 2019.

Figure 1. 340B Program Sales 340B Price vs. Estimated Reimbursement Value (Millions)



	2015	2016	2017	2018	2019
Estimated 340B Provider Profits	$20,182	$36,104	$37,208	$38,923	$40,456

Source: HRSA, SSR Health, LLC., Health Capital Group LLC analysis

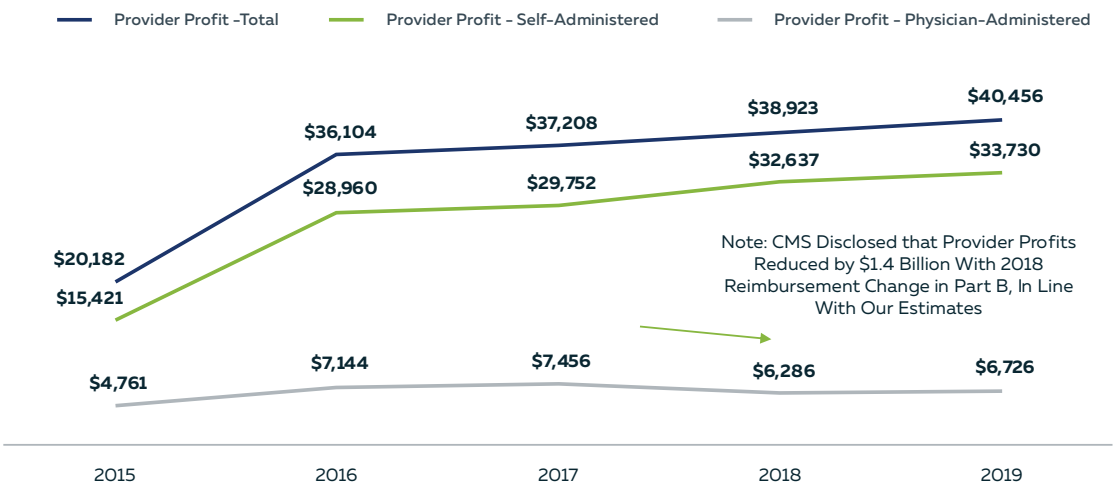
Self-Administered vs Physician-Administered 340B Profits

Figure 2 shows that while physician-administered products have shown steady growth, profits from self-administered drugs have been much greater, consistent

with the growth in contract pharmacy arrangements. We estimate that more than 75% of total 340B profits are generated by self-administered drugs; while some of those drugs are distributed directly by in-house pharmacies, a large portion is surely driven by contract pharmacies who identify 340B patients after their prescriptions are filled.

For physician-administered drugs, CMS **calculated** that covered entities would lose $1.4 billion in 340B-related profits under the rate change in 2018. As shown in Figure 2, our methodology implies almost exactly the same reduction in covered entity profitability for physician-administered drugs, providing us with some confidence that our methods provide reasonable estimates.

Figure 2. Estimated 340B Profits: Physician vs. Self-Administered Drugs (Millions)



Margin - Total	$20,182	$36,104	$37,208	$38,923	$40,456
Self - Administered	73%	81%	78%	75%	71%
MD Administered	58%	57%	51%	40%	37%

Source: HRSA, SSR Health, LLC., Health Capital Group LLC analysis

Focus on Oncology

Table 1 shows that oncology generally – and oral oncology in particular – have grown quickly in terms of both sales and profits.

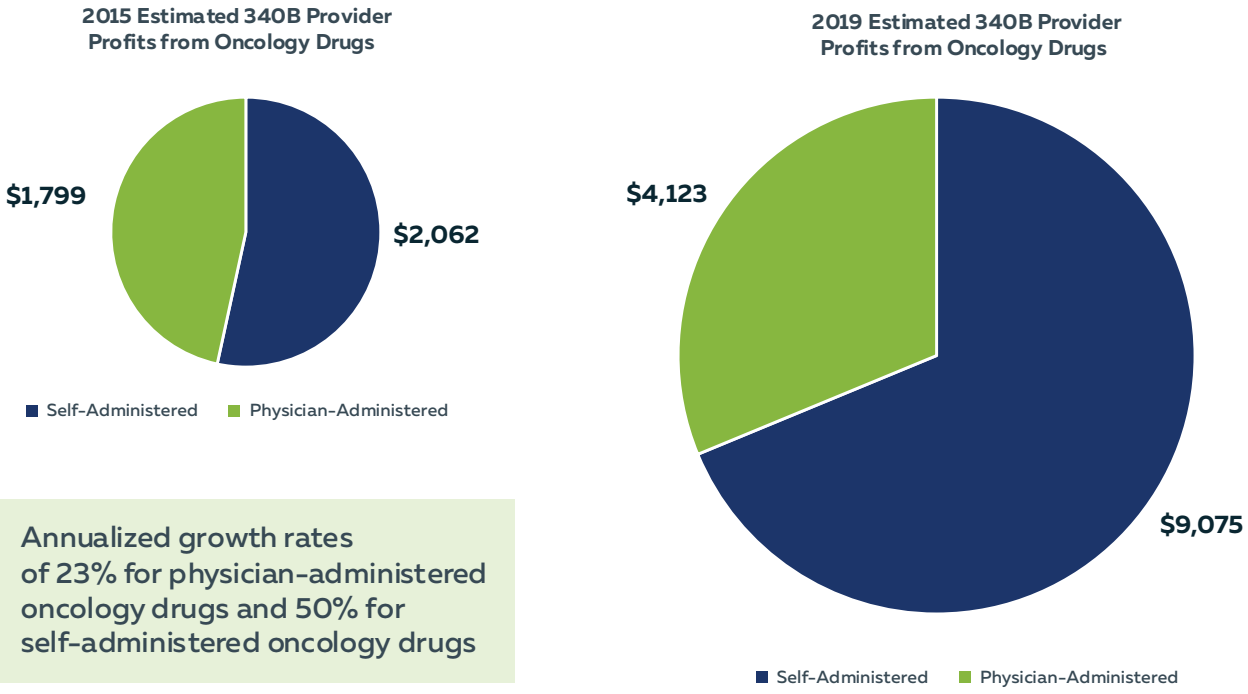
Table 1. Oncology as a Share of Profits, Physician-Administered and Self-Administered 340B Products, 2015 – 2019 (millions)

	2015	2016	2017	2018	2019
Total 340B Sales (at acquisition price)	$ 10,064	$ 13,476	$ 16,742	$ 21,070	$ 26,192
Oncology 340B Sales (at acquisition price)	$ 3,775	$ 5,804	$ 7,837	$ 10,980	$ 13,732
Oncology Share	**37.5%**	**43.1%**	**46.8%**	**52.1%**	**52.4%**
Total 340B Provider Profits	$ 20,182	$ 36,104	$ 37,208	$ 38,923	$ 40,456
Oncology 340B Provider Profits	$ 3,861	$ 7,370	$ 9,639	$ 11,365	$ 13,198
Oncology Share	**19.1%**	**20.4%**	**25.9%**	**29.2%**	**32.6%**
340B Provider Profits: All Self Administered	$ 15,421	$ 28,960	$ 29,752	$ 32,637	$ 33,730
340B Provider Profits: Oncology Self Administered	$ 2,062	$ 4,283	$ 5,840	$ 7,895	$ 9,075
Oncology Share	**13.4%**	**14.8%**	**19.6%**	**24.2%**	**26.9%**
340B Provider Profits: All Physician - Administered	$ 4,761	$ 7,144	$ 7,456	$ 6,286	$ 6,726
340B Provider Profits: Oncology Physician - Administered	$ 1,799	$ 3,088	$ 3,799	$ 3,470	$ 4,123
Oncology Share	**37.8%**	**43.2%**	**51.0%**	**55.2%**	**61.3%**

Source: HRSA, SSR Health, LLC., Health Capital Group LLC analysis

Oncology's share of 340B sales has increased from 37.5% in 2015 to 52.4% in 2019, and oncology-generated 340B profits increased from 19.1% of total 340B provider to 32.6% over the same period. Oncology dominates profits in the physician-administered category, and oncology's share of the much larger self-administered market has grown from 13.4% to 26.9%. Figure 3 illustrates the growth in pure dollar terms.

Figure 3. Oral Oncology Drives 340B Profit Growth



Annualized growth rates of 23% for physician-administered oncology drugs and 50% for self-administered oncology drugs

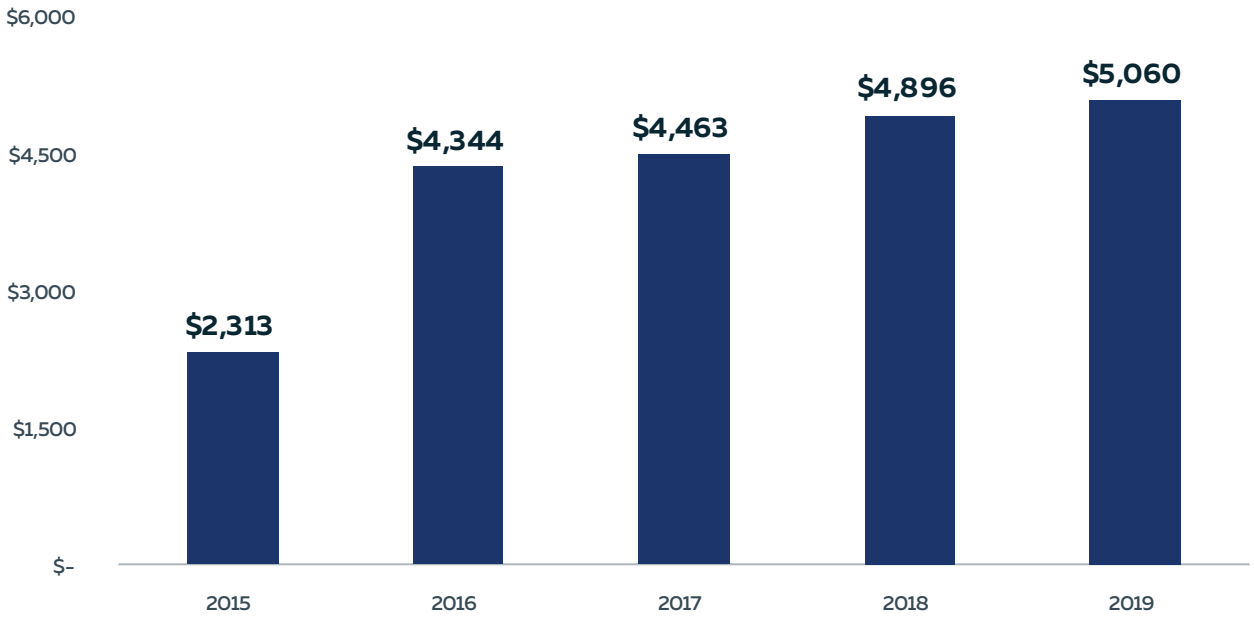
Source: HRSA, SSR Health, LLC., Health Capital Group LLC analysis

Estimating the Contract Pharmacy Share of 340B Profits

Covered entities use various methods to pay contract pharmacies. According to a **GAO report**, typically the pharmacy earns between 15% and 20% of the total 340B revenue generated based on the affiliation with the covered entity. The fees can be percentage-based, and are often higher for branded, specialty drugs, and for drugs dispensed to patients with health insurance. We conservatively assume that contract pharmacies retain 15% of the total profits generated for 340B self-administered drugs. Note, our estimates exclude physician-administered drugs that

might be purchased at specialty pharmacies but administered by physicians (i.e. "white bagging"). By excluding these figures, this represents an underestimate of the potential 340B profit share retained at contract pharmacies. Figure 4 illustrates the growth estimated contract pharmacy profits.

Figure 4. Estimated 340-Generated Profit – Retail and Specialty Pharmacies (millions)



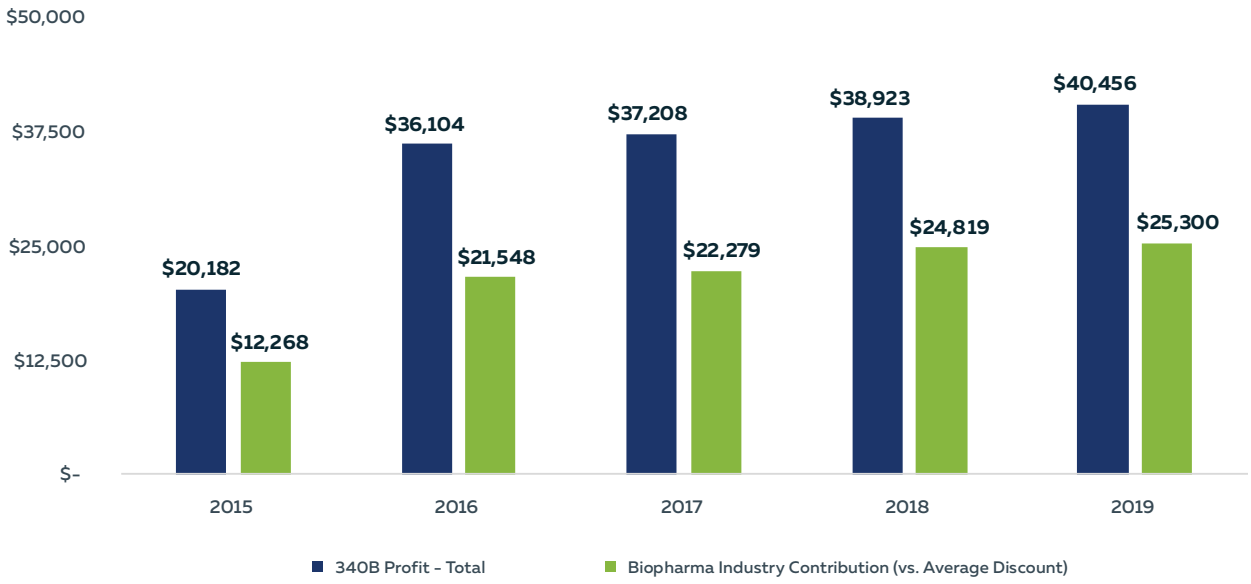
Source: HRSA, SSR Health, LLC., Health Capital Group LLC analysis

If instead we calculate pharmacy shares as 15% of total *revenue*, pharmacies would have captured roughly $7 billion in 2019.

Who Pays for 340B?

What does the 340B program cost drug companies? It would overstate the case to attribute the entire 340B discount because companies routinely provide discounts to non-Medicaid payers. The industry's contribution to 340B can be understood as the value of discounts the drug manufacturers provide over and above the discounts offered to non-covered entities on the market. For our purposes, we assume that manufacturers can separate 340B discounts from negotiated commercial rebates, though in practice manufacturers have limited visibility into 340B claims and may well end up paying both discounts. To the extent that manufacturers pay the discounts twice, our methodology is again conservative in terms of the manufacturer cost of 340B, but given the impossibility of separating the discounts in our analysis, we assume it is one discount or the other. We applied the difference between discounts to our product-level estimates of 340B volumes to calculate product-level "exposures" to 340B by year and aggregated them to estimate the total company contribution to 340B profits. These estimates are shown in Figure 5.

Figure 5. 340B Profit vs. Pharma Industry Exposure



Pharma Contributes Roughly 63% of $40 Billion in 340B Profits, Leaving 37% for Other Payers (Medicare, Commercial, Patients)

Source: HRSA, SSR Health, LLC., Health Capital Group LLC analysis

We estimate that the drug industry contribution to 340B is roughly $25 billion, or 63% of total 340B profits; the remaining $15 billion is borne by payers and consumers in the form of higher insurance premiums and/or higher overall prices at the counter. Since our assumptions are conservative and may well understate the level of true 340B discounting, it seems reasonable to assume that manufacturers account for such uncertainty in their negotiations. One likely outcome is that 340B rebates (which may factor in Medicaid best price requirements) may crowd out more traditional commercial rebates, precisely what happened when Medicaid's best price rules were first introduced in the early 1990s and commercial rebates **dropped significantly** in response.

Conclusions

The 340B program has grown exponentially over the past decade and has become a major source of funding for thousands of grantees and hospitals. Our estimates provide a new, somewhat more precise way to estimate the profits associated with the program and how they have changed over time. It is up to policymakers to determine whether these changes are consistent with the original program's intent.