THE IMPACT OF THE 340B PROGRAM ON DRUG PRICES CHARGED BY MANUFACTURERS AND COVERED ENTITIES

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KEY FINDINGS

1. The 340B program is a mandatory program for pharmaceutical manufacturers wishing to participate in the Medicaid drug rebate program. Today, the program has more than 53,000 participating covered entities and the total amount of drugs purchased at the 340B ceiling price under the program is almost $44 billion (Drug Channels).

2. Drug list prices, like other prices in health care, are increasing. The research for this white paper suggests that 340B is one of many factors putting upward pressure on launch prices.

3. Covered entities can generate savings from the prices charged for 340B drugs. There are no requirements for hospitals for how they use the savings, so pricing for services vary.

4. Lack of comprehensive data across the program limits insights on pricing and discount strategies.

EXECUTIVE SUMMARY

Leavitt Partners examined publicly available resources to determine the 340B Drug Pricing Program's (340B) impact on drug prices charged by both covered entities and pharmaceutical manufacturers. One of the new findings is that drug list prices are increasing and that 340B is one of many factors that is applying upward pressure on launch list prices. In addition, some covered entities are charging patients and payers more than the 340B discounted price and it is unclear how much of this revenue is then being used to lower out-of-pocket costs or increase access to services for patients. Without more data, however, it is not possible to determine the magnitude of the impact of the 340B program on the drug prices charged by both manufacturers and covered entities. Leavitt Partners could provide a better idea of the magnitude if manufacturers and covered entities made available additional information surrounding pricing, discounts, and the direct benefit of the program to patients.

These conclusions were drawn after Leavitt Partners undertook a comprehensive literature review of publicly available governmental reports, peer-reviewed journal articles, white papers, news articles, and other publicly available sources to identify the degree to which, and to what extent, the 340B program may impact drug prices. To supplement this literature review, Leavitt Partners also conducted interviews with ten subject matter experts representing the perspectives of covered entities (including Federally Qualified Health Centers, Ryan White Clinics, and Disproportionate Share Hospitals) and drug manufacturers, as well as the analysis of health economists and academic researchers.

Due to the varying definitions for measuring price and some opaqueness around pricing data, it is difficult to accurately track trends in pricing. This is particularly difficult given that what a patient pays usually differs from how drug prices are measured. In our white paper, we focused on drug list price as the best method for analyzing pricing dynamics. While the data is not always clear, we know generally that drug spending, similar to other sectors within health care, is steadily increasing, and that list prices are going up. There are a multitude of factors that impact the list price manufacturers set for a drug, such as an individual manufacturer's product portfolio and market position, payer mix, payer relationships, leadership, corporate culture, and overall strategy. Complicating things further, the list price is rarely what a patient pays for a drug due to discounts negotiated by pharmacy benefit managers and mandated price concessions by government payers. Manufacturers are likely to factor in all forms of discounts when determining a launch list price.

Given that all of these factors come into play simultaneously, it is virtually impossible to objectively disentangle a single factor in a manner that allows us to measure its sole impact on increases in prices or higher launch prices. Ultimately, through our literature review and interviews, we found support for the idea that the 340B program has some upward impact on how drug manufacturers set prices. However, a consistent theme we heard from most interview participants was that a lack of data has made it difficult to fully assess the degree to which the 340B program impacts drug prices charged by manufacturers.

In the case of covered entities, the data, literature, and anecdotal evidence make it clear that it is common practice for some covered entities to charge prices that are at least some amount higher than the 340B ceiling price which generates revenue. The extent to which this practice is utilized could vary by the type of covered entity, given that they have different regulatory requirements. However, data on pricing is not available generally and is not broken down by each type of covered entity. The Health Resources and Services Administration (HRSA) states that the purpose of the 340B program is "to stretch scarce federal resources," and this is accomplished by creating savings that providers can spend on services in line with their mission. This may include passing on savings to certain types of patients or payers, but is not limited to that sole

objective intentionally. Many interviewees concluded that savings providers generate through the program are unlikely to be passed on directly to patients or payers. In addition, some interviewees believe that the 340B program incentivizes behavior on a macro level that leads to increases in the prices charged by covered entities.

It is important to highlight the data limitations regarding drug prices covered entities charge patients and payers. On the one hand, the limited evidence from research, as well as the anecdotal responses from surveys and interviews, indicates that covered entities in many cases do use the 340B revenue to benefit patients either through reduced prices or increased access to services. On the other hand, while some HRSA grantees have requirements to use the discounts to advance their mission of helping low-income patients, other types of covered entities are not limited in how they account for and use the savings generated from the discounts. Our literature review found no authoritative, definitive source of data that could characterize how each type of covered entity approaches utilizing 340B savings. Additional information that could shed further light on the 340B program's impact on drug prices would be data showing the number and types of patients who receive a discounted medication, either through the 340B discounted price being directly passed on with a discount card or through another means, such as charitable assistance, copay programs, or a sliding fee scale.

METHODOLOGY

Leavitt Partners received a grant to examine the 340B Drug Pricing Program's impact on drug prices charged by both covered entities and pharmaceutical manufacturers ("drug prices"). This paper summarizes the results of that analysis and includes:

- A brief outline of the design and function of the 340B program
- A high-level analysis of drug pricing trends since the creation of the 340B program
- A review of relevant federal policy changes made to the 340B program
- An analysis of the quantitative and qualitative evidence of the impact of the program on drug pricing
- An identification of data gaps and additional questions for further research
- A concluding analysis that synthesizes research and interview findings

This white paper was produced utilizing a combination of both primary and secondary research sources. Leavitt Partners undertook a comprehensive literature review of publicly available governmental reports, peer-reviewed journal articles, white papers, news articles, and other publicly available sources to identify the degree to which, and to what extent the 340B program may impact drug prices.

To supplement this literature review, Leavitt Partners also conducted interviews with ten subject matter experts representing the perspectives of both covered entities (including Federally Qualified Health Centers, Ryan White Clinics, and Disproportionate Share Hospitals hospitals) and drug manufacturers, as well as health economists and academic researchers. These interviews were conducted on background, enabling insights gleaned to be used in this paper while sources remain anonymous. The synthesized insights from these interviews informed the conclusions of the paper, and in many cases, the insights of experts are referenced throughout the paper (without direct attribution).

The goal of the interviews was to provide additional understanding into how the 340B program impacts drug prices charged by manufacturers and covered entities, fill in information and data gaps, and reconcile conflicting findings identified as part of the literature review. The analysis and conclusions included in this white paper are a product of these research efforts.

The methodology utilized for this paper is subject to several limitations. First, other than the insights from the interviewees, this paper uses only publicly available information. Since most pricing data is not publicly disclosed, this makes it difficult to perform a quantitative analysis of the effects of the program on pricing. Effort has been made to integrate the insights of as many relevant, high quality, reputable sources of differing perspectives as possible to be data-driven and fair-minded in the analysis. Second, the insights gleaned by the interviews with subject matter experts are limited to the perspectives of individuals with whom we spoke. Given the wide range of stakeholders that interact with the 340B program, it is likely that additional interviews may have generated alternative perspectives that could have been incorporated in this analysis. Third, the perspective of subject matter experts was limited to those individuals who agreed to speak with Leavitt Partners within the multiple-week research period in the fall 2022. Fourth, there may be additional general context about the 340B program, its history, and operations which this paper does not include that some readers would find to be important details or valuable context regarding the program.

PART I: BACKGROUND, DESIGN, AND FUNCTION OF THE 340 PROGRAM

The 340B Drug Pricing Program was created in 1992 and is named after its statutory location: Section 340B of the *Public Health Service Act* (PHSA).[1] While the purpose of the program is not specified in federal statute, according to the Health Resources and Services Administration (HRSA), which administers the 340B program, the program aims to "stretch scarce federal resources to reach more eligible patients or provide more comprehensive services."[2] The program requires pharmaceutical manufacturers participating in the Medicaid Drug Rebate Program to sell covered outpatient drugs at discounted prices to certain health care organizations.[3] These organizations, referred to as "covered entities," include a range of health care provider types specified in statute. These include:

- Disproportionate share hospitals (DSH) that have a DSH adjustment greater than 11.75 percent.4
- Sole community hospitals (SCH)
- Rural referral centers (RRC)
- Critical access hospitals (CAH)
- Children's hospitals and cancer hospitals that are excluded from the Medicare Prospective Payment System (MPPS)
- Organizations receiving grants from HRSA, including federally qualified health centers (FQHC), Native

[1] 42 C.F.R. Part 10 (2022)
[2] Health Resources and Services Administration. "340B Drug Pricing Program." Office of Pharmacy Affairs. U.S. Department of Health and Human Services. November 2022. https://www.hrsa.gov/opa
[3] Fact sheet: The 340B Drug Pricing Program: AHA. American Hospital Association. https://www.aha.org/system/files/media/file/2019/03/fact-sheet-340b-drug-pricinig-program-0119.pdf. Published March 2021.
[4] Health Resources and Services Administration. "Disproportionate Share Hospitals." Office of Pharmacy Affairs. U.S. Department of Health and Human Services. June 2022. https://www.hrsa.gov/opa/eligibility-and-registration/hospitals/disproportionate-share-hospitals

Hawaiian Health Centers, hemophilia diagnostic treatment centers, black lung clinics, and HIV/AIDS treatment organizations.[5]

Under HRSA guidance, outpatient clinics with the same physical address as the registered parent 340B covered entity do not need to separately enroll in the 340B Program, but offsite locations must separately register as "child sites" of the parent organization.[6] HRSA states that "child sites" may qualify for 340B status if "it is an integral part of a hospital that participates in the program, as evidenced by the fact that it is reimbursable on the hospital's Medicare cost report."[7]

The 340B ceiling price, which is the minimum discount that a manufacturer must offer, is calculated by taking the Average Manufacturer Price (AMP) from the preceding calendar quarter and subtracting the Unit Rebate Amount (URA).[8] The Centers for Medicare and Medicaid Services (CMS) calculates the URA for five different categories of drugs with each category having a different rebate calculation amount. The categories of drugs include single-source, innovator multiple sources, non-innovator multiple sources, clotting factor, and exclusive pediatric.[9] While 340B discount prices are not publicly available, the federal government estimates that the program enables covered entities to purchase "covered outpatient drugs" at a discounted rate of approximately 25 to 50 percent below their list price.[10] Eligible drugs include most outpatient drugs, insulin, and biologics.[11] Eligible outpatient drugs also include outpatient drugs used in connection with inpatient or outpatient services provided by DSH hospitals, children's hospitals, critical access hospitals, and rural referral centers.[12] The program excludes orphan drugs, which are "drugs intended to treat a condition affecting fewer than 200,000 persons in the United States,"[13] at rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals.[14]

Covered entities may dispense drugs purchased with 340B discounts to "eligible patients," defined by HRSA as patients who have an established relationship with the covered entity and receive health care services from a health care professional employed by the covered entity, but do not include services that are self-administered or administered in the home.[15] In addition, patients being served by FQHCs or HRSA grantees are only eligible if the health care service received is consistent with the service for which grant funding or FQHC status has been provided to the covered entity.[16] The Government Accountability Office (GAO) [17] and the HHS

[5] Health Resources and Services Administration. "340B Eligibility." Office of Pharmacy Affairs. U.S. Department of Health and Human Services. June 2022. https://www.hrsa.gov/opa/eligibility-and-registration

[6] Health Resources and Services Administration. "340B Drug Pricing Program Frequently Asked Questions." U.S. Department of Health and Human Services. HHS-0906--F-5220. June 22, 2020. https://www.hhs.gov/guidance/document/340b-drug-pricing-program-frequently-asked-questions

[7] Health Resources and Services Administration. "340B Glossary." 340B OPAIS. Office of Pharmacy Affairs. U.S. Department of Health and Human Services. 2022. https://340bopais.hrsa.gov/help/Links/340B_Glossary.htm

[8] Health Resources and Services Administration. "340B Drug Pricing Program Frequently Asked Questions." U.S. Department of Health and Human Services. HHS-0906--F-5220. June 22, 2020. https://www.hhs.gov/guidance/document/340b-drug-pricing-program-frequently-asked-questions

[9] Centers for Medicare and Medicaid Services. *Medicaid Drug Rebate Program*. "Unit Rebate Amount Information." U.S. Department of Health and Human Services. October 7, 2022. https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/unit-rebate-amount-calculation/index.html

[10] U.S. Gen. Accountability Office, GAO-20-212, 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement. (2020). https://www.gao.gov/products/gao-20-212

[11] 42 U.S.C. § 1396r–8 – Note: while the program is defined in the Public Health Services Act, the definition of covered outpatient drugs is included in the Social Security Act

[12] 42 C.F.R. Part 10 (2022)

[13] Center for Drug Evaluation and Research. "Orphan Drugs." *CDER Small Business Assistance Chronicles*. July 2012. https://www.fda.gov/media/83372/download

[14] Health Resources and Services Administration. "Orphan Drugs." Office of Pharmacy Affairs. U.S. Department of Health and Human Services. September 2022. https://www.hrsa.gov/opa/program-requirements/orphan-drug-exclusion

[15] Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 64 Fed. Reg. 55,156 (October 24, 1996). https://www.govinfo.gov/content/pkg/FR-1996-10-24/pdf/96-27344.pdf

[16] Mulligan, K. *The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments*. USC Leonard D. Schaeffer Center for Health Policy & Economics, University of Southern California. October 14, 2021. https://healthpolicy.usc.edu/research/the-340b-drug-pricing-program-background-ongoing-challenges-and-recent-developments/

[17] GAO-18-480, DRUG DISCOUNT PROGRAM: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement

Office of Inspector General [18] have raised questions about the scope and clarity of the current patient definition, which they view as quite broad.

In order to participate in the 340B program, covered entities must accurately account for eligible 340B dispensing, annually recertify their eligibility, prevent reselling of 340B eligible drugs, and not transfer 340B eligible drugs to ineligible patients.[19] In addition, the drug cannot be acquired using a group purchasing organization or a similar type of arrangement.[20] Finally, federal law prohibits covered entities from subjecting drug manufacturers to duplicate discounts in which drugs provided to Medicaid beneficiaries are subject to both the 340B Program discounted price and a Medicaid rebate.[21]

Importantly, the 340B statute itself only restricts how FQHCs and other HRSA grantees may use the savings associated with lower drug acquisition costs.[22] FQHCs "are statutorily required to invest all revenues, including 340B, into activities that are approved under their HRSA/Bureau of Primary Health Care Scope of Project and advance their charitable mission."[23] Likewise, other HRSA grantees must reinvest savings in the programs tied to their federal grants and account for how those dollars are being used.[24] Other types of covered entities, including DSH hospitals, are not limited in how they use 340B savings. Many covered entities state the savings generated by their participation in the 340B program are used to provide discounted care to uninsured, underinsured, or low-income patients.[25] At the same time, there is no federal statutory requirement that 340B hospital covered entities use the 340B savings in a prescribed manner, including to directly benefit uninsured, underinsured, or low-income patients. Additionally, there is no requirement that acquisition cost is the amount billed to patients and their insurers. The absence of a specific *requirement* has raised questions about whether or not the 340B program has effectively incentivized covered entities to increase some prices charged to patients and insurers, in order to capture a greater amount of 340B generated savings. This topic is material to the question of what is known about the prices charged by covered entities and is thus explored more in Part V of this paper. However, it should be said that aside from the absence of a formal requirement, many covered entities strongly support the 340B program because it makes it possible for them to provide certain benefits and services to patients.

PART II: HIGH LEVEL EXAMINATION OF DRUG PRICING

In order to understand the impact of the 340B program on drug prices, it is helpful to first consider the different ways of defining and measuring "price" in order to consistently and accurately track trends. It is important to note that a manufacturer's list price is rarely equal to what a patient or their plan pays. This is in part due to the role that pharmacy benefit managers, wholesalers, and pharmacies play in the system. In addition, when you layer in rebates and other discounts the price that a patient ultimately pays can change greatly. In short, there are multiple potential ways to assess a drug's "price" in the U.S.

[18] Examining Oversight Reports on the 340B Drug Pricing Program (05/18) (hhs.gov)
[19] Program Requirements | HRSA
[20] phs-act-section-340b.pdf (hrsa.gov)
[21] 42 U.S. Code § 256b - Limitation on prices of drugs purchased by covered entities | U.S. Code | US Law | LII / Legal Information Institute (cornell.edu)
[22] Part B Payments for 340B Purchased Drugs (OEI-12-14-00030; 11/15) (hhs.gov)
[23] PowerPoint Presentation (nachc.org)
[24] 2019_CANN_340B_Commission_Final-Report-v5_03-07-19.pdf (google.com)
[25] Fact Sheet: The 340B Drug Pricing Program | AHA

- **Wholesale acquisition cost (WAC):** "the manufacturer's list price for [a] drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price."[26] We will refer to the WAC as the "list price" throughout our analysis in this paper.

- **Average Manufacturer Price (AMP):** "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer."[27]

- **Average Sales Price (ASP):** the "revenue from a manufacturer's sales of a drug to all purchasers in the U.S. in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in the same quarter. The ASP is net of any discounts."[28]

- **Average Wholesale Price (AWP):** the average price paid by a retailer to purchase from a wholesaler.[29]

- **Usual and Customary Price (U&C):** what an individual without health insurance would pay at the pharmacy counter.[30]

Due to different measurements of price and some opaqueness around pricing, it can be challenging to accurately measure trends in pricing. As we stated earlier, AMP serves as the starting point for calculating the 340B ceiling price.[31]For the purposes of our analysis, we will focus on pricing trends for list price. From 2017-2022, gross spending at list price "increased from $581Bn to $776Bn — an average of 5.9% per year."[32] More recently, HHS found that "there were 1,216 products whose [list] price increases during the twelve-month period from July 2021 to July 2022 exceeded the inflation rate of 8.5 percent for that time period."[33] While the data is not always clear, we know generally that, similar to other sectors of health care, drug spending is steadily increasing, and that list prices are going up. However, pricing trends vary widely by a specific drug, manufacturer, and type of drug and also can fluctuate from year to year.

It is important to note that there is a multitude of factors that impact the list prices manufacturers set for a drug, such as an individual manufacturer's product portfolio and market position, payer mix, payer relationships, leadership, corporate culture, and overall strategy. Additionally, all manufacturers are also impacted by macro-economic conditions, state and federal policy changes, and global supply chain vulnerabilities. Complicating things further, the list price is rarely what a patient pays for a drug due to discounts negotiated by pharmacy benefit managers and mandated price concessions by government payers. Manufacturers are likely to factor in all forms of discounts when determining a launch list price. Given that all of these factors come into play simultaneously, it is virtually impossible to objectively disentangle a single

[26] Prescription Drug Wholesale Acquisition Cost (WAC) Increases - HCAI
[27] 42 C.F.R § 447.504
[28] Average sales price (ASP) payment system. *Glossary*. Alliance for Health Policy. https://www.allhealthpolicy.org/glossary/average-sales-price/. 2022.
[29] Levinson. D., *Medicaid Drug Price Comparison: Average Sales Price to Average Wholesale Price*. OEI- 03-05-00200. Office of Inspector General. U.S. Department of Health and Human Services. June 2005. https://oig.hhs.gov/oei/reports/oei-03-05-00200.pdf
[30] Dicken, J. *Prescription Drugs: Trends in Usual and Customary Prices for Commonly Used Drugs*. U.S. Gen. Accountability Office. February 10, 2011. https://www.gao.gov/assets/gao-11-306r.pdf
[31] Health Resources and Services Administration. "340B Drug Pricing Program Frequently Asked Questions." U.S. Department of Health and Human Services. HHS-0906--F-5220. June 22, 2020. https://www.hhs.gov/guidance/document/340b-drug-pricing-program-frequently-asked-questions
[32] Aitken, M., Kleinrock, M., Pritchett, J., *The Use of Medicines in the U.S. 2022: Usage and spending trends and outlook to 2026*. IQVIA Institute. April 21, 2022. https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us-2022
[33] Bosworth, A., Sheingold, S., Finegold, K., De Lew, N., Sommers, BD. "Price Increases for Prescription Drugs, 2016-2022." Office of Health Policy, Assistant Secretary for Planning and Evaluation. U.S. Department of Health and Human Services. September 30, 2022. https://aspe.hhs.gov/reports/prescription-drug-price-increases

factor in a manner that allows us to measure its sole impact on increases in prices or higher launch prices. Ultimately, through our literature review and interviews, we found support for the idea that the 340B program has some upward impact on drug prices.

PART III: FEDERAL 340B POLICY CHANGES AND THEIR IMPACT ON DRUG PRICES

The 340B program has undergone notable policy changes over its 30-year history that have led to significant expansion of the program. This is important to understand since the growth of mandatory discounts means the program has received more attention over time. The 2010 passage of the *Affordable Care Act* included expansions to the 340B program, including "expanding the definition of eligible entities… [and] the law also gives HRSA gives HRSA the power to enforce penalties on drug manufacturers or distributors who overcharge 340B entities."[34] In 2010, HRSA revised its guidance to allow covered entities to contract with an unlimited number of contract pharmacies.[35] As a result, the collective expansion of eligible covered entities (both in the types of entities and number of entities), the addition of child sites, and the unrestrained use of contract pharmacies have led to a significant increase in the number of pharmaceuticals purchased using the 340B ceiling price. The number of covered entities has grown from 8,100 in 2000 to more than 28,000 in 2014 and 53,000 in 2022.[36, 37] In addition, the total amount of drugs purchased at the 340B ceiling price under the program increased from $4 billion per year from 2007-2009 to almost $44 billion in 2021.[38, 39] Estimates indicate that "drug purchases through the 340B program amounted to roughly 7 percent of the total U.S. drug market."[40]

PART IV: ANALYSIS OF THE IMPACT OF 340B ON DRUG PRICES CHARGED BY PHARMACEUTICAL MANUFACTURERS

While the internal processes that pharmaceutical manufacturers use to set drug list prices are proprietary and thus purposefully opaque, as stated above, a multitude of factors are thought to influence pricing decisions including an individual manufacturer's product portfolio and market position, payer mix, payer relationships, leadership, corporate culture, and overall strategy, as well as macro-economic conditions, state and federal policy changes, and global supply chain vulnerabilities. Subject matter experts that we spoke with also reported that figuring into pricing decisions are the costs imposed on manufacturers by government-mandated drug discount programs, including the 340B program.

Through our literature review and interviews, we found support for the idea that the 340B program has some impact on how drug manufacturers set prices. One study we looked at found that the 340B program reduced manufacturer revenues by 1.9 percent in 2015 and that if manufacturers had not had to offer 340B discounts,

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[34] Primer: Understanding the 340B Drug Pricing Program - AAF (americanactionforum.org)

[35] Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services. 75 FR 10,272 (March 5, 2010). https://www.federalregister.gov/documents/2010/03/05/2010-4755/notice-regarding-340b-drug-pricing-program-contract-pharmacy-services

[36] Mulligan, K. *The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments*. USC Leonard D. Schaeffer Center for Health Policy & Economics, University of Southern California. October 14, 2021. https://healthpolicy.usc.edu/research/the-340b-drug-pricing-program-background-ongoing-challenges-and-recent-developments/

[37] "Overview of the 340B Drug Discount Program." Congressional Research Service. October 14, 2022. https://crsreports.congress.gov/product/pdf/IF/IF12232

[38] Mulligan, K. *The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments*. USC Leonard D. Schaeffer Center for Health Policy & Economics, University of Southern California. October 14, 2021. https://healthpolicy.usc.edu/research/the-340b-drug-pricing-program-background-ongoing-challenges-and-recent-developments/

[39] Fein, AJ. "The 340B Program Climbed to $44 Billion in 2021—With Hospitals Grabbing Most of the Money." *Drug Channels.* August 15, 2022. https://www.drugchannels.net/2022/08/the-340b-program-climbed-to-44-billion.html

[40] Clark, B., and Puthiyath, MS. "The Federal 340B Drug Pricing Program: What It Is, and Why It's Facing Legal Challenges" (explainer), Commonwealth Fund, Sept. 8, 2022. https://doi.org/10.26099/c4z8-pf65

their revenues could have been notably greater.[41] Some experts we spoke with noted that it seems plausible that manufacturers would seek to make up for some of this "lost" revenue through other mechanisms. Researchers have posited that the 340B program may contribute to rising drug prices due to manufacturers shifting some of the perceived revenue losses by increasing drug prices for other payers.[42]

Drug manufacturers have previously stated that the size of the 340B program creates market-distorting incentives that affect consumer prices for medicines.[43] For example, a study in the *Journal of the American Medical Association* found that list prices for medicines are likely higher than they otherwise would be "to offset revenue losses incurred as a larger number of drug sales become eligible for 340B discounts (and thus, fewer drugs are sold at full price)."[44] The study based this assertion partially on the assessment that an analogous response was seen when Congress enacted mandatory rebates for the purchase of drugs for Medicaid-eligible patients.[45, 46]

An additional study examining drug pricing trends for anticancer drugs found that government-mandated price discounts for certain classes of buyers may have contributed to launch price increases as firms sought to offset the growth in the discount segment by setting higher prices for the remainder of the market.[47] This study concluded that because the 340B discount is based on a drug's average price, the program presents manufacturers with an incentive to set higher launch prices to offset discounts.[48]

In contrast to the perspective on launch prices, there is some research suggesting that inflationary penalties may discourage future price increases. Specifically, a cross-sectional study of 606 brand-name drugs (that were used annually by more than 5,000 individuals with Medicare Part D coverage from 2013 to 2017) found that increases in the percentage of drug sales subject to inflation penalties in the 340B program were associated with lower drug price increases.[49] The study's author found no data to indicate that inflation penalties or discounts in the 340B program were associated with higher price increases, and the author concludes that the broader application of inflation penalties may help to reduce drug price increases.[50]

An additional study examined manufacturer net revenues after list price reductions for hepatitis C treatments.[51] In 2018, three hepatitis C antiviral curative treatments experienced price reductions of 60 percent. Following the price change, 340B-covered entity revenues for each course of treatment decreased by 60 percent to 75 percent and manufacturer revenues from sales to 340B-covered entities increased by 82 percent to 750 percent for each course of treatment. The average per-treatment manufacturer revenue (weighted by the share of 340B and non-340B sales) increased by 19 percent to 28 percent for each course of

[41] Dickson, S., Coukell, A., Reynolds, I. "The Size of the 340B Program and Its Impact on Manufacturer Revenues", Health Affairs Blog, August 8, 2018. DOI: 10.1377/hblog20180807.985552.
[42] Conti RM, Bach PB. "Cost Consequences of the 340B Drug Discount Program." JAMA. 2013;309(19):1995–1996. doi:10.1001/jama.2013.4156
[43] "Comments on HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs." CMS-2018-0075-2808. Pharmaceutical Research and Manufacturers of America. July 19, 2018. https://www.regulations.gov/document/CMS-2018-0075-2808
[44] Conti RM, Bach PB. "Cost Consequences of the 340B Drug Discount Program." JAMA. 2013;309(19):1995–1996. doi:10.1001/jama.2013.4156
[45] Id.
[46] Congressional Budget Office. "How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry." January 1996. https://www.cbo.gov/sites/default/files/104th-congress-1995-1996/reports/1996doc20.pdf
[47] Howard, DH., Bach, PB., Berndt, ER., and Conti, RM. 2015. "Pricing in the Market for Anticancer Drugs." Journal of Economic Perspectives, 29 (1): 139-62. DOI: 10.1257/jep.29.1.139
[48] Id.
[49] Dickson, S. "Association Between the Percentage of US Drug Sales Subject to Inflation Penalties and the Extent of Drug Price Increases." JAMA Netw Open. 2020;3(9):e2016388. doi:10.1001/jamanetworkopen.2020.16388
[50] Id.
[51] Dickson, S., Reynolds, I. "Estimated Changes in Manufacturer and Health Care Organization Revenue Following List Price Reductions for Hepatitis C Treatments." JAMA Netw Open. 2019;2(7):e196541. doi:10.1001/jamanetworkopen.2019.6541

treatment. The authors of the study hypothesize that manufacturers may prefer to reduce the list price of certain drugs that have a larger 340B market share, which could reduce both the overall 340B discount and relevant PBM rebate payments, leading to overall higher revenues. The authors conclude that a large 340B market share for a product may encourage manufacturers to offer discounts through reduced list prices rather than through PBM rebates, counter to the idea that 340B discounts lead to higher prices.

In general, covered entities have been skeptical of the concern that the growth in the 340B program may be a factor in the prices drug manufacturers charge. A 2017 study sponsored by a trade association representing covered entities assessed the financial impact of the 340B program on drug manufacturers and found that the 340B program represents only a small part of overall drug spending, and that 340B obligations are a small portion of the total discounts provided by manufacturers to other market entities.[52] The study concluded that the 340B program was not a major driver of changes in overall U.S. drug expenditures, nor a major cause of cost-shifting by drug manufacturers to make up for the discounts provided under the program.[53]

Although the studies cited above offer compelling evidence that the 340B program does have some impact on the way pharmaceutical manufacturers price their drugs, it is difficult to quantify with any certainty how much of an impact the 340B program has on list prices. Research into this area has been limited, and the studies have reached varied and sometimes conflicting conclusions. Several of the subject matter experts we spoke with said they believed the 340B program does indeed have an impact on the way that manufacturers set prices, although by what degree and in what instances is unknown. They noted that pricing is a complex process, and that all market factors are considered when setting the launch price or changing the list price of a product, including the impact of the 340B program. While they observed the 340B program was clearly a meaningful factor to consider, they did not view the program as an overriding factor in changes to the list price for a drug once it is on market.

However, in contrast to changes to a drug's list price once it is on market, several of the experts we spoke with suggested the pricing impact of the 340B program is more of a consideration for new drugs than for existing products on the market. That is because the size and potential impact of 340B discounts are calculated as part of the pre-launch planning process, and the assumptions about the 340B program's impact on overall sales figures into the life-cycle planning of a new product. At least one interviewee noted that as the 340B program continues to grow, a manufacturer will have to factor in larger 340B discounts into pricing decisions. This interviewee also noted 340B's impact on pricing is product dependent, with 340B having a greater pricing impact on specialty drugs due to the potential for larger rebates.

The experts we interviewed all agreed that while the 340B program likely has some upward impact when manufacturers set the list price of drugs, assessing the magnitude of the program's impact on manufacturer pricing is very challenging. A consistent theme we heard from most interview participants was that a lack of data has made it difficult to fully assess how the 340B program impacts drug pricing.

PART V: ANALYSIS OF THE IMPACT OF 340B ON DRUG PRICES CHARGED BY COVERED ENTITIES

To better understand the prices for drugs charged by covered entities to patients and their health plans (usually via an in-house pharmacy or an arrangement with a contract pharmacy), it is important to understand

[52] Dobson, A., Murray, K., DaVanzo, JE. *Assessing the Financial Impact of the 340B Drug Pricing Program on Drug Manufacturers*. 340B Health. Dobson & DaVanzo. July 2017. https://www.340bhealth.org/files/340B_Financial_Impact_7_17.pdf

[53] Id.

whether covered entities charge drug prices that are higher than the 340B ceiling price, which is the maximum price that manufacturers may charge covered entities for eligible drug purchases (the 340B ceiling price). GAO found that, "covered entities can generate revenue when they purchase 340B drugs for eligible patients whose insurance reimbursement exceeds the 340B price paid for the drugs."[54] In fact, generating revenue through this mechanism is an important tool that hospitals can use to increase revenue available for services and operations. For example, the Medicare Payment Advisory Committee reported that "340B hospitals seek to preserve the current criteria for eligibility for the program and their ability to use revenue generated through the program without restrictions."[55] Some covered entities have acknowledged that "they generated 340B program revenue that exceeded drug-related costs."[56] In addition, every interviewee – economists, researchers, manufacturers, and covered entities – noted that some covered entities are charging prices higher than the 340B ceiling price. Thus, our literature review and interviews support the finding that some covered entities charge drug prices that are higher than the 340B ceiling price.

Covered entities underscore that the point of the 340B program is to enable them to stretch scare federal resources and generate savings which in turn can be deployed to provide services in line with their mission of helping patients. This may include passing on savings to certain patients, but is not limited to that sole objective intentionally. Savings may also help reduce costs and/or provide additional benefits and services. Survey results from a trade association of covered entities report that "88 [percent] of DSH/RRC/SCH hospitals used 340B savings to offset the cost of uncompensated and unreimbursed care and 89 percent reported savings helped support medication adherence to help patients get well and stay well."[57] The trade association of Ryan White Clinics reported that some savings go directly to lowering drug costs to patients but RWCs also use savings for other purposes. They said, "most covered entities do, in fact, provide medications to needy patients at little or no cost … But using the program for the sole purpose of lowering patient drug costs would do a grave injustice to patients… The strength of the 340B program is that it allows a covered entity to use drug savings to address and mitigate the barriers to care that are unique to patients within that entity's service area."[58]

In our interviews, covered entities stated that 340B savings are used for a variety of services that advance the mission of the specific covered entity type. One interviewee from a FQHC highlighted that health centers are required by statute to provide a sliding fee scale to patients based on income, ensuring that some of the savings are passed on directly.[59] One study from 2012 found that, on average, uninsured patients receiving 340B medications from a FQHC saved more than $62 per medication than they otherwise would have.[60] They also noted that program savings also allows health centers to provide a variety of needed services, that they

[54] Draper, DA. "Drug Discount Program: Improvements Needed in Federal Oversight of Compliance at 340B Contract Pharmacies." Testimony before the House Energy and Commerce Health Subcommittee. U.S. Gen. Accountability Office. July 11, 2018. https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Testimony-Draper-HE-Hrg-on-Opportunities-to-Improve-the-340B-Drug-Pricing-Program-2018-07-11.pdf

[55] Medicare Payment Advisory Commission. "Overview of the 340B Drug Pricing Program." *Report to the Congress.* May 2015. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf

[56] U.S. Gen. Accountability Office, GAO-11-836, Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement. (2011). https://www.gao.gov/assets/gao-11-836.pdf

[57] 340B Health. "2021 340B Health Annual Survey: 340B Continues to Support Essential Programs and Services in the Face of Significant Financial Stress on Hospitals." (2022). https://www.340bhealth.org/files/340B_Health_Survey_Report_2021_FINAL.pdf

[58] Ryan White Clinics for 340B Access. "Federal and State Policymakers: Beware of Drug Companies' Disinformation Campaign." September 31, 2022. https://rwc340b.org/wp-content/uploads/2022/09/RWC-340B-Rebuttal-to-Drug-Industry-Attacks-on-340B.pdf

[59] National Association of Community Health Centers. "330 Statute." 2020. https://www.nachc.org/focus-areas/policy-matters/health-center-funding/330-program-requirements/

[60] Castellon YM, Bazargan-Hejazi S, Masatsugu M, Contreras R. "The impact of patient assistance programs and the 340B Drug Pricing Program on medication cost." The American Journal of Managed Care. 2014 Feb;20(2):146-150. PMID: 24738532.

otherwise would not be able to offer, to underserved patients across a large, geographically diverse footprint.

An interviewee from a DSH hospital noted that the services 340B program savings enable hospitals to provide are more expansive than the "community benefit" definition required by the IRS for a not-for-profit hospital's tax status. While a DSH hospital's status as a covered entity in the 340B program is not tied statutorily to the amount of community benefit it provides, the interviewee highlighted this perspective because many researchers have used community benefit as a proxy for quantifying the services a hospital provides to uninsured patients that are funded using the 340B revenue. The interviewee said their hospital not only gives back more in community benefit than they generate in revenue from the 340B program, but the hospital is also a loss leader providing services such as a burn unit, that otherwise would not exist without the extra revenue from the 340B program.

Economists and researchers are generally more cautious about what can be said definitively about the extent to which covered entities are using program savings to help provide lower costs or greater benefits and enhanced services for patients. As one would expect, they point to the heterogeneity of covered entities in the program, diversity of patient populations, varieties of business models, the various ways to measure extra benefits and services, etc., and note that without more comprehensive data, it is challenging to characterize covered entities as a whole. HHS OIG has attempted to overcome this challenge by surveying subsets of covered entity types (FQHCs and DSH hospitals). The agency found that some covered entities "do not offer the discounted 340B price to uninsured patients in their contract pharmacy arrangements."[61] Another study found that uncompensated care varies widely for 340B covered entities, with 25 percent of covered entities spending "less than 1.9 percent of their budget on uncompensated care" while another 25 percent spent 6.5 percent of their budget.[62] The same authors in another study compared hospital behavior before and after joining the 340B program and found that "newly participating hospitals may increase charity care, potentially through offering more patients discounted care." However, this same study found that such "increases appear to be fully offset by reductions in other community benefit programs" indicating that joining the program did not result in a net new benefit to patients.[63] A recent media story explained how one 340B DSH hospital used revenue generated from the 340B program at a community hospital that mostly served lower income patients to invest in child site clinics in wealthier neighborhoods. These child sites, in turn, took advantage of the 340B savings to drive significant revenue.[64]

It is important to highlight the data limitations in trying to obtain a precise understanding of the drug prices covered entities provide. On the one hand, the limited evidence from research and the anecdotal responses from surveys and interviews indicates that covered entities in many cases do use the 340B revenue to reduce prices directly or indirectly for benefits or services that benefit patients. On the other hand, however, "there is no statutory requirement for covered entities to document how they use revenue from the program," and our literature review found no authoritative, definitive source of data that could better characterize covered entities' practices as an overall sector.[65] This dynamic somewhat helps explain why the function of the

[61] Wright, S., *Contract Pharmacy Arrangements in the 340B Program*. OEI-05-13-00431. Office of Inspector General. U.S. Department of Health and Human Services. February 4, 2014. https://oig.hhs.gov/oei/reports/oei-05-13-00431.asp

[62] Nikpay, S., Buntin, MB., Conti, RM. "The 340B Program: Mandatory Reporting, Alternative Eligibility Criteria Should Be Top Priorities For Congress", Health Affairs Blog, October 10, 2017. DOI: 10.1377/hblog20171021.982593

[63] Nikpay, SS, Buntin, MB & Conti, RM 2020, 'Relationship between initiation of 340B participation and hospital safety-net engagement', Health services research, vol. 55, no. 2, pp. 157-169. https://doi.org/10.1111/1475-6773.13278

[64] Thomas, K., Silver-Greenberg, J. "Profits Over Patients: How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits." *The New York Times.* September 24, 2022. https://www.nytimes.com/2022/09/24/health/bon-secours-mercy-health-profit-poor-neighborhood.html

[65] Medicare Payment Advisory Commission. "Overview of the 340B Drug Pricing Program." *Report to the Congress.* May 2015. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf

program has been characterized at times by studies with different findings, as well as seemingly contradictory narratives and competing anecdotes.

An economist interviewee said the 340B program functions economically similarly to a hospital fundraiser, in that it generates revenue that is invested into activities that most impact that hospital's ability to remain financially solvent and carry out their mission. The economist noted that, because money is fungible, 340B revenue could lead a hospital to either reduce out-of-pocket costs and increase services to low-income patients, or to invest in other highly lucrative lines of service – or engage in both activities during different time frames. Several of these activities could *reduce* prices for patients or provide new services or benefits at no cost. However, economists and researchers unanimously agreed that because the program lacks transparent data, it is extremely challenging to make definitive conclusions how program savings are used, and to what extent program participation reduces prices covered entities charge.

One related question that researchers have sought to answer is whether or not the 340B program on a macro level incentivizes behaviors that lead to increases in the prices charged by covered entities. This includes examining whether the 340B program inadvertently encourages the prescribing of more expensive drugs to the patient. A Milliman study compared "the drug mix and utilization between 340B and non-340B hospitals and concluded that a mix of drugs with higher average allowed claim costs is the primary driver of the higher pharmacy spend at 340B DSH hospitals compared to non-340B DSH hospitals." [66] Notably, "the utilization of drugs is relatively similar at both 340B and non-340B hospitals," but "the average allowed cost of those scripts was more than 150% greater than the cost per script among non-340B [hospitals]." An economist interviewee noted DSH hospitals that have a high number of commercial patients in a particular specialty with expensive drugs that have high margins due to the 340B discount have a financial incentive to invest in these specialties. In contrast, hospitals will limit investments in specialties whose patient case mix is largely comprised of uninsured and Medicaid eligible patients, resulting in limited 340B discounts. However, covered entity interviewees underscored prescribing patterns are driven by physicians who are focused on adhering to the best clinical standards of care and meeting the needs of patients. Moreover, they noted that individual physicians are not aware of what the negotiated rates are for each drug they may prescribe. Furthermore, they noted physicians often help patients avoid excess costs by utilizing less expensive generics and biosimilars where possible, to improve a patient's ability to stay on treatment.

A second macro level factor to consider as it relates to the 340B and the drug prices charged by covered entities is the role the program may play in driving consolidation of market power that would lead to price increases. The data is clear that consolidation and vertical integration in health care often ultimately lead to higher prices.[67] Studies have found that consolidation by hospitals and physician practices generally increased prices by 11 – 54 percent and 14 – 30 percent due to increased market power.[68]

Evidence suggests that there is not an insignificant connection between some forms of hospital and provider consolidation and the 340B program. One study found that "hospital eligibility for the 340B Program was associated with 2.3 more hematologist–oncologists practicing in facilities owned by the hospital,

[66] Hunter, MT., Holcomb, K., Kim, C. *Analysis of 2020 Commercial Outpatient Drug Spend at 340B Participating Hospitals.* Milliman. September 2022. https://www.milliman.com/-/media/milliman/pdfs/2022-articles/9-13-22_phrma-340b-commercial-analysis.ashx

[67] Brown, EF. "State Policies to Address Vertical Consolidation in Health Care." Center for Health System Costs, National Academy of State Health Policy. August 7, 2020. https://www.nashp.org/state-policies-to-address-vertical-consolidation-in-health-care/

[68] Schwartz, K., Lopez, E., Rae, M., Neuman, T. "What We Know About Provider Consolidation." Kaiser Family Foundation. September 2, 2020. https://www.kff.org/health-costs/issue-brief/what-we-know-about-provider-consolidation/

or 230 percent more hematologist–oncologists than expected in the absence of the program."[69] Specialty care at hospitals tends to be very expensive, so additional investments of this magnitude are not insignificant.[70] Additionally, some hospital executives have acknowledged that 340B is a factor in considering partnerships and acquisition opportunities.[71]

Most interviewees concluded that the 340B program does incentivize consolidation to acquire more market power and capture commercial insurance patients whose health plan may reimburse for 340B drugs at a rate much higher than the 340B ceiling price. As one economist described it, consolidation and the increase in 340B covered entities have inherently led to higher prices in aggregate, we just do not know the order of magnitude of such prices or who bears these prices. The effect would vary by market and provider.

Covered entities point out that consolidation is a secular trend driven by the economic, market, and policy realities well outside of the reach of the 340B program so the program's role should not be considered the driving factor for increased prices associated with consolidation. In addition, one covered entity noted that without acquiring 340B status, many smaller hospitals would have no choice but to close their doors, which would reduce services to patients in the area.

PART VI: IDENTIFICATION OF DATA GAPS

As previously stated, a multitude of factors are thought to influence manufacturer pricing decisions. While one can speculate on what factors a manufacturer may weigh most heavily when making pricing decisions, individual manufacturer pricing formulas are proprietary, and manufacturers do not generally disclose this information. While our interviews were helpful in establishing that the 340B program factors into drug pricing decisions, without additional data establishing how manufacturers weigh 340B discounts, it will remain difficult to fully quantify the impact of the 340B program on manufacturer drug pricing decisions.

It is also not possible to provide a complete analysis of the 340B program's impact on the drug prices charged by covered entities without comprehensive data about the drug prices covered entities charge commercial payers and patients for 340B drugs. In addition, data showing changes in dispensing rates for brand drugs, generics, biologics, and biosimilars over the last decade would shed more light on whether the program may discourage the adoption of more affordable medication that would consequently drive down drug prices.

Additional information that could prove useful in the further evaluation of the 340B program's impact on drug prices would be data showing the number and types of patients who receive a discounted medication, either through the 340B discounted price being directly passed on with a discount card or through other means, such as charitable assistance, copay programs, or a sliding fee scale.

Finally, limited data availability leads many studies and stakeholders to draw sweeping generalizations about other actors as it relates to the 340B program. If more data were to become available, more definitive and granular conclusions could be drawn if the data were segmented by manufacturer portfolio and type of covered entity. Such breakdowns could allow for a better understanding of the true scope of the pricing factors discussed in this paper and whether or not a certain factor or behavior is limited to a certain kind of

[69] Desai, S., McWilliams, JM. " Consequences of the 340B Drug Pricing Program." N Engl J Med 2018; 378:539-548; DOI: 10.1056/NEJMsa1706475
[70] New Study: Hospitals Charge Double for Drugs - Specialty… - AHIP
[71] Pollack, A. "Dispute Develops Over Discount Drug Program." *The New York Times.* February 12, 2013. https://www.nytimes.com/2013/02/13/business/dispute-develops-over-340b-discount-drug-program.html

organization or is more indicative of the entire system.

PART VII: CONCLUSION

Through the course of our research and interviews, we found compelling evidence that the 340B program does impact how pharmaceutical manufacturers set list prices for drugs and the drug prices covered entities charge patients and various payors. Manufacturers weigh numerous factors when setting drug list prices, which our research suggests includes consideration of how the 340B program will impact new drugs entering the market and the program's continued effect on existing drugs on the market. There is also evidence that some covered entities charge patients and payors drug prices that are higher than their 340B acquisition cost to generate additional revenue, a permissible feature of the 340B program.

Measuring the magnitude of the 340B program's impact on drug pricing decisions by manufacturers and covered entities have been more challenging. This has been due to constraints on the availability of data, as well as a generally limited amount of comprehensive research into this subject area. Existing research has suggested that the 340B program impacts the way manufacturers set list prices, but studies have sometimes reached conflicting conclusions as to whether the program leads to higher or lower list prices. While several interviewees expressed a belief that the 340B program impacts manufacturer list prices, none could offer a conclusive assessment of the scope of such an impact.

It has also been challenging to measure the 340B program's impact on covered entity drug pricing decisions. The 340B program allows covered entities to capture 340B generated savings by increasing prices charged to patients and various payors above the cost of drug acquisition. Sufficient data on prices covered entities charge for 340B drugs is not publicly available, making it nearly impossible to assess how the 340B program impacts covered entity pricing decisions as a whole.

The 340B program has grown considerably since its inception and appears poised for continued growth in the coming years. Should additional data concerning how pharmaceutical manufacturers and covered entities factor the 340B program into pricing decisions become available in the future, there will likely be continued interest in further exploration of this complex topic.

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