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Fact Sheet: The 340B Drug Pricing Program

The Issue

For more than 30 years, the 340B Drug Pricing Program has provided financial help to hospitals serving vulnerable communities to manage rising prescription drug costs.

Section 340B of the Public Health Service Act requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to health care organizations that care for many uninsured and low-income patients. These organizations include federal grantee organizations and several types of hospitals, including critical access hospitals (CAHs), sole community hospitals (SCHs), rural referral centers (RRCs), and public and nonprofit disproportionate share hospitals (DSH) that serve low-income and indigent populations.

The program allows 340B hospitals to stretch limited federal resources to reduce the price of outpatient pharmaceuticals for patients and expand health services to the patients and communities they serve. Hospitals use 340B savings to provide, for example, free care for uninsured patients, offer free vaccines, provide services in mental health clinics, and implement medication management and community health programs.

According to the Health Resources and Services Administration (HRSA), which is responsible for administering the 340B program, enrolled hospitals and other covered entities can achieve average savings of 25% to 50% in pharmaceutical purchases. Despite significant oversight from HRSA and the program's proven record of decreasing government spending and expanding access to patient care, some want to scale it back or drastically reduce the benefits that eligible hospitals and their patients receive from the program.

AHA Position

- Protect the 340B program for all providers and ensure the program continues to help providers stretch limited resources and provide more comprehensive services to more patients.
- Advocate that the Department of Health and Human Services (HHS) remedy all affected hospitals for the unlawful Medicare payment cuts and expand drug manufacturer transparency.
- Thwart drug manufacturers' efforts to unilaterally and unlawfully change the 340B program.

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- Support eliminating the orphan drug exclusion for certain 340B hospitals.
- Oppose efforts to scale back, significantly reduce the benefits of, or expand the regulatory burden of the 340B program, including proposals to dramatically expand reporting requirements on certain 340B hospitals and impose a moratorium on new entrants into the program.
- Support expanding the program to reach additional vulnerable communities, including investor-owned hospitals that provide care for underserved populations.
- Support program integrity efforts that are equitable and accountable for both providers and drug companies to ensure adherence to the program's rules and regulations.

Why?

- **340B-eligible hospitals are the safety net for their communities.** The 340B program allows eligible hospitals to further stretch their limited resources and provide additional benefits and services. These hospitals care for a significant share of the nation's underserved populations including children, cancer, and rural patients.
- **The 340B program generates valuable savings for eligible hospitals to invest in programs that enhance patient services and access to care.** Communities in need could lose access to valuable, life-saving care without the financial support from the 340B program.
- **The 340B program is a small program with big benefits.** In 2010, Congress expanded the benefits of the 340B program to CAHs, RRCs, SCHs and free-standing cancer hospitals. While these newly-eligible hospitals represent 54% of actively participating 340B hospitals, the drugs used by these hospitals account for only a small fraction of drugs sold through the 340B program. Other factors that attribute to the program's growth include the increased volume of outpatient care and the increased use of specialty drugs.
- **The Medicare payment cuts to 340B hospitals are unlawful, payment should be restored and other hospital payments should be protected.** As part of the outpatient prospective payment system final rule for calendar year 2018 and subsequent years, CMS implemented drastic cuts to Medicare payments for drugs that are acquired under the 340B program. These payment cuts came on top of the fact that Medicare chronically underpays hospitals for services. The AHA, joined by member hospitals and health systems and other national hospital organizations sued the government over the payment cuts. A federal district court sided with the AHA and found that the payment reductions were unlawful. In June 2022, the Supreme Court unanimously ruled in favor of the AHA. The issue is currently pending before CMS to determine a remedy for these five years of underpayments. Any remedy by CMS must promptly repay 340B hospitals the full amount of money that was unlawfully withheld

and ensure that all hospitals are held harmless from any recoupments due to the agency's own mistakes.

- **Drug manufacturers are undermining the program.** Several of the largest drug manufacturers have unilaterally stopped providing discounts to 340B drugs dispensed through community and specialty pharmacies that contracted with 340B covered entities, violating the 340B statute. This illegal action threatens the integrity of the 340B program and the savings on which covered entities rely to provide care to millions of low-income Americans. This move is especially outrageous considering hospitals are facing record-high inflationary cost pressures driving negative operating margins for many hospitals around the country.
- **The 340B Program is not a rebate program.** In yet another attempt to damage the program, drug manufacturers are attempting to convert the means by which covered entities access discounted 340B pricing from an upfront discount to a back-end rebate. This approach complicates providers' access to discounts, requires that financially-strapped organizations provide upfront financing and await reimbursement, and adds considerable burden and cost to the health care system. This new rebate model also violates federal policy. AHA has urged HRSA to order drug manufacturers and their third party vendor to immediately halt their attempts to convert the 340B program to a back-end rebate program.
- **The 340B program requires participating hospitals to meet numerous program integrity requirements.** Hospitals must recertify annually their eligibility to participate and attest to meeting all the program requirements; participate in audits conducted by HRSA and drug manufacturers; and maintain auditable records and inventories of all 340B and non-340B prescription drugs. The AHA and its 340B hospital members support efforts that help covered entities comply with the program requirements.
- **340B hospitals are committed to improving transparency.** The AHA is working with its 340B member hospitals on efforts to strengthen the 340B program by increasing transparency in the program and helping 340B hospitals communicate publicly the immense value the program brings to patients and communities, such as through the AHA Good Stewardship Principles.
- **Additional transparency is needed from drug manufacturers.** As a result of AHA's successful lawsuit, HRSA issued its final rule to strengthen the agency's oversight of 340B ceiling prices to discourage manufacturers from raising prices faster than inflation and improve transparency. The AHA is pleased HRSA has implemented this important rule and provided the required web-based information so 340B hospitals can access the 340B ceiling prices. While this is an important first step, additional transparency is needed from drug companies as they continue to raise the prices of their drugs significantly and introduce new drugs at record-high prices.

August 26, 2020

The Honorable Alex M. Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar:

On behalf of the nation's 340B hospitals, we urge you to protect vulnerable communities from actions taken by five of the nation's largest pharmaceutical manufacturers that undermine access to critical drugs and other health care services. We ask the Department of Health and Human Services (HHS) to use its authority to require that these and other pharmaceutical manufacturers comply with the law. This is particularly critical now as these hospitals need every resource available to care for their patients in vulnerable communities during the COVID-19 public health crisis.

So far, a number of companies are complicit with these unlawful tactics:

Eli Lilly

Last month, Eli Lilly announced that effective July 1, 2020, the company will no longer provide 340B pricing on three of its products when purchased by 340B hospitals to be dispensed by 340B contract pharmacies.[1] This refusal to sell a drug at a 340B price is a violation of the statute's requirement that manufacturers offer 340B prices to eligible covered entities. Eli Lilly has left open the possibility that it will extend this policy to other drugs, which include several high-priced drugs to treat diabetes.

AstraZeneca

The drug manufacturer AstraZeneca recently announced that, starting October 1, 2020, it will no longer offer 340B pricing to covered entities for any drugs that will be dispensed through contract pharmacies. AstraZeneca sells a wide range of products eligible for 340B pricing, including many costly cancer and diabetes drugs that do not have lower-priced generic alternatives. Cutting off access to 340B pricing for these expensive products would significantly reduce hospital access to program savings, affecting their ability to provide services to patients.

[1] Limited Distribution Plan Notice for Cialis® (tadalafil) Erectile Dysfunction NDCs, https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/limited-distribution-plan-notice-cialis.pdf.

Section 340B(a)(1) of the Public Health Services Act requires manufacturers to sell covered outpatient drugs to covered entities at or below the 340B ceiling price if such drug is made available to any other purchaser at any price.[2] There is no provision under the statute that allows these companies to deny 340B pricing to a covered entity for any drug. Therefore, these policies are a clear violation of the law, and HHS is compelled to take action to stop it from being carried out.

Merck

On June 29, Merck sent letters to 340B covered entities asking them to submit contract pharmacy claims data for "commonly dispensed" Merck drugs to allow the company to prevent duplicate discounts related to contract pharmacies. Without "significant cooperation" from covered entities, Merck says it "may take further action to address 340B Program integrity." While Merck did not state that such action would include no longer offering 340B pricing to covered entities for drugs dispensed by contract pharmacies, we are concerned the company appears poised to do so.

Sanofi

The drug manufacturer Sanofi sent letters last month similar to those sent by Merck threatening to deprive 340B covered entities' access to discounted drugs for dispensing through contract pharmacies if the claims data demanded are not supplied to the company by October 1.

Novartis

In a similar manner, Novartis recently sent letters to 340B covered entities requiring them to submit all 340B claims data originating from contract pharmacies beginning October 1, stating that 340B discounts will be unavailable to entities that fail to do so.

As you are aware, Congress created the 340B drug pricing program to allow hospitals and other covered entities serving vulnerable populations "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[3] Covered entities use the savings from the high prices of prescription drugs enabled under the 340B drug program to support care for vulnerable communities in a variety of ways, including supporting clinic and medical services that would otherwise be unavailable.

If left unaddressed, these actions will open the way for other drug manufacturers to deny discounts for other products. This is clearly contrary to the intent of the 340B program

[2] 42 U.S.C. § 256b(a)(1).
[3] H.R. Rep. 102-384(II) at 12 (1992).

and will result in significant harm to the millions of patients and communities who rely on providers that participate in the program for their care.

At a time when our nation and our hospitals are focused on confronting the global pandemic of COVID-19 and dealing with the continuing increase in prescription drug costs, we urge the Department to use its authority to address these troubling actions and assure that the pharmaceutical industry does not prioritize excess profits over care for vulnerable communities. We thank you for your continued leadership.

Sincerely,

340B Health
America's Essential Hospitals
American Hospital Association
American Society of Health-System Pharmacists
Association of American Medical Colleges
Catholic Health Association
Children's Hospital Association

cc: Eric D. Hargan, Deputy Secretary, Department of Health and Human Services
Thomas J. Engels, Administrator, Health Resources and Services Administration
Krista Pedley, Director, Office of Pharmacy Affairs, Health Resources and Services Administration

6/22/2022

Hospitals Rely on 340B for Patient Care

Kate Traynor (mailto:ktraynor@ashp.org)
Senior Writer
News Center

At hospitals across the country, pharmacy leaders rely on the 340B Drug Pricing Program to partially offset the cost of uncompensated care and to provide critical services in the community.

During the 2021 fiscal year, Sharp HealthCare in San Diego, California, reported (https://www.sharp.com/about/community/community-benefits/upload/FY21-Community-Benefits-Report-Digital.pdf) more than $0.5 billion in unreimbursed services and community benefit program expenses. The health system's three 340B-participating hospitals realized about $93 million in savings from the discount program during the fiscal year.

Suzanne Shea

"That 340B savings doesn't even come close to covering our unreimbursed care. It's just a drop in the bucket, really," said Suzanne Shea, vice president of system pharmacy and clinical nutrition for Sharp HealthCare.

But Shea said the 340B savings allows Sharp HealthCare to maintain its transitional care, specialty pharmacy, and infusion services and to support other important patient-care activities.

Shea noted that 340B-funded services can have immediate benefits for patients. For example, Shea recently heard from a patient who was excited about the personal attention she received from the 340B-funded specialty pharmacy team that taught her how to self-inject a new medication.

"She just really wanted to reach out and tell me … she'd never really been provided a service like that," Shea said. "And because of her chronic conditions, she was just so happy and felt taken care of."

Sharp HealthCare also uses 340B program savings to help cover the cost of medications for patients who can't afford them. The health system reported that 340B-supported financial assistance gave patients access to more than $9.1 million worth of prescription medications during the 2021 fiscal year.

Johns Hopkins All Children's Hospital in St. Petersburg, Florida, reported (https://www.hopkinsallchildrens.org/Community/In-the-Community/340B-at-Johns-Hopkins-All-Children-s-Hospital) more than $84 million in community benefit costs during the 2020 fiscal year and a savings of $6 million on 340B-covered outpatient medications.

That $6 million allowed the hospital to maintain its LifeLine critical care transport team, pediatric trauma and behavioral health centers, and neonatal abstinence syndrome follow-up clinic, said Pharmacy Director Matthew Werling.

“We have a lot of programs that we are able to do here because we’re a 340B hospital,” Werling said. “It’s just such a critical program to disproportionate share hospitals. It supports so much of our programming. … And it means so much to our patients.”

Pharmacy Business Manager Pam Kravitz said Johns Hopkins All Children's Hospital has “substantial patient assistance programs for patients that can’t make their copays or can’t pay for their meds.”

“We’re able to do that from 340B funding,” Kravitz emphasized.

The 340B program was established in 1992 to allow safety net hospitals and other covered entities to purchase outpatient medications at a discounted price and direct that savings to services that improve the care of vulnerable patient populations. The Health Resources and Services Administration (HRSA), which oversees the 340B program, describes it as a mechanism to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.

ASHP has long engaged with HRSA on issues related to the 340B program and has partnered with the American Hospital Association, 340B Health, and other organizations whose stakeholders rely on the 340B program to meet critical patient needs. ASHP and its partners have secured notable advocacy wins on 340B program threats, including a June 15 Supreme Court decision that the Medicare program’s 30% cut in reimbursement for 340B-covered drugs, implemented in 2018, was unlawful.

In addition, ASHP helps pharmacists engage with their elected representatives about how 340B-supported services benefit legislators’ constituents and their communities.

Although federal law doesn’t require hospitals to redirect their 340B outpatient drug savings toward medication-related services, many hospitals do use those dollars to support medication assistance programs and other pharmacy-managed care.

A research team led by pharmacists at the University of Illinois Chicago reported (https://doi.org/10.1016/j.sapharm.2021.03.010) last year that 340B-participating hospitals offered 6.2 medication-access services, on average, compared with 3.9 services at non-340B hospitals — a statistically significant difference.

Of the nine specific services evaluated, 340B hospitals were more likely than non-340B hospitals to provide prior authorization assistance, discharge prescriptions, free immunizations, free or discounted outpatient medications, medication therapy management, and patient assistance programs.

The report states that 340B program savings may be a key factor in offsetting the costs of beneficial medication-access services that aren’t eligible for reimbursement.

Unreimbursed costs can be substantial for hospitals. For example, West Virginia University (WVU) Medicine reported (https://wvumedicine.org/about/leadership-and-more/community-benefit/) a Medicaid shortfall of more than $272 million in 2020.

Todd Karpinski

The shortfall — the difference between the cost of care for Medicaid-eligible patients and the payment received for these services — accounted for the largest share of the health system's unreimbursed care and community benefit expenses.

Those costs are partially offset by 340B savings of about $200 million annually, said Todd Karpinski, WVU Medicine chief pharmacy officer and system vice president. Karpinski said the 340B savings supports indigent care, low-cost insulin for patients with diabetes, targeted care for patients with chronic conditions, and pharmacy-managed patient assistance programs.

"We have a fairly robust specialty pharmacy program at our organization that wouldn't be in place if we didn't have the 340B pricing," Karpinski added. "We leverage those dollars to put additional pharmacists in clinics throughout the organization to be able to provide that direct patient care."

Karen Famoso, enterprise director for compliance and 340B for WVU Medicine, said that because the health system serves many poor, uninsured, and underinsured patients, the 340B program "is vital to our existence."

"It really keeps the doors open," Karpinski concurred.

In general, hospitals can participate in the 340B program if they serve a Medicare and Medicaid population that meets a federally defined threshold, known as the disproportionate share hospital percentage.

"The intent of the program is not necessarily … to provide direct savings to the patients. It's really to provide savings back to … safety net hospitals to provide care to a broad range of patients," Karpinski explained. "That's how we're using those dollars."

Kravitz noted that because hospitals have flexibility in where to direct their 340B savings, those dollars can be used for tailored population-level initiatives that fill gaps in care.

"The program allows us to … put it back into programs that are most impactful for your particular hospital," Kravitz said. "For us, that's where it's worked well. Because we know where we need to put the funding, and we assess that annually."

ASHP has made support (https://www.ashp.org/advocacy-and-issues/key-issues/340b) of the 340B program a key advocacy priority and has taken many actions (https://www.ashp.org/search?q=340b) to promote and protect the program. ASHP's 340B program educational resources include a 340B University (https://leaders.ashp.org/340b-university) session at the upcoming ASHP Conference for Pharmacy Leaders and the Apexus Advanced 340B Operations Certificate Program (https://www.ashp.org/professional-development/professional-certificates/apexus-advanced--340b-operations-certificate-program).

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July 28, 2023

Sen. Tammy Baldwin
141 Hart Senate Office Building
Washington, DC 20510

Sen. Shelley Moore Capito
172 Russell Senate Office Building
Washington, DC 20510

Sen. Benjamin L. Cardin
509 Hart Senate Office Building
Washington, DC 20510

Sen. Debbie Stabenow
731 Hart Senate Office Building
Washington, DC 20510

Sen. Jerry Moran
521 Dirksen Senate Office Building
Washington, DC 20510

Sen. John Thune
511 Dirksen Senate Office Building
Washington, DC 20510

RE: 340B Health's Response to the Senate Request for Information

Dear Senators Baldwin, Capito, Cardin, Moran, Stabenow, and Thune:

On behalf of our more than 1,500 member hospitals that participate in 340B, we are writing to provide comments in response to your 340B request for information (RFI). We appreciate the opportunity to share information on how the 340B drug pricing program could be strengthened. Hospitals use their savings to meet 340B's original intent: to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.[1] 340B savings help support a wide range of activities and projects that expand access to services, improve patient care, subsidize essential services that operate at a loss, and support community health initiatives and capital improvement projects to help maintain a strong institution to ensure health care access for the community.

National and state-specific research demonstrates 340B hospitals' commitment to providing services to low-income individuals. This includes 340B hospitals' high share of Medicaid and low-income Medicare patients, uncompensated care levels, and services these hospitals provide that are not included in uncompensated care calculations, such as transportation, translation services, lodging, and food banks. 340B supports programs and services targeted to meet the health and social needs of underserved populations as well as the broader community, many of which would not otherwise be financially sustainable.[2] 340B hospitals provide these services despite experiencing significantly lower operating margins, on average negative, than non-340B hospitals.[3] 340B provides resources for these safety-net hospitals at no cost to taxpayers, as

[1] H.R. Rep. 102-384(II) at 12 (1992)
[2] 340B Health. 340B Health Annual Survey 2022: Vital 340B-Supported Patient Services Threatened as Manufacturer Restrictions Cut Into Savings. July 2023. https://www.340bhealth.org/files/340B_Health_Survey_Report_2022_FINAL.pdf.
[3] Dobson DaVanzo & Associates, LLC. 340B DSH Hospitals Increased Uncompensated Care in 2020 Despite Significant Financial Stress. July 2020. https://www.340bhealth.org/files/Dobson_DaVanzo_Op_Margins_and_UC_FINAL.pdf.

drugmakers provide the discounts and providers invest the savings from the discounts into patient care.

Drug companies have advocated for cutting 340B, which would reduce their financial obligation to support the health care safety net as a condition of accessing the Medicaid and Medicare Part B programs. Over the years, they have advocated for strictly limiting hospital locations that can participate in 340B and reducing the types of patients that currently qualify for 340B drugs. More recently, several drug companies have unilaterally refused to provide 340B discounts at community and specialty pharmacies for patients of 340B hospitals and certain 340B grantees. These pharmacies have been a vital component of 340B since 1996, prompting the Health Resources and Services Administration (HRSA) to expand access to contract pharmacies in 2010. Not only do drug company restrictions harm 340B covered entities and their patients, but they are likely to result in higher drug prices for the public.

340B serves as a significant restraint on drug company pricing for non-340B drugs, resulting in savings of $7 billion from 2013 to 2017 for Medicare Part D alone.[4] This is due to the 340B inflationary penalty, which increases the amount of the discount higher than the required 23.1% when drug companies increase prices faster than inflation. This penalty is most successful in discouraging price increases when a drug company is required to pay both the inflation penalty and a pharmacy benefit manager (PBM) rebate.[5] The more drug companies can limit the number of their drugs subject to 340B, the easier it is to continue with sky-high price increases.

340B Health does not support efforts to cut 340B, either by reducing the number of eligible locations or reducing the number of eligible prescriptions. We recommend that Congress pass legislation to protect 340B hospitals from drug companies' harmful 340B restrictions and conditions. We also recommend that Congress enact measures to safeguard and strengthen 340B, including protecting 340B providers from discriminatory payer policies and eliminating statutory provisions that increase drug costs for safety-net providers such as the orphan drug loophole and group purchasing organization (GPO) prohibition. Congress also should direct the administration to implement added measures to prevent Medicaid duplicate discounts and make common sense reforms to hospital outpatient clinic registration policies.

340B Health is aware of proposals to impose burdensome and unworkable 340B reporting requirements on 340B hospitals. Hospitals are treating patients amid high inflation and increased labor costs. These challenges have hit especially hard for 340B hospitals, which have extremely tight operating margins. All hospitals already report extensive financial information through the Medicare cost report, and nonprofit hospitals have additional reporting requirements via the IRS Form 990, their community health benefits report, and their community health needs assessment. 340B Health strongly supports voluntary reporting, such as through the 340B Health Impact Profile, which allows hospitals to share information on their 340B savings and discuss the services and benefits that the hospital provides to its patients and the community.

Thank you for considering our comments and recommendations. Please see below for our answers to questions posed in the RFI. We look forward to continuing to work with you to ensure

[4] Dickson, Sean. Association Between the Percentage of US Drug Sales Subject to Inflation Penalties and the Extent of Drug Price Increases. Sept. 2020. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2770540.
[5] *Id.*

the future strength and success of 340B. You can contact me at maureen.testoni@340bhealth.org with further questions.

Sincerely,

Maureen Testoni
President and Chief Executive Officer
340B Health

340B Health's RFI Response

1. **What specific policies should be considered to ensure HRSA can oversee the 340B program with adequate resources? What policies should be considered to ensure HRSA has the appropriate authority to enforce the statutory requirements and regulations of the 340B program?**

HRSA has been successfully enforcing its 340B statutory requirements that apply to covered entities for decades. For example, HRSA implemented its patient definition guidelines in 1996, and this guidance is still being followed today. HRSA conducts at least 200 audits of covered entities per year, and findings requiring repayment to manufacturers are low.

While HRSA exercises robust oversight of 340B covered entities, 340B Health believes that HRSA should provide greater oversight of manufacturers using their existing statutory authority. HRSA audits significantly more covered entities than manufacturers. As of July 26, 2023, HRSA has conducted 1,888 covered entity audits compared to only 36 manufacturer audits since audits began in 2012. HRSA should be encouraged to conduct more frequent manufacturer audits to ensure manufacturers are fulfilling their 340B obligations.

The 340B statute also permits HRSA to audit wholesalers, though we are not aware that HRSA has ever done so. As discussed in our response to Question #2, 340B Health is aware of manufacturers imposing conditions that limit access to 340B drugs via their wholesalers. HRSA should audit wholesalers as well as manufacturers to protect the integrity of 340B.

Additionally, HRSA should be encouraged to fully operationalize the 340B administrative dispute resolution (ADR) process. In 2010, Congress directed the administration to create a 340B ADR process for both covered entities and manufacturers to bring allegations of 340B noncompliance, yet a final rule establishing the ADR process was not issued until late 2020.[6] In November 2022, HRSA proposed a new ADR rule after encountering policy and operational challenges with the final ADR rule.[7] The proposed rule recommended several significant changes to the ADR, but no final rule has been issued, creating further concern that full implementation of the ADR could be years away. 340B Health urges HRSA to finalize the ADR

[6] 340B Drug Pricing Program; Administrative Dispute Resolution Process, Office of Information and Regulatory Affairs Office of Management and Budget. 1 Aug. 2017. https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201704&RIN=0906-AA90.
[7] 87 Fed. Reg. 73516 (Nov. 30, 2022).

rule to ensure that covered entities can bring claims against manufacturers refusing to offer the 340B pricing.

As described in the following section, 340B Health is concerned that manufacturers are no longer following HRSA guidance requiring that they offer 340B discounts for covered entity patients through contract pharmacies and HRSA guidance prohibiting the use of conditions or other actions that would undermine 340B or discourage entities from participating in 340B.[8] We believe congressional action is necessary in these areas.

340B Health is aware that some manufacturers have suggested that HRSA should be granted additional regulatory authority relating to 340B implementation by covered entities. 340B Health does not believe this is necessary. We note that HRSA has proposed guidance in the past that would have significantly reduced the scope of 340B and imposed unnecessary burdens on covered entities, upending decades of 340B policy.[9] These proposals generated significant opposition from covered entities, members of Congress, and other organizations, ultimately prompting the proposal to be withdrawn. For example, the 340B "mega-guidance" proposed in 2015 included several provisions that would have prevented the use of 340B for hospital patients, significantly shrinking 340B savings and harming patients. These provisions would have eliminated 340B savings for:

- Prescriptions given to patients upon discharge from an inpatient stay, even though the individuals had received health care services from the hospital, are hospital patients, and are filling the prescriptions on an outpatient basis.
- Infusion services for hospital patients when the order is written outside the hospital, a practice that is common at rural hospitals, where patients obtain their cancer diagnosis and treatment plan at an urban hospital and their local hospital administers their chemotherapy, saving the patient potentially hours in travel time.
- Outpatient drugs given to hospital patients unless the hospital bills for the prescriber's professional services, something most hospitals cannot do.
- Prescriptions written outside the hospital as a result of referrals made by the hospital patients to receive necessary care, even when the hospital retains responsibility for the patient.

Any consideration of HRSA regulatory authority would need to protect against narrowing the scope of 340B.

2. What specific policies should be considered to establish consistency and certainty in contract pharmacy arrangements for covered entities?

Congress should enact legislation to restore the 340B benefit for drugs dispensed through contract pharmacies, prohibit drug companies from implementing conditions that restrict 340B, and allow covered entities a private cause of action against manufacturers. Over the past three years, nearly two dozen drug companies have restricted access to 340B pricing for drugs dispensed by contract pharmacies. The restrictions have harmed both hospitals and their patients at a time when hospitals are still recovering from the COVID-19 pandemic and dealing with

[8] 75 Fed. Reg. 10272 (March 5, 2010); 59 Fed. Reg. 25110 (May 13, 1994).
[9] 80 Fed. Reg. 52300 (Aug. 28, 2015).

severe workforce shortages. The Department of Health and Human Services (HHS) determined that these actions are unlawful, but litigation by the drug industry has delayed enforcement. Unfortunately, one appellate court decision largely sided with the drug manufacturers, while two appellate decisions are outstanding. As legal action continues, the harm to 340B hospitals grows more and more severe as manufacturers expand their restrictions to the point where very little 340B contract pharmacy is available.

The 21 drug companies that had restrictions in place as of June 1, 2023, are responsible for an annual 340B benefit to hospitals of $8.4 billion through contract pharmacies.[10] Virtually all these savings will be lost as manufacturers tighten their restrictions. Cuts at this level put at risk critically important programs that typically operate at a loss, such as trauma care, burn treatment, behavioral health, and obstetrics.[11]

340B Health's analysis of the drugs being restricted found, not surprisingly, that drug manufacturers are using the restrictions to protect their high-priced specialty drugs from being subject to a 340B discount and to prevent drugs for which they have repeatedly increased prices from being subject to the 340B inflationary penalty.[12]

Manufacturer restrictions limiting the maximum distance between a hospital and a contract pharmacy or limiting the number of contract pharmacies per hospital are targeted at removing high-priced specialty drugs from being subject to 340B. Some manufacturers refuse to allow covered entities to use contract pharmacies that are more than 40 miles from their hospital. What manufacturers do not explain is that hospitals have no choice, as specialty pharmacies are often located over 40 miles or much more from most hospitals. Growth in sales of drugs placed in specialty distribution channels has been rapid, going from 27% in 2010 to 55% in 2021. Drugs marketed through the specialty channel are typically very expensive, and while some may require special handling and are used for serious chronic conditions, such as cancer and rheumatoid arthritis, many do not yet are still distributed through the specialty channel. Specialty pharmacies are typically mail-order, not open to walk-in customers, far fewer in number than retail pharmacies, and not even available in most communities.[13] Only one in five 340B hospitals have their own specialty pharmacies, making contract pharmacy relationships critical for providing access to 340B discounts on these expensive drugs.[14]

Limiting the number of contract pharmacy relationships an individual hospital can have further restricts access to specialty drugs. Many payers share common ownership with specialty pharmacies and will only cover drugs that are dispensed though those pharmacies. This requires hospitals to have contract pharmacy agreements with each payer's specialty pharmacy to ensure appropriate coverage for their patients. Moreover, specialty pharmacy services are often

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[10] 340B Health. Drugmakers Pulling $8 Billion Out of Safety-Net Hospitals, More Expected As Growing Numbers Impose or Tighten 340B Restrictions. July 2023. https://www.340bhealth.org/files/Contract_Pharmacy_Financial_Impact_Report_July_2023.pdf.
[11] Dobson DaVanzo & Associates, LLC. 340B DSH Hospitals Serve Higher Share of Patients with Low Incomes. Sept. 2022. https://www.340bhealth.org/files/340B_and_Low_Income_Populations_Report_2022_FINAL.pdf.
[12] 340B Health. Drugmakers Pulling $8 Billion Out of Safety-Net Hospitals, More Expected As Growing Numbers Impose or Tighten 340B Restrictions. July 2023. https://www.340bhealth.org/files/Contract_Pharmacy_Financial_Impact_Report_July_2023.pdf.
[13] *Id.*
[14] 340B Health. 340B Health Annual Survey 2022: Vital 340B-Supported Patient Services Threatened as Manufacturer Restrictions Cut Into Savings. July 2023. https://www.340bhealth.org/files/340B_Health_Survey_Report_2022_FINAL.pdf.

centralized in one geographic location and a single specialty pharmacy often does not have access to all specialty drugs for all payers and manufacturers. Thus, multiple contract pharmacy arrangements are required to access all specialty products used by a 340B hospital's patients. With a growing number of manufacturers imposing 40-mile limits for contract pharmacies and permitting only one contract pharmacy per hospital, manufacturers are increasingly cutting specialty drugs out of 340B.

340B Health estimates that the 21 manufacturers that had restrictions in place as of June 1, 2023, are responsible for $5.3 billion in annual 340B savings related to specialty drugs for hospitals.[15] For 11 of these companies, more than 75% of the contract pharmacy benefit comes from specialty drugs.[16] Limiting contract pharmacies by geography or by number removes a significant number of drugs from 340B and allows manufacturers to increase profits at the expense of the health care safety net.

In addition to the contract pharmacy restrictions, 340B Health is concerned about manufacturers imposing conditions on covered entities intended to limit 340B purchases even when the drugs are dispensed directly by the entity and not through a contract pharmacy. This is a key issue in the ongoing contract pharmacy litigation, with some arguing that manufacturers may withhold 340B discounts pending a manufacturer's review of each covered entity claim to determine compliance with the manufacturer's interpretation of patient definition and duplicate discount rules. Our concern is not just based on the burden and confusion of complying with conditions imposed by potentially hundreds of manufacturers, which on its own would be disastrous, but also that manufacturers could conceivably impose any condition they want, no matter how onerous. For example, under the guise of preventing fraud, manufacturers could seek access to patient health records and credentialing contracts that hospitals have with physicians, which are necessary elements in HRSA guidance for proving the eligibility of patients that received 340B drugs.

We are already seeing some manufacturers refuse to offer 340B pricing unless covered entities purchase the drugs through a wholesaler chosen by the manufacturer. Such a requirement is extremely burdensome, as it requires hospitals to enter legally binding agreements with this wholesaler and open multiple purchasing accounts for locations where these drugs are used. These actions discourage covered entities from using this manufacturer's drugs if there are equally effective drugs on the market, thereby ensuring that the manufacturer will not be required to provide 340B discounts on its drugs. This is a significant benefit for drugs that are subject to the 340B inflationary penalty as a result of manufacturer decisions to increase drug prices year after year. HRSA guidance clearly sets its expectation that manufacturers will not use conditions or implement other actions that would undermine 340B or discourage entities from participating in 340B.[17] Enforcement actions, however, could prove costly and extremely time-consuming. 340B Health recommends that Congress take action in this area.

Congress also should provide covered entities with a private cause of action to directly challenge manufacturers that unlawfully restrict access to the 340B benefit. HRSA has a history of

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[15] 340B Health. 340B Health Annual Survey 2022: Vital 340B-Supported Patient Services Threatened as Manufacturer Restrictions Cut Into Savings. July 2023. https://www.340bhealth.org/files/340B_Health_Survey_Report_2022_FINAL.pdf.
[16] *Id.*
[17] 75 Fed. Reg. 10272 (March 5, 2010); 59 Fed. Reg. 25110 (May 13, 1994).

significant delays in finalizing rules related to its existing regulatory authority against drug companies. A private cause of action will ensure that covered entities have a path to protect the 340B benefit in court absent HRSA action.

340B Health recommends that Congress enact legislation that protects covered entities from current and future harmful manufacturer actions by:

- Clarifying that manufacturers are required to offer 340B pricing for drugs dispensed at contract pharmacies.
- Prohibiting manufacturers from implementing conditions or restrictions designed to dissuade or inhibit a covered entity's ability to purchase drugs at the 340B price.
- Granting HRSA explicit regulatory authority to impose CMPs on drug companies that refuse to offer the 340B price and/or implement conditions or restrictions designed to block access to the 340B price.
- Granting covered entities a private cause of action that allows a covered entity to directly challenge illegal manufacturer restrictions or conditions in federal court.

3. **What specific policies should be considered to ensure that the benefits of the 340B program accrue to covered entities for the benefit of patients they serve, not other parties?**

Some payers and PBMs have implemented policies that pay 340B covered entities less for 340B drugs, resulting in a portion of the 340B benefit going to those entities instead of to providers. Some also prevent covered entities from using 340B. In response to manufacturer refusals to pay rebates to payers and PBMs for 340B drugs, some payers and PBMs impose burdensome requirements such as 340B point-of-sale claim identification (which most hospital virtual inventory systems cannot do) or denying coverage for drugs purchased by a hospital for administration to their patients, resulting in "white bagging" or "brown bagging" to allow patients to have their medications administered by their trusted hospital professionals. These actions undermine the health care safety net by reducing the 340B benefit that providers use to serve their patients and communities. They also limit the volume of drugs subject to the 340B inflationary penalty, likely resulting in higher price increases by drug manufacturers.

In response to these actions, more than half of states prohibit 340B discriminatory payer policies. These state actions do not reach all individuals in their state, as some plans are subject to federal law. 340B should be protected from discriminatory action in all states and for all payers. 340B Health recommends that Congress prohibit payers from denying reimbursement for drugs that hospitals administer or dispense directly to their patients and eliminate white bagging and brown bagging. Additionally, Congress should enact legislation that prohibits 340B-specific discriminatory policies, such as those addressed by the PROTECT 340B Act of 2023 (H.R. 2534), bipartisan legislation introduced in the House by Abigail Spanberger (D-Va.) and Dusty Johnson (R-S.D.), which would bar payers from lowering reimbursement for 340B providers and engaging in other discriminatory 340B practices.

4. **What specific policies should be considered to ensure that accurate and appropriate claims information is available to ensure duplicate discounts do not occur?**

Congress should direct the Centers for Medicare and Medicaid Services (CMS) to require states to adopt the Oregon model for Medicaid managed care duplicate discount prevention. Oregon has long implemented a successful policy to ensure that its state Medicaid program does not request rebates from drug manufacturers for 340B claims. Unlike some states that require identification of a claim as 340B at the time it is processed (which is impossible for most hospitals due to the virtual inventory system necessary for 340B compliance), Oregon requires covered entities to periodically submit claims data that pertain to 340B after the claims have been submitted, which is consistent with existing 340B processes. The data is submitted directly to the state's rebate vendor, which then removes those claims from the state's rebate requests.[18] 340B Health is aware of instances where the 340B claim was appropriately identified, yet the process of flowing through multiple PBM and payer software systems resulted in the drug not being identified as 340B when it reached Medicaid. The Oregon model avoids this problem by limiting the parties involved to the provider and the Medicaid vendor, thereby reducing potential errors when the information goes through multiple entities and making it easy to implement and audit. The Oregon model demonstrates that retrospective 340B claim identification is achievable without the use of 340B identifiers on claims. Alternatively, Congress could pass legislation where the federal government, rather than states, would take on the role of Medicaid managed care duplicate discount prevention, as provided for in the PROTECT 340B Act of 2023, mentioned above, which includes provisions that would authorize HHS to contract with a third party to collect and review data from state Medicaid agencies and covered entities to prevent Medicaid duplicate discounts.

340B Health also recommends HRSA update its duplicate discount reporting policies to increase the transparency and accuracy of duplicate discount publicly posted audit findings. More than a third of covered entities audited in fiscal years 2020 and 2021 with a published duplicate discount finding have provided HRSA with evidence that no duplicate discount occurred. However, HRSA continues to list these providers as having a duplicate discount audit finding. Though HRSA notes that no duplicate discount actually occurred in a separate field related to corrective action, that information is confusing because the primary finding is listed as a duplicate discount. This inflates the number of duplicate discount findings listed and inaccurately depicts the actual number of duplicate discount findings occurring during an audit year.

5. **What specific policies should be considered to implement common sense, targeted program integrity measures that will improve the accountability of the 340B program and give health care stakeholders greater confidence in its oversight?**

340B Health supports targeted, common sense 340B improvements that ensure 340B providers are able to stretch scarce resources and provide more services in their communities. 340B Health has identified the following policies that would strengthen 340B's ability to support covered entities and their patients:

- **Close the orphan drug loophole**. Non-rural providers have had access to 340B pricing for orphan drugs for more than 30 years, but the 340B statute does not require manufacturers to offer 340B pricing for orphan drugs purchased by rural hospitals. Many orphan drugs, which are drugs approved to treat a rare disease, also are used to treat

[18] Oregon Health Authority. Retroactive 340B Claims File Instructions. https://www.oregon.gov/oha/HSD/OHP/Tools/340B%20Claims%20File%20Instructions%20and%20Design.pdf.

common diseases. There is simply no research to support excluding orphan drugs from 340B for these providers, and no evidence that including orphan drugs for non-rural hospitals for the past 30 years has harmed the development of orphan drugs in any way.

- **Direct HRSA to implement common sense reform of its child site registration policy.** HRSA's child site registration policy does not accurately reflect hospital operations and needs improvement. Under current HRSA policy, hospitals are required to register offsite hospital locations by line of service, resulting in many registrations for a single hospital building. Further, HRSA follows Medicare policy for registration of hospital locations, with the exception that HRSA does not allow registration of new hospital locations that have not yet appeared on a filed Medicare cost report. Offsite hospital locations should be registered by building, not by individual service, and hospitals should not have to wait until the next Medicare cost report filing to register hospital locations. HRSA's current requirements do not reflect how a hospital is organized, nor how it reports for purposes of the Medicare cost report. For example, a multi-campus hospital would be considered as one reporting unit on the Medicare cost report, but each service within a facility would have to register as a separate child site for purposes of 340B even if each of these sites use a single pharmacy department. A hospital that has a medical office building with a separate physical address that is within 250 yards of the hospital would include the medical office building as part of the hospital for purposes of Medicare, but each service within the building would have to register separately for 340B purposes.
- **Eliminate the group purchasing organization (GPO) prohibition**. The GPO prohibition requires DSH hospitals to purchase covered outpatient drugs at higher prices when the hospital is unable to use 340B pricing for the drug, which can arise for multiple reasons, such as initial purchases of drugs by a hospital or inability to use 340B for the hospital's Medicaid patients. In those situations, hospitals must purchase those drugs at the usually much higher wholesale acquisition cost, increasing the cost of drugs for safety-net providers. No GPO purchasing prohibition exists for rural hospitals, demonstrating the lack of a strong policy need for this provision.
- **Prohibit states from mandating that providers use or not use 340B for Medicaid patients.** Some states require 340B providers to use 340B for Medicaid patients and then pay providers at the 340B cost for the drugs, ensuring that the state receives the 340B benefit, while providers bear the cost of significant 340B compliance requirements. Other states prohibit covered entities from using 340B for Medicaid patients, ensuring that the state can seek a rebate from the manufacturer for those drugs while imposing significantly higher drug costs on covered entities. In both situations, the covered entity is deprived of the benefit of the 340B discount.

6. **What specific policies should be considered to ensure transparency to show how 340B health care providers' savings are used to support services that benefit patients' health?**

The breadth and depth of existing hospital reporting requirements provide significant transparency documenting that 340B hospitals use 340B to help serve their disproportionate share of low-income patients. For this reason, 340B Health opposes additional hospital reporting requirements. 340B Health supports voluntary reporting by hospitals of their 340B savings and a description of services and activities provided to their low-income patients and community.

Imposing additional reporting requirements would be duplicative of existing hospital reporting requirements and create an unnecessary burden. Current reporting requirements include:

- **Medicare cost report Form S-10**. All hospitals participating in the Medicare program are required to file a Medicare cost report. This highly detailed report on hospital finances, volume, and facilities includes Form S-10, which provides hospital-level data on the dollar amount of financial assistance provided, bad debt, and shortfalls from means tested government programs.[19]
- **IRS Form 990 Schedule H**. The IRS requires tax-exempt hospital organizations to report extensively on the net costs of community benefit activities on Schedule H of Form 990.[20] This schedule covers the net cost of providing financial assistance, subsidizing various services, bad debt attributable to people who would likely qualify for financial assistance, shortfalls from means-tested government programs, and other community benefits. It requires the organization to provide the number of patients served for each community benefit activity and the percentage that the net costs associated with these activities represent of total expenses. Hospital organizations also report community-building activities, including physical improvements and housing, economic development, community support (childcare, support groups, violence prevention), environmental improvements, leadership development, coalition building, community health improvement advocacy, workforce development, and others. Hospitals must disclose their funding sources for these activities.
- **Community health needs assessment (CHNA).** Each nonprofit and public hospital is required to conduct and make available to the public a CHNA every three years. A CHNA is an assessment of the significant health needs of the community and must take into account input from persons who represent the broad interests of the community served by the hospital facility, including those with special knowledge of or expertise in public health, and must be made widely available to the public. The hospital must develop and make public an implementation strategy to meet the community health needs identified through the CHNA.
- **Various other reports to state and local officials.** Hospitals often must report information to states and localities. This includes reporting for Medicaid DSH funds or state-run low-income pools. Some states have transparency reports that include many of the items mentioned above along with an inventory of property, executive compensation, and charges, for example. Some areas require hospitals to file payment in lieu of taxes (PILOT) reports to justify their property tax exemption.

From existing public data, researchers have shown:

- 340B hospitals provide three-quarters (77%) of all hospital care for patients with Medicaid. Medicaid revenue as a percent of total operating revenue is nearly twice as high at 340B DSH hospitals than at non-340B hospitals.[21]

[19] Centers for Medicare and Medicaid Services. Form CMS-2552-10, Worksheet S-10 – Hospital Uncompensated and Indigent Care Data. https://www.costreportdata.com/instructions/Instr_S100.pdf.
[20] Internal Revenue Service. Instructions for Schedule H (Form 990)(2022). https://www.irs.gov/instructions/i990sh.
[21] Dobson DaVanzo & Associates, 340B DSH Hospitals Serve Higher Share of Patients with Low Incomes. Sept. 2022. https://www.340bhealth.org/files/340B_and_Low_Income_Populations_Report_2022_FINAL.pdf.

- 340B hospitals provide two-thirds (67%) of uncompensated and unreimbursed care in the U.S. In fact, even though 340B hospitals saw significantly lower operating margins than non-340B hospitals in 2020 due to COVID, their share of uncompensated care increased.[22]
- 340B hospitals treat higher percentages of patients who historically have encountered difficulties accessing care when needed. Patients receiving care at 340B hospitals are significantly more likely to be dually eligible for Medicare and Medicaid, be eligible for Medicare because of a disability, or to identify as Black than those seeking care at non-340B hospitals and physician offices.[23]
- Medicare patients treated for cancer in 340B hospitals are more likely to be low-income, disabled, and/or young. According to the Medicare Payment Advisory Commission (MedPAC), younger cancer patients warrant more costly treatment.[24]
- In 2018, 340B hospitals provided $67.9 billion in total benefits to their communities. This represents 13.7% of expenses. Financial assistance, shortfall for means-tested programs, and other community benefits totaled $55 billion.[25]

340B Health is especially concerned about reporting that evaluates 340B on the basis of hospital uncompensated care levels and/or requires hospital reporting at the child site level. Helping to subsidize uncompensated care is one of many ways 340B helps hospitals, but the definition of uncompensated care is narrow, encompassing only medical services and supplies. 340B supports activities that fall outside this definition and are critical for supporting their patients' health, such as helping individuals to access care (e.g., transportation, translation, and care coordination services), bringing new services and specialties to a community that would otherwise be unavailable, and much-needed capital improvements that are simply not possible when relying on low reimbursement rates from public payers. Uncompensated care levels are simply not appropriate to use as the primary measure for 340B effectiveness.

340B Health is aware of reporting proposals that would require hospital reporting at the child site level, which HRSA defines as each location where an individual service is furnished. Reporting requirements at the outpatient department level miss the point of 340B, which is to generate savings on drug purchases that may be reinvested where most needed across the hospital or in community-based programs and services. Savings generated in one hospital clinic may be used to subsidize services and activities across the hospital that are poorly reimbursed or not reimbursed at all, such as behavioral health, HIV/AIDS care, care coordination, and care at clinics dedicated to serving uninsured populations.

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[22] Dobson DaVanzo & Associates, LLC. 340B DSH Hospitals Increased Uncompensated Care in 2020 Despite Significant Financial Stress. July 2022. https://www.340bhealth.org/files/Dobson_DaVanzo_Op_Margins_and_UC_FINAL.pdf.
[23] L&M Policy Research. Examination of Medicare Patient Demographic Characteristics for 340B and Non-340B Hospitals and Physician Offices. July 2022. https://www.340bhealth.org/files/LM-340B-Health-Demographic-Report-07-28-2022_FINAL.pdf.
[24] MedPAC. Report to Congress. March 2020. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default- source/reports/mar20_medpac_ch15_sec.pdf. Yufei L, Xu Susan. Association of Beneficiary-Level Risk Factors and Hospital-Level Characteristics With Medicare Part B Drug Spending Differences Between 340B and Non-340B Hospitals. Feb. 2022. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2789170.
[25] American Hospital Association. 2021 340B Hospital Community Benefit Analysis. Sept. 2021. https://www.aha.org/system/files/media/file/2021/09/340b-community-benefits-analysis-0921.pdf.

Collecting information at the child site level would be highly burdensome because drug purchases, drug use, payer mix, charity care, and other data elements do not exist in the same software and are not used for reporting for each service at each location. Some information would have to come from patients' electronic medical record, the pharmacy inventory management system, the general ledger, and outside vendors. The information would then have to be matched across these systems to individual patients. This would be particularly complex in instances where 340B is not uniformly used across all departments in a hospital, such as when Medicaid patients are carved out of 340B or patients otherwise receive medications from the hospital but do not qualify as 340B patients. Software solutions would have to be developed and staff dedicated to this effort. All this burden would be for data that does not provide policymakers with effective information to evaluate 340B savings.

340B Health supports voluntary reporting mechanisms such as 340B Health's Impact Profile, which we created in 2015. The Impact Profile is designed to help hospitals gather and voluntarily share data on their 340B annual savings and information explaining how 340B helps the hospital and its patients. The Impact Profile does not attempt to track 340B dollar-for-dollar, because 340B is a discount and not an appropriation, but rather helps hospitals tell the important narrative of how 340B is used to increase access to care for underserved communities. Hospitals are aware of the importance of 340B to the services they provide, and we encourage hospitals to voluntarily share that information with policymakers.

The 340B Drug Pricing Program: Existing Evidence and Policy Implications for Kentucky

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The 340B Drug Pricing Program: Existing Evidence and Policy Implications for Kentucky

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Executive Summary

The 340B drug pricing program was instituted to bolster the health care safety net without relying on taxpayer money. It allows participating health care facilities, called covered entities, to purchase drugs filled at in-house or contracted external pharmacies at discounts from manufacturers. This generates additional funds that can help safety net providers sustain or expand relatively unprofitable departments as well as services for low-income individuals.

However, providing these discounts leads to a potentially important reduction in revenue for drug manufacturers. They have raised concerns about the rapid growth in the network of contract pharmacies, which has increased the number of drugs receiving the discount. Drug companies responded by enacting restrictions that in turn led to a flurry of lawsuits and legislative activity. In particular, eight states have enacted laws intended to preserve contract pharmacy networks, and many others – including Kentucky – are considering such legislation.

This paper aims to inform policymakers and other stakeholders – particularly those in Kentucky – as to the history of the 340B program, scholarly evidence on how covered entities respond to the program, and the implications of this evidence for public policy moving forward. While the volume of studies is substantial, challenges with distinguishing correlation from causality and generalizing results beyond specific settings have largely prevented a consensus from being reached as to whether covered entities respond in desirable or undesirable ways.

Although the evidence thus far is suggestive rather than conclusive, it points to potentially important impacts that warrant further investigation. First, the 340B program appears to enable at least some covered entities to better serve vulnerable populations by providing more charity care or adding lines of service, particularly oncology. Some evidence also suggests that it reduces Medicare Part B drug spending. At the same time, contract pharmacies and associated outpatient clinics are on average located in more affluent communities than the covered entity itself, raising questions about the appropriate reach of the program. Finally, some evidence suggests that the fact that 340B discounts are larger for more expensive drugs slows the adoption of low-cost biosimilar drugs by covered entities.

However, given the limited and inconclusive nature of much of this evidence, the only indisputable effect of the program is to redistribute money from drug manufacturers to covered entities. Therefore, the appropriateness of public policy actions related to the program largely hinges on the desirability of such transfers. In states such as Kentucky that do not have a major drug manufacturing presence, a law preserving 340B discounts for contract pharmacies would ensure that the most possible out-of-state money flows into the state.

Keywords: 340B, hospitals, prescription drugs
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I. Introduction

The 340B drug pricing program was established under the Veterans Health Care Act of 1992. The program mandates manufacturers to provide discounts on drugs purchased by participating not-for-profit healthcare entities. These discounts solely apply to drugs dispensed in outpatient interactions by entities or their contracted pharmacies (Veterans Health Care Act 1992). The intention of eligibility criteria is to include safety-net healthcare providers. Participants, called "covered entities", include federally qualified health centers (FQHCs); some specialized clinics; and disproportionate share, children's, cancer, critical access, rural referral center, and sole community hospitals.

Over the past 30 years, the 340B program has become increasingly important. Covered entities, pharmacies, and spending associated with 340B have all increased considerably. There were over 50,000 participating covered entities in 2020, and 340B-eligible drug purchases eclipsed $66 billion in 2023 (Mulligan 2021; Health Resources Service Administration 2024). The median benefit per participating hospital from Medicare Part B administrations alone has been estimated to be $0.8 million, or 9.4% of median uncompensated care costs (Conti et al., 2019).[1]

As the size of the 340B program continues to rise, so too does the value of evidence about its impacts. The most direct and obvious effect of the program is to redistribute money from drug manufacturers to covered health care entities. At issue in the scholarly literature is whether there are also important indirect effects that occur via provider responses to revenue generated and incentives created by the program.

[1] These calculations are for 2016 and are based on a simulation assuming a 50% discount.

On one hand, the additional revenue could play an important role in ensuring that struggling safety-net hospitals do not have to reduce the provision of charity care, close relatively unprofitable departments like obstetrics,[2] or in some cases even close completely.[3] For hospitals on stronger financial footing, the revenue may enable them to expand charity care or open new departments that fill voids in the community. Since many safety-net hospitals are located in rural areas with relatively low-income residents and few health care options, such as Eastern Kentucky, this means the 340B program could be vital to ensuring adequate access to care. Moreover, hospitals in these areas tend to be major employers who serve as critical components of the local economy.[4]

On the other hand, drug manufacturers argue that the 340B program has grown beyond its original intent. Specifically, they have raised concerns about the proliferation of external pharmacies associated with the program; double discounting, in which 340B and Medicaid Drug Rebate Program discounts are applied to the same prescription; and diversion, which is the sale of 340B drugs to someone not a patient of a covered entity. Also, there is no guarantee that revenues will be used for the provision of safety net care as opposed to, for instance, further investments in profitable departments.

In recent years, tensions between covered entities and manufacturers have manifested in multiple federal court cases over manufacturer-imposed restrictions and a wave of federal and

[2] According to Kozhimannil et al. (2022), around 40% of rural hospitals' obstetrics programs lose money.
[3] According to the Center for Healthcare Quality and Payment Reform (2025), 194 rural hospitals in the U.S. have closed since 2005, while roughly half of those remaining operate at a loss, one-third are at risk of closing, and 14% are at immediate risk of closing. In Kentucky, four rural hospitals have closed since 2005, another 17 are at risk of closing, and five are at immediate risk.
[4] To illustrate, When Our Lady of Bellefonte Hospital closed in Russell in Greenup County, 1000 jobs were lost and the city of 3,400 people lost nearly 25% of its payroll tax base. See The Lane Report (2020) https://www.lanereport.com/121244/2020/01/catholic-hospital-near-ashland-to-close-costing-1000-jobs/ and Goetz (2020) https://www.wowktv.com/news/local/our-lady-of-bellefonte-hospital-closing-today/ .

state legislative proposals aimed at reforming or enshrining current program practices. The growth in contract pharmacies – and corresponding increase in the share of 340B-eligible drugs receiving the discount – has been the subject of particular debate. Eight states have recently enacted laws to preserve discounts for networks of contract pharmacies in the face of manufacturer restrictions, with many others – including Kentucky – considering such laws.

There are now numerous studies using varying methodologies and data sources on the effects of the 340B program. This paper provides a critical evaluation of this evidence and assesses the policy implications with a particular focus on Kentucky. As is often the case with public policies, the ability to draw clear conclusions is hindered by challenges in disentangling causal effects from mere correlations. Since the program targets safety-net providers, covered and uncovered entities differ along numerous dimensions aside from 340B participation that could confound estimates of its impact. Some researchers aim to circumvent the causality problem by examining impacts of changes in the program's eligibility rules rather than participation itself, but this creates questions about statistical power and generalizability. Moreover, the applicability of evidence from studies that utilize data from across the U.S. to specific states like Kentucky is unclear.

Given these challenges, there is no consensus that covered entities have exclusively embraced or abandoned program aims. The preponderance of evidence points to several noteworthy effects, but the quality and/or quantity of the evidence is not yet sufficient to qualify as conclusive. Numerous anecdotal studies document 340B funds being used to improve access to care or reduce prices for low-income patients, though the generalizability of these anecdotes is unclear. There is also some evidence from more rigorous studies that 340B participation increases charity care and oncology provision and reduces Medicare Part B charges at Critical

Access Hospitals (CAHs). On the other hand, evidence also suggests that contract pharmacies and associated outpatient clinics are on average located in more affluent communities than the covered entity itself, raising questions about whether the program has reached beyond its intended purpose of helping vulnerable communities. Some studies also find that 340B slows covered entities' adoption of low-cost biosimilar drugs, presumably because the discount increases with the cost of the drug. Evidence on other outcomes such as uncompensated care, provision of services besides oncology, patient health, and vertical integration is less clear.

Given the lack of conclusive evidence thus far in the literature, the clearest effect of the 340B program remains the most obvious one: to transfer money from drug manufacturers to safety-net health care providers. Accordingly, current public policy debates should center primarily on the appropriate level of such redistribution. When viewed from a national perspective, this is a complicated question. Economic theory generally suggests that redistribution hurts efficiency but can be justified on subjective equity grounds. However, in markets that already face numerous distortions, such as health care, redistribution can improve efficiency if it is in the opposite direction of the distortions.

However, the policy evaluation is simpler from the perspective of policymakers at the state level: when opportunities arise to bring money from out of state into the state without imposing a cost to taxpayers, it is generally desirable to do so. The 340B program meets these criteria, as the drug manufacturers footing the bill are (in most cases, including Kentucky's) out of state, the safety-net providers receiving the money are inside the state, and no tax revenue is required. In fact, the net effect on taxpayers is almost certainly positive: money flowing into the state creates jobs and tax revenue, which in turn reduces the government's need for other sources of financing. The amount of money at stake in the current debate over preserving contract

pharmacy discounts is substantial, as drug companies' restrictions on contract pharmacies have been estimated to cost Kentucky hospitals $122 million per year (Kentucky Hospital Association, 2024).

Our work builds upon prior reviews of the 340B literature by Levengood et al. (2024) and Knox et al. (2023). Our contribution relative to those reviews is to include updated and more detailed discussions of (1) the institutional details and history of the program; (2) the current policy and legal landscape surrounding it; (3) challenges facing 340B researchers, including causal inference and generalizability, and the extent to which existing studies are susceptible to these concerns; and (4) the implications of the available evidence for ongoing policy debates, viewed through the lens of economic theory.

II. Background

Participation and Expansions

Currently, participation and purchases made under 340B are sizeable. Over 2,600 hospitals participated in the program in 2023, representing over 40% of the 6,120 hospitals in the U.S. (Government Accountability Office 2023; American Hospital Association 2024). An estimated $66.3 billion in 340B-covered purchases were made in 2023 (Health Resources and Service Administration 2024). This was up from roughly $53.7 billion in 2022, when it represented 13.2% of estimated spending on prescription drugs and 1.2% of estimated spending on health care (Health Resources and Service Administration 2023; American Medical Association 2024). Disproportionate share hospitals (DSHs) comprised 45% of participating hospitals in 2014 and made 78% of 340B-eligible purchases in 2023 (Medicare Payment Advisory Commission 2015; Health Resources and Service Administration 2024). While certain

designations, such as critical access hospital (CAH), are sufficient for eligibility, qualification as a DSH requires a minimum Medicare DSH payment adjustment percentage of 11.75%.

Medicare and Medicaid both provide DSH subsidies to hospitals that serve a disproportionate number of low-income patients. Under the Medicare Inpatient Prospective Payment System (IPPS), covered inpatient cases are categorized into diagnostic-related groups (DRGs). Cases are reimbursed based on the average resources used to treat Medicare patients in a DRG. DSH payment adjustment percentages are used to provide add-on Medicare payments by applying the DSH percentage to the DRG base payment rate (Center for Medicare and Medicaid Services 2024a).

The primary qualification method for Medicare DSH payment adjustments is determined by a hospital's disproportionate patient percentage (DPP). The DPP is the sum of two ratios. The first is the share of Medicare total patient days made up of patients entitled to both Medicare Part A and Supplemental Security Income; in effect, this means the proportion of Medicare patients who are low income. The second is the share of total patient days made up by Medicaid patients not entitled to Part A. If a hospital's DPP exceeds 15%, then it qualifies for a DSH payment adjustment (Center for Medicare and Medicaid Services 2024b).

To obtain the adjustment percentage, the DPP is inserted into a Center for Medicare and Medicaid Services (CMS) formula based on hospital DPP, beds, and urban or rural status. For example, the CMS would use one of two formulas for an urban hospital with more than 100 beds. If the DPP were below 20.2%, the DSH percentage = 2.5% + [0.65 × (DPP-15%)]; if it were above, the formula changes to 5.88% + [0.825 × (DPP-20.2%)]. If this hypothetical hospital's DPP was 40%, it would have a DSH percentage of 22.22%. It is this DSH percentage that is used for 340B eligibility. This percentage is capped at 12% for hospitals of certain sizes,

types, and locations, and the hospital in our example would have faced this cap if it had less than 100 beds (Center for Medicare and Medicaid Services 2024c). As an alternative to the primary method, urban hospitals with 100 or more beds can qualify for DSH payments if 30% of their net inpatient care revenues come from non-Medicare, non-Medicaid state or local sources for indigent care (Center for Medicare and Medicaid Services 2024b).

The Medicare Modernization Act (MMA) in 2003 and the Affordable Care Act (ACA) in 2010 both expanded eligibility for the 340B program. The MMA applied the DSH formula used for large urban hospitals to rural and smaller urban hospitals and capped its value at 12%, allowing such hospitals to pass the 11.75% eligibility threshold. Previously, many of these hospitals had been capped at 5.25% (Medicare Modernization Act 2003; Center for Medicare and Medicaid Services 2004). The ACA directly expanded eligibility in 2010 to children's hospitals, cancer hospitals, CAHs, rural referral centers, and sole community hospitals (Patient Protection and Affordable Care Act 2010). It also indirectly expanded eligibility among DSHs via state Medicaid expansions, which increased hospitals' DSH percentages in expansion states and made them more likely to qualify (Nikpay 2022). Accordingly, participation in 340B grew by over 40,000 entities between 2000 and 2020. In 2020, nearly 60% of the over 50,000 participants were hospitals or their child sites, which are affiliated locations such as outpatient clinics and departments that are not housed within the main facility and have separate addresses (Mulligan 2021; Health Resource Service Administration n.d.).

Contract Pharmacies

Participation for entities without in-house pharmacies is enabled by the allowance of contract pharmacies, which are external pharmacies contracted to dispense covered drugs for an entity. Entities with in-house pharmacies, however, may also use contract pharmacies. For a

covered entity to benefit from 340B discounts, a prescription must be filled in-house or at a contract pharmacy. If it is, the pharmacy passes on payments received from the patient and insurer to the entity, usually for a dispensing fee for external pharmacies (Government Accountability Office 2018). The entity then purchases a replacement at its 340B discount and has it shipped to the pharmacy. The difference between prescription reimbursement and cost of replacement represents the entity's benefit. If the prescription is not filled in-house or at a contracted pharmacy the benefit is not captured.

In 2010, the Health Resources and Services Administration (HRSA), the Health and Human Services (HHS) agency that oversees 340B, issued guidance allowing covered entities to contract with an unlimited number of pharmacies (Health Resources and Services Administration 2010). The use of contract pharmacies since has increased considerably. In 2009, about 600 retail pharmacies were contract pharmacies. In 2022, roughly 46% of all pharmacies were contract pharmacies and only 5% of the nearly 27,000 contract pharmacies were owned by covered entities (McGlave et al. 2024).

Recent Federal Legislation and Legal Cases

The revenues accrued from 340B discounts are intended to "stretch federal resources" to help more "eligible patients" and provide more "comprehensive services" (Health Resources and Services Administration 2024). As the law is not explicit about how to realize this aim, covered entities have discretion in their use of 340B funds. The growth in program size, discretion with funds, and that the funds are transfers from manufacturers have led to program criticism, calls for reform, litigation, and legislation. Multiple Congressional bills introduced since 2017 sought to either enshrine interpretations of 340B by the HRSA, which typically favor covered entities, or impose more explicit restrictions and reporting requirements on participants that are favored by

manufacturers (PAUSE Act 2017; HELP ACT 2018; PROTECT 340B Act of 2023; 340B PATIENTS Act of 2024; 340B ACCESS Act 2024).

The program has seen a host of pertinent federal cases and the courts have reprimanded government agencies concerning 340B multiple times in recent years. For example, effective in 2018, the CMS reduced Medicare Part B reimbursements for 340B-covered drugs. The range for 340B cost savings was estimated to be between 20% and 50% in 2011 (Government Accountability Office 2011). The reimbursement for 340B participants under Medicare's Outpatient Prospective Payment System (OPPS) in 2018 was reduced from a drug's average sales price (ASP) plus 6% to ASP minus 22.5%. This differential reimbursement was struck down unanimously by the United States (US) Supreme Court in 2022 and required make-up payments of $9 billion. Budget neutrality of OPPS, however, required offsetting reductions to Part B nondrug reimbursements of $7.8 billion (Center for Medicare and Medicaid Services 2023; Nikpay 2024).

More recent federal cases have concerned the amount of freedom parties have to interpret 340B law. Multiple US Circuit Court of Appeals decisions denied the HRSA's claim that manufacturers were prohibited from restricting distribution to contract pharmacies. The HRSA asserted this claim after several manufacturers imposed restrictions on covered entities' use of contract pharmacies in 2020. As described by the 3rd Circuit Court, AstraZeneca would only recognize one contract pharmacy in the absence of an in-house pharmacy. Its fellows in the lawsuit, Sanofi and Novo Nordisk, had similar policies but would recognize more contract pharmacies only if covered entities provided 340B claims data or obtained express permission respectively (3rd Circuit Court 2023). The D.C. Circuit noted that United Pharmaceuticals would not recognize contract pharmacies added after quarter three of 2020 and would also impose

claims data requirements. United Therapeutics' fellow appellee, Novartis, would only recognize contract pharmacies within 40 miles of a hospital (D.C. Circuit Court 2024).

By mid-2023, at least 19 other manufacturers, including Eli Lily, Johnson and Johnson, AbbVie, Merck, and Pfizer, had some combination of numeric and or geographic restrictions on contract pharmacies, with several also requiring claims data submissions (National Association of Community Health Centers 2023). The purpose manufacturers have proposed for claims requirements is to check for federally prohibited duplicate discounting and diversion (Sanofi 2020). Duplicate discounting occurs when discounts are claimed both under the Medicaid Drug Rebate Program and the 340B Drug Pricing Program for the same prescription. Diversion occurs if a covered entity sells 340B drugs to someone who is not the entity's patient (3rd Circuit Court 2023).

In 2023 and 2024 respectively, the 3rd and D.C. Circuit Courts found that the law did not expressly prohibit manufacturer restrictions on distribution (3rd Circuit Court 2023; D.C. Circuit Court 2024). Also in 2024, however, the 8th Circuit Court found that Arkansas was not excluded from legislating such prohibitions, and the Supreme Court declined to review this decision (8th Circuit Court 2024; Supreme Court 2024). This suggests that where Congress remains silent on distribution the states can speak, however, if both are silent, manufacturers may speak.

Attempts manufacturers may make to define what qualifies as diversion, however, may prove legally fraught. The definition of what it means to be a patient of a covered entity has itself come under legal scrutiny in recent years. In 2022, the 4th Circuit Court of Appeals remanded Genesis Healthcare Inc. v Xavier Bacerra back to the District Court of South Carolina for adjudication. The case's primary contention was the HRSA's definition of "patient," which was central to removing Genesis from the 340B program. According to the HRSA, to be a 340B

eligible patient, the covered entity "must have initiated the healthcare service resulting in the prescription" (District Court of South Carolina 2023). In 2023, however, the District Court found this to be contrary to the intended “plain language of the statute” (District Court of South Carolina 2023). It found that the statute neither defined “patient” nor required a prescription to “originate from a ‘covered entity’…for an individual to be considered an eligible 340B patient” (District Court of South Carolina 2023). The court asserted that, in the absence of an explicit definition, Congress intended “patient” to have the plain meaning of "an individual awaiting or under medical care and treatment." (District Court of South Carolina 2023). This broader definition may confound efforts to identify diversion and may increase the number of 340B-eligible prescriptions. For example, a study applying both definitions to Medicare Part D claims suggested that the change could increase 340B-eligible Part D prescription fills by 25% (Nikpay et al. 2024).

State Legislation

State 340B legislation has grown in recent years. As of May 2023, 32 states including Kentucky had legal prohibitions against insurers and pharmacy benefit managers (PBMs) differentially interacting with 340B entities and pharmacies (National Association of Community Health Centers 2024). Prohibited actions may include differential reimbursements or fees or exclusion from networks due to 340B participation. As of July 2024, 8 states had enacted contract pharmacy protections against manufacturers, with only Arkansas’ and Louisiana’s being enacted before 2024. More than 10 other states, including Kentucky, began considering similar protections that year (Ingmire 2024). States with such laws, however, have been sued by manufacturer representatives and most cases are yet undecided (Grimm et al. 2024). If other

courts decide contrarily to the 8th Circuit, the matter of states' 340B legislation could still go before the Supreme Court.

Kentucky placed legislative restrictions on 340B-relevant PBM activities in March 2020 (SB 50 2020). Once enacted, this legislation required the commonwealth to select a single PBM to serve all of the Medicaid managed care organizations contracted with the commonwealth. It also limited the PBM's ability to interact differentially with pharmacies, such as with fees, reimbursements, or based on pharmacies' relationship with the PBM. Additional restrictions on PBMs were signed into law in April of 2024. These included requirements for PBMs' pharmacy networks to be "reasonably adequate and accessible" (SB 188 2024). Among the accessibility provisions, for example, was network inclusion of non-mail-in pharmacies within 30 miles of patients' residence.

Kentucky's consideration of prohibiting manufacturer-imposed 340B restrictions began in 2024 with the introduction of Senate Bill 27. The bill prohibits manufacturer discrimination against "340B covered entities." However, the definition of "340B covered entities" within the bill includes entities' owned and contract pharmacies (SB 27 2024). Prohibited discrimination against "340B covered entities" includes manufacturer refusal to offer 340B pricing in Kentucky that is offered in other states; and limitations, conditions, or delays imposed on 340B sales that are not expressly provided under federal law or are beyond a manufacturer's control (SB 27 2024). The bill passed in the Kentucky Senate in March of 2024 but was not voted on in the House during the 2024 legislative session.

III. Evidence

We next turn to our summary and evaluation of the existing scholarly literature on how 340B-eligible health care facilities respond to the program. We categorize possible responses as

"intended", "unintended", or "other" based on their consistency with the intent of the legislation. "Possible intended effects" largely relate to provision of care that is relatively unprofitable or serves critical community needs. "Possible unintended effects" refer to strategic responses by covered entities that seem at odds with program intent. "Other possible effects" are either outside the control of covered entities or cannot easily be classified as intended or unintended. As implied by the inclusion of the word "possible", categorization is based on outcomes rather than results. For instance, a study that examines the effect of 340B on uncompensated care would fit into the "possible intended effects" category regardless of whether or not it finds that any effect occurs.

Our process of identifying relevant studies began with independent analyses of the empirical evidence described within literature reviews by Knox et al. (2023) and Levengood et al. (2024). We then utilized Google Scholar to identify additional studies not included by Knox et al. (2023) and Levengood et al. (2024), finding around twenty. In most cases, those studies were published after the time frame covered by those reviews.[5]

When synthesizing a scholarly literature, an essential step is evaluating the quality of the individual studies. Not all evidence is created equal; for instance, a single study that credibly identifies causal effects among a large and representative sample can carry more weight than 100 studies suffering from a common major flaw. We separate the 340B literature into three groups based on the size and representativeness of the sample and the rigor of the methods used. Evidence focused on a single location or a few locations is classified as "anecdotal" and given lowest priority in our discussion. Evidence from a broader set of observations but lacking a strategy to obtain causally interpretable results (i.e. descriptive, correlational, or associational) is

[5] Due to lags in the journal publication process, these prior reviews are not as up-to-date as their publication dates would suggest.

labeled “non-causal” and receives middle priority. Studies whose methods aim to identify causality – regardless of their level of success in doing so – are labeled “causal” and receive highest priority.

The 340B program presents clear empirical challenges to identifying causal relationships between program participation and outcomes of interest. To participate in the program, a health care entity must (1) be eligible and (2) voluntarily choose to participate, both of which lead to important differences between enrollees and non-enrollees. Facilities serving low-income communities are most likely to meet eligibility criteria, while those who choose to participate among the eligible are likely those in most need of the funding. For both reasons, we should expect 340B-covered entities to appear worse off along measurable dimensions than non-340B entities. This in turn means that naïve comparisons will not capture causal effects of the program. For instance, facilities serving disadvantaged populations likely provide relatively high levels of uncompensated care and are also relatively likely to be 340B participants. Therefore, a naïve comparison will give the appearance that 340B increases uncompensated care, even if there is no real causal effect.

Econometric approaches to identifying causal effects therefore involve either statistically adjusting for pre-intervention differences between treated and untreated entities or finding sources of variability in 340B enrollment that are “as good as random”, thereby ensuring that enrollees and non-enrollees would look the same if the program did not exist. Such approaches are collectively referred to as “natural experiments” or “quasi-experiments”.

The strategy of adjusting away baseline differences, typically called “difference-in-differences” (DiD) or “fixed effects” (FE), requires having data from both before and after the intervention. If underlying differences between treated and untreated groups can plausibly be

assumed to be constant over time, then the difference between changes over time in the treated and untreated groups has a causal interpretation even if the static difference between the groups does not. For instance, changes in uncompensated care among new 340B enrollees can be compared to changes during the same time period among health care entities that did not enroll. However, the assumption of constant underlying differences over time can be problematic, and in practice it is difficult to make the case for causality if treatment is voluntarily chosen, as is the case with 340B.[6]

Identifying treated and untreated groups that are identical aside from the treatment is preferable, but such cases are rare in the absence of randomization. One possibility for 340B would be to compare facilities just under the eligibility cutoff to those just over the cutoff – an approach known as regression discontinuity (RD). While conceptually appealing, in practice, there may not be enough facilities close to the cutoff to enable precise enough estimation to be useful. The researcher can end up being unable to rule out either no effect or very large effects, in which case the analysis is of little value. The bandwidth around the cutoff can be widened to increase the sample size, but this comes at the cost of comparability of the groups on each side.

This example illustrates the broader point that researchers often face tradeoffs between causality and precision. To obtain comparable treated and untreated groups, large amounts of variation generally need to be discarded (e.g. all facilities not within a narrow bandwidth surrounding the 340B cutoff), leading to estimates functionally driven by a small subsample – even if the sample size nominally remains large. Even if estimates are sufficiently precise to be useful, the question remains of whether these estimates are generalizable beyond the

[6] Also, DiD estimation in particular experienced significant changes in 2020 and 2021 as bias concerns arose over staggered treatment timing (Borusyak et al. 2024; Callaway and Sant'Anna 2021; de Chaisemartin and D'Haultfœuille 2020; Goodman-Bacon 2021; Sun and Abraham 2021).

observations used for identification. For example, even if an RD approach successfully identifies the causal effect of 340B on facilities near the cutoff, it is uncertain that the effect would be the same at facilities further from the cutoff. The process of synthesizing evidence from various natural experiments to reach conclusions can be described as repeatedly shining a flashlight in different parts of a dark room in order to understand the overall picture. Just as a clear view of only one spot in a room may not be especially informative, causally interpretable evidence from a single setting is insufficient to justify broad claims about the population at large.

Possible Intended Effects

The intention of the 340B program was to stretch federal resources to better meet the needs of underserved communities. Therefore, "possible intended effects" include increased provision of care that is unprofitable or serves critical community needs, spillover reductions in Medicare expenditures, and health improvements among vulnerable populations. The literature mostly focuses on hospitals. Some hospital services are unprofitable because of patients' inability to pay. These are typically measured as charity care, which is care intentionally given for free or at a reduced cost, or uncompensated care, which also includes services for which payment was sought but not obtained. In other cases, such as obstetrics, the services themselves are relatively unprofitable due to low reimbursements from private or public insurers. Profitable and unprofitable service lines in the discussed evidence were chosen based on prior work such as Horwitz (2005).

A number of studies related to intended effects of 340B fall into our lowest priority "anecdotal" category. They have largely documented 340B hospitals' efforts to provide low-income patients better prescription access, often via reduced pricing, and to support expanded or sustained patient care such as for those with hepatitis C (Fischer et al. 2022; Lasser et al. 2017;

Mansour 2015; Mascardo 2012; Taliaferro et al. 2023; Wu et al. 2019; Jones et al. 2019). Other work suggests 340B participation supports reductions in medication costs for low-income patients and the provision of some additional services at FQHCs (Bidwal et al. 2017; Burde et al. 2019; Castellon et al. 2014; Clifton et al. 2003; Gallegos et al. 2022; Hudd and Tataronis 2011; Jessop et al. 2022; Rodis et al. 2019; Robbins et al. 2021; Wagner et al. 2023).

Several "non-causal" studies examine benefits to vulnerable populations. Nikpay et al. (2018) find that before 2004, urban hospitals who already participated in 340B prior to the expansions served more low-income populations and had higher levels of uncompensated care as a share of their budget than newer and non-participants (Nikpay et al. 2018). This is consistent with the program's intent to serve relatively disadvantaged patient populations. Other evidence indicates expanded medication access at FQHCs and cross-subsidized service provision (Clark et al. 2012; Lopata et al. 2021; Malouin et al. 2018; Shi et al. 2018; Watts et al. 2024). On the other hand, covered entities' 340B participation and their child site expansions have been found to not be associated with reduced racial/ethnic disparities among Medicare beneficiaries with chronic asthma (Tripp et al. 2023; Tripp et al. 2024).

We next turn in more detail to the related "causal" literature. First, Nikpay et al. (2020) examine effects on uncompensated care, charity care, charity care policies, other beneficial community spending, and profitable and unprofitable service line provision. In a DiD setting, the authors estimated the effect of 340B participation among non-critical-access general acute care hospitals (GACHs) on these outcomes from 2011-2015. The treated group of hospitals is those who enrolled in 340B during the sample period. The authors utilize three separate control groups, which progressively exclude the GACHs who enrolled in 340B prior to the sample period and then those that never enrolled, ultimately leaving only those that enrolled in 340B after the

sample period. The study finds consistent evidence of an over 20% increase in charity care provision and greater generosity in discounted care policies. They find no evidence of increases in total community benefit spending, uncompensated care, or unprofitable service line provision, but the estimates tend to be imprecise and sizeable increases cannot be ruled out.

Nikpay et al.'s paper provides a good illustration of the benefits and pitfalls that are common to many studies that utilize DiD. On one hand, DiD clearly improves over "non-casual" methods by adjusting for baseline differences between hospitals. This ameliorates causality concerns to the extent that differences across hospitals in patient characteristics and financial health stay the same over time. On the other hand, DiD methods are still flawed if these and other relevant characteristics change over time. In the case of 340B adoption, there are reasons for such concerns. Presumably, some hospitals enrolled in 340B between 2011 and 2015 because they became newly eligible due to a negative shock in circumstances. Others may have been eligible all along but enrolled only after sudden financial strain or changes in leadership or strategy. None of these scenarios would be accounted for by a research design that only adjusts for baseline differences.

Realizing this, authors often – as Nikpay et al. did – experiment with different control groups and specification changes in an effort to show robustness. Simply put, if the results remain similar utilizing several different approaches that are all imperfect in slightly different ways, then one might surmise that these imperfections are not meaningfully impacting the findings. DiD studies also generally aim to show that differences between treatment and control groups are reasonably stable over time in the pre-treatment period, which suggests that they would have remained stable in the post-treatment period if treatment had not occurred. Such strategies can be compared to a prosecution based on circumstantial evidence, in contrast to the

"DNA evidence" of randomized experiments. Circumstantial evidence alone cannot prove guilt with 100% certainty but can meet the standards of "preponderance of evidence" or "beyond a reasonable doubt". Of course, there is some subjectivity as to whether these standards are met.

Desai and McWilliams (2021) investigate whether 340B participation among GACHs and CAHs led to changes in uncompensated care. The authors focus on two time periods that shortly followed statutory expansions of the program. The first is 2003-2009, as the 2003 MMA increased eligibility among GACHs, leading to a wave of new participants over the next several years. The second is 2011-2015, following CAHs and other types of facilities becoming eligible in the 2010 ACA. Accordingly, their sample is restricted to GACHs in the first analysis and CAHs in the second. The control groups are hospitals that never participated or participated after the sample period. The authors find no evidence of increased uncompensated care provision for either set of hospitals.

At first glance, Desai and Williams' approach might appear to utilize public policies as sources of identification, which could be more credible than hospital enrollment decisions because these policies are not under the direct control of hospitals. Indeed, implementation of new laws provides arguably the most common source of variation in DiD studies currently published in leading journals. However, this is not actually what Desai and Williams' analyses do. Leveraging policy variation requires data from both before and after the intervention, as well as the construction of a control group of similar hospitals not made eligible due to the intervention. This is difficult to do with nationwide policy changes such as the MMA and ACA, as typically the control group comes from states or other geographic areas that did not receive the treatment. Accordingly, Desai and Williams' data come from after the interventions rather than both before and after, and their analyses leverage hospital enrollment decisions rather than the

policy changes themselves. Therefore, their approaches are susceptible to the same sort of threats to causality as those of Nikpay et al. (2020).

Caveats aside, Nikpay et al's (2020) and Desai and McWilliams' (2021) still provide the most rigorous investigations to date of the impact of 340B participation on uncompensated care provision, and they both find null results. However, Nikpay et al. also find evidence of a sizeable increase in charity care provision. How could charity care increase but uncompensated care remain unchanged? As Nikpay et al. (2020) discuss, uncompensated care is the sum of charity care and bad debt, so this pattern of results implies that 340B reduces bad debt by an amount that roughly offsets the rise in charity care. This is consistent with hospitals implementing more generous charity care policies, but the newly eligible patients being those who previously would have been billed but not paid. If true, the benefit to patients lies in not having bills turned over to collection and having their credit scores impacted.

With all that said, we should use caution when taking null results at face value. Finding no evidence of an effect is not the same as finding evidence of no effect. Therefore, with any null result, it is important to ask what effect sizes can be ruled out. Based on their reported coefficient estimates and standard errors, Nikpay et al.'s (2020) 95% confidence intervals are able to rule out increases in uncompensated care from 340B participation of larger than 7% to 10% depending on the specification. While these upper-bound magnitudes are considerably smaller than the statistically significant point estimates for charity care of 21% to 29% (and their corresponding upper-bound magnitudes of 41% to 46%), they are arguably still consequential. Desai and Williams (2021) find a negative point estimate and only a slightly positive upper bound for the effect of 340B on uncompensated care in their 2003-2009 analysis, but a positive point estimate and a more substantial upper bound of 9% in their more recent 2011-2015

analysis. In short, it would be more precise to say that we do not yet have a clear answer for the impact of 340B on uncompensated care, rather than that we have conclusive evidence that there is no meaningful effect.

In another study meeting our "causal" criteria, Owsley and Bradley (2023) explore the influence of 340B participation on the initiation of oncology services in rural and primarily CAHs from 2011-2020. They motivate their study by pointing out the limited availability of oncology services in rural communities. They use a DiD setting with broadly similar pros and cons to those of Nikpay et al. (2020) and Desai and McWilliams (2021). The authors find that 340B participation led to an 8.3 percentage point increase in the probability of initiating oncology services. Only about 9% of never-participating hospitals added oncology during the timeframe (our calculation based on numbers in Exhibit 4), implying that 340B participation nearly doubled this likelihood. This effect was stronger in states that expanded Medicaid under the ACA but still statistically significant (i.e. conclusively different from zero) in non-expansion states. The effect also grew with the length of participation, from under 4 percentage points in the treatment year to about 15 percentage points six years later.

Owsley et al. (2024) use similar DiD methods to investigate whether participation in 340B led non-critical-access short-term hospitals to offer more unprofitable or profitable service lines from 2010-2019. They separate their investigation between participants by public ownership status. Their results suggest that 340B participation increased substance abuse, psychiatric, and total unprofitable services for public hospitals. Among non-public, nonprofit hospitals, they find only an increase in oncology. One caveat to these results is that the authors conduct an extensive series of regressions with numerous outcomes, raising questions about whether the modest number of statistically significant results they found could have occurred

simply by chance. This is known as the "multiple hypothesis testing" problem. Nonetheless, the evidence of increased oncology service provision aligns with the results of Owsley and Bradley (2023).

Based on their results, we would also cautiously add increased obstetric provision to their significant effects. The results for obstetrics are statistically significant for the full sample and less precise but supportive of this finding for the subsamples. Our caution comes from Nikpay et al. (2020), who do not find significant changes in obstetric offerings and whose implied confidence intervals appear to only narrowly include Owsley et al.'s estimated effect size.

Smith et al. (2023) estimate the effect of 340B DSH eligibility on health-related outcomes such as all-cause mortality and 30-day readmission rates. They utilize an RD method comparing GACHs within 10 percentage points of the 340B eligibility cutoff. As with many RD designs, this approach has the benefit of making treatment and control hospitals more similar than comparisons using all hospitals, but at the cost of some identifying variation and therefore precision. Data come from GACHs in 15 states from 2008-2015, except for California whose data ended in 2011. They find no statistically significant effects on low-income patients but significant reductions in acute myocardial infarction mortality and onset of postoperative sepsis for all patients. Although most of their estimates are statistically insignificant, all 12 coefficients in their preferred hospital-level results are negative, which points towards health improvements. The likelihood of this occurring by chance is 0.5^12, or two-hundredths of a percent. 10 of the 12 supplemental discharge-level coefficient estimates are also negative.

Han (2023) estimates the effect of the ACA eligibility expansion for CAHs on Medicare Part B drug spending and utilization from 2008-2013. Using a DiD approach that leverages differences in eligibility exposure across hospital referral regions, Han finds that higher

eligibility exposure led to reductions in Part B drug spending without corresponding reductions in utilization. These results suggest that CAHs may have passed 340B savings on to Medicare patients via reduced charges. This is consistent with the cost-based reimbursement structure for Part B drugs at CAHs.

Han et al.'s study is arguably the most credible in the literature in terms of causal identification because it leverages a public policy change that is outside of the control of hospitals for identification, as opposed to hospital enrollment decisions. In theory, this should lead to better balance across groups with different levels of treatment. Nonetheless, the study's approach is not completely immune to concerns about causality, as hospital referral regions with greater eligibility are likely relatively disadvantaged. If regions with different levels of disadvantage would have experienced different trends in Part B spending and utilization over time even in the absence of 340B expansion, this would pose a threat to validity. With that said, we would typically expect spending and utilization to evolve similarly, so the fact that Han finds an effect on spending but not utilization seems more consistent with a causal effect coming from CAH's unique reimbursement structure rather than spurious underlying trends.

Possible Unintended Effects

Studies categorized under "possible unintended effects" examine whether covered entities make certain strategic decisions that are inconsistent with the 340B program's intended purpose. Most such studies focus on extending the program into relatively affluent areas, consolidating market power, or influencing utilization in a way that increases costs.

The "non-causal" studies exploring unintended effects cover miscellaneous topics. Several papers show that covered entities' associated clinics and contract pharmacies tend to be located in relatively more affluent areas than the covered entity itself (Conti and Bach 2014; Lin

et al. 2022; Masia and Kuwonza 2023; Nikpay et al. 2022). Dean et al. (2021) present mixed evidence on 340B participation's influence on the use of less expensive biosimilars as opposed to more expensive biologics. Some evidence suggests 340B Medicare patients were no less likely than others to receive generic Part D prescriptions nor face riskier prescribing practices if they had advanced prostate cancer (Dickson and James 2023; Faraj et al. 2024). There are conflicting results on whether 340B hospitals apply higher markups for cancer drugs than non-340B hospitals (Robinson et al. 2024; Talwar et al. 2023; Xiao et al. 2022). Owsley and Karim (2024) suggest that 340B CAHs were less financially vulnerable and in less vulnerable communities than non-participating but eligible CAHs. Mulligan et al. (2021) suggest that hospitals may manipulate their DSH percentages to qualify for 340B. Machta et al. (2020) find that 340B participation may have factored into greater vertical integration in psychiatry and hematology-oncology.

We next turn to the causal evidence on potential unintended consequences. Some of the following studies also examined outcomes not specific or related to 340B and we do not discuss those aspects of them. The causal identification strategies tend to be similar to those used in the "intended consequences" portion of the literature and so we do not discuss their pros and cons again here.

Two "causal" studies investigate whether the 340B program had adverse effects on vertical integration within oncology, reaching conflicting conclusions. As a specialty that relies on drugs for about 77% of its revenue, reimbursement reductions such as those from Medicare Part B in 2005 may have made oncologists more amenable to integration (Akscin et al. 2007). With 340B discounts, oncology could still be a profitable service line for hospitals, and integration would be a way to expand its provision and bring in new patients. Alpert et al. (2017)

seek to understand the role 340B played in vertical integration within oncology from 2003 to 2015. They leverage the 2010 ACA-induced 340B eligibility expansion in a DiD framework similar to that of Han (2023), finding no evidence that greater exposure led to greater vertical integration. Desai and McWilliams (2018) use the RD approach later adopted by the aforementioned Smith et al. (2023) paper to examine the 340B program's effects on vertical integration in hematology-oncology and ophthalmology. They find that eligibility led to greater vertical integration, more Part B administrations of related drugs, more Medicare patients served but with a lower proportion of them being dually eligible, and no statistically significant change in mortality.

Reconciling these conflicting findings is not straightforward. Since the two papers use completely different quasi-experimental approaches, it is possible that one is correct and the other incorrect. However, both approaches have strengths and weaknesses, and it is not obvious which is superior. An alternate possibility is that the discrepancy in results could be attributable to the differences in types of hospitals (CAHs for Alpert et al. (2017) and GACHs for Desai and McWilliams (2018)) or the breadth of specialties being examined. This would mean both results could be correct for their particular setting, but there would be no way to reach conclusions about the program in general. In either case, the effect of 340B on vertical integration is not a settled question.

Two other "causal" studies revisit the question of how 340B impacts use of biologic and/or biosimilar drugs using more sophisticated methods than the "non-causal" papers mentioned earlier. The idea is that biologics are more expensive, and applying the 340B percentage discount to more expensive drugs nets a larger dollar amount for the covered entity. Bond et al. (2023) utilize a similar RD method to Desai and McWilliams (2018) to examine

whether 340B eligibility affected biosimilar use for two biologic drugs (Filgrastim and Infliximab) at DSHs from 2017-2019. They find a significant decrease in biosimilar adoption, more annual biologic administrations per hospital, and an increase in revenue from biologics. Chang et al. (2023) use a DiD approach to explore the spillover effects of hospitals' 340B participation on five biologic cancer treatments for privately insured individuals from 2007-2019. They define drug-specific episodes using the number of drug administrations and treatment timing for examined drugs. The authors find 340B participation increased treatment episodes and expenditures for privately insured patients. Total-episode drug expenditures increased by over $4,000 in year one of participation, falling to about $2,500 by year three.

Other Possible Effects

Other outcomes are driven by policy changes or manufacturer responses to the program. These include growth in covered entities and contract pharmacies, changes in manufacturer pricing, and changes in the proportions of Medicare Part D prescriptions covered and captured under 340B.

One such study fits our criteria to be considered "anecdotal". Lee et al. (2019) shows that wholesale acquisition prices and 340B acquisition prices trended somewhat similarly (Lee et al. 2019). In other words, 340B prices appear to follow an expected trajectory.

A group of "non-causal" studies examine manufacturer-related pricing and discount decisions (Dickson and Reynolds 2019; Dickson 2020; Dickson et al. 2023a). They suggest that 340B may exert downward pressure on manufacturer prices/price increases for drugs with large shares of 340B purchases. They also suggest that the discounts negotiated by insurers and PBMs, compared to those for 340B, account for a much higher proportion of the gross-to-net price gap for insulin.

Several studies have noted substantial growth in contract pharmacies, particularly since 2010 (Lin et al. 2022; McGlave et al. 2024; Nikpay et al. 2022; Nikpay et al. 2023). Accordingly, Dickson et al. (2023b) document the change in the 340B capture rate for 340B covered Medicare Part D prescriptions, where capture occurs when a 340B-covered prescription is filled at a 340B pharmacy. They note that from 2013 to 2020, the Part D capture rate for filled prescriptions increased from 18.4% to 49.9%, the proportion of written Part D prescriptions covered under 340B increased from 9.4% to 19.3%, and the proportion of total Part D prescriptions covered and captured under 340B rose from 1.7% to 9.6%.

Finally, a "causal" study by Nikpay (2022) examines how changes in Medicaid coverage impacted enrollment in DSH and 340B programs from 2003-2019. Eligibility for each program relies on Medicaid patient volume and is potentially sensitive to coverage changes. The author defines appropriate targets for DSH and 340B enrollment by whether hospitals' uncompensated care represents at least 5% of their operating revenue. Nikpay leverages the Medicaid expansions of the ACA in a DiD framework to estimate changes in programs' targeting efficiency. Medicaid expansions reduce uncompensated care, increase Medicare DSH receipt, and increase 340B participation for expansion state hospitals. This leads to statistically significantly worse targeting for DSH programs but not 340B.

Summary and Discussion of Evidence

The literature on the effects of the 340B program examines a wide range of outcomes and utilizes several different methodological approaches, with some being more convincing in establishing causality than others. Table 1 summarizes the results from the studies in this literature, organizing them by the possible effect being examined and whether they are in our "anecdotal", "non-causal", or "causal" classifications. The table simply counts the number of

studies in each outcome/classification bin that find affirmative evidence of the effect in question, no evidence, or a mixed pattern of results where some outcomes indicate an effect and others do not. The table does not discuss effect sizes and does not evaluate whether null estimates are precise enough to rule out meaningfully large impacts. These are important considerations, but in our judgment attempting to include them would have made the table too complicated to be useful.

Based on Table 1 and the prior detailed discussion of evidence, our most important takeaways are as follows. First, there is abundant evidence that at least some hospitals use at least some 340B revenue as intended – to improve access to or reduce the cost of care for low-income patients. This is documented by 17 anecdotal studies. While any single anecdotal study is of limited value, the volume of evidence is difficult to ignore. There is no way to know conclusively whether this collection of individual anecdotes is representative of hospital decision-making more generally, which is why we hedge by saying "at least some". Five of seven "non-causal" studies reach similar conclusions, which suggests some degree of generalizability, but these studies are hampered by methodological limitations.

The highest quality "causal" evidence on 340B's effect on costs for low-income patients comes from only a few studies, suggesting caution is warranted when drawing conclusions. Nonetheless, some interesting results have emerged. The only causal paper to examine the effect of 340B participation on charity care finds an increase of over 20%. The two causal studies on uncompensated care find null results, implying that bad debt decreases by an amount that roughly offsets the rise in charity care. However, this still indicates a benefit to patients, as some who would have otherwise faced debt collectors and credit score reductions are instead not billed at all.

A few studies examine the causal impact of 340B on service line provision. The clearest evidence is an increase in oncology service offerings. This is supported by two "causal" studies and the effect is large. Evidence on provision of relatively unprofitable services such as obstetrics is mixed. This is consistent with some hospitals increasing these offerings, but this not occurring frequently enough to drive clearly measurable effects across a broad sample.

One high-quality study shows savings to the federal government from 340B in the form of reduced Part B drug spending at CAHs. While a single study is never enough to draw firm conclusions, this particular result seems highly plausible since reimbursement for Part B drugs at CAHs is cost-based, and 340B brings these costs down. We caution that the results cannot be assumed to generalize to GACHs since their reimbursement structure is different.

Turning to unintended consequences, the clearest result is that child sites (offsite outpatient facilities) and contract pharmacies tend, on average, to be in more affluent areas than those of the covered entity. Four studies have documented this for either or both types of facilities, with no research suggesting otherwise. While the studies all fit into our "non-causal" classification, the question itself – where certain facilities are located – is inherently non-causal, as it does not ask how one variable affects another.

The more important limitation of this work is that facility locations are not the same as patient locations. Pharmacies already exist before covered entities contract with them, and there may not be enough pharmacies located in lower-income areas to meet the needs of the covered entity's patients (Masia and Kuwonza, 2023). In the case of child site locations, suitable office space may not always be available in lower-income areas. Therefore, while the locations of child sites and contract pharmacies suggest that some covered entities might be stretching beyond program intent and treating higher-income patients, the evidence is not conclusive. Moreover,

program intent is difficult to precisely define in this regard, as 340B is a facility-level rather than patient-level program, with qualification based on overall patient mix rather than a given patient's income. A hospital can see higher-income patients and still meet the DSH requirement.

The other potentially adverse effect that, in our view, has enough empirical support to warrant discussion is the lack of biosimilar take-up, which obviously implies higher costs. While "non-causal" studies on the topic reach mixed results, the only two "causal" studies on the topic find evidence of continued and expanded biologic use. Moreover, the misaligned incentives created by the program are clear: since 340B revenue increases as the cost of the drug increases, prescribing higher-cost drugs when feasible is advantageous.

Finally, a clear result from the literature is that the number of contract pharmacies – and with it the capture rate of 340B-eligible prescriptions – has risen rapidly. We place studies on these topics in the "other possible effects" section because they are the subjects of ongoing debate. However, the intended effect of the 2010 HRSA guidance allowing unlimited contract pharmacies was clearly to increase these numbers to at least some extent. The optimal capture rate is difficult to identify without sophisticated economic modeling. However, it seems hard to argue that the 18% rate from 2013 noted by Dickson et al. (2023b) was adequate. This is akin to an 18% take-up rate in a public program (e.g. the Supplemental Assistance Nutrition Program or Medicaid), which would be considered extremely low and worthy of investigation as to how to increase it. In other words, no government program aims to only reach 18% of those eligible. Even the 50% rate from 2020 would be considered low if viewed in terms of a take-up rate.

IV. Conclusion

The 340B drug pricing program aimed to stretch federal resources for safety-net health care by enabling qualifying health care entities to purchase drugs filled at in-house or contracted

external pharmacies at discounts. The most obvious and direct impact of the program is to transfer resources from drug manufacturers to covered entities. A sizeable literature has examined whether the indirect effects point to desirable or undesirable responses by hospitals and other 340B participants. However, existing studies vary widely in terms of outcomes, methodological rigor, type of facility, location, and time period. While this literature has produced several noteworthy results, they should all be considered suggestive rather than conclusive until more high-quality research is conducted.

With that caveat in mind, a partial picture of 340B's impacts is beginning to emerge. At least some covered entities appear to use 340B savings to provide more charity care or add lines of service, with oncology being the one most supported by the available evidence. Medicare Part B drug spending at CAH's also appears to decline. However, evidence that contract pharmacies and associated "child sites" tend to locate in more affluent communities than the covered entity itself raises questions about program scope, while evidence that covered entities substitute from biosimilar to biologic medications points towards possible misaligned incentives from the savings being proportional to drug cost.

Nonetheless, the clearest effect of 340B remains the redistribution from drug manufacturers to safety-net providers. Is this redistribution desirable, and if so, how much? From a national perspective, this is a difficult question to answer without detailed mathematical modeling that would require a number of strong assumptions. With that said, some broad concepts from economics are helpful in framing the question.

Economic theory posits two justifications for government intervention into markets. The first is to improve efficiency, which would only occur if the intervention corrects a market failure such as externalities (spillover effects on others) or imperfect information. Since it is difficult to

connect the 340B program to a specific market failure, one might deduce that it hurts efficiency. However, that logic only applies when an intervention is made into a market that was previously efficient. The market for health care bears little resemblance to the free market of economics textbooks, with regulations, taxes, and subsidies distorting prices and quantities in myriad ways. If, for instance, existing distortions net out in the favor of drug companies and against safety-net health care providers, then redistribution from the former to the latter could improve efficiency.

The distortions in health care are too numerous to fully dissect here, but the give-and-take processes through which the 340B program was modified by the MMA and ACA illustrate how expansions of the program were specifically designed to offset distortions that favored pharmaceutical companies. The MMA expanded 340B but also increased demand for drugs by implementing the Part D program while prohibiting the reimportation of drugs and negotiation of drug prices by the government (Oliver et al 2004). In effect, the law added three distortions in drug companies' favor and one against. By getting them to agree to 340B expansion, the government found a way to provide a revenue stream for struggling safety-net providers that did not require taxpayer money. In effect, instead of directly subsidizing these providers, the MMA subsidized pharmaceutical companies, who in turn subsidized the providers. The "subsidies" for drug companies occurred through paying for drugs under Part D as well as enacting restrictions that artificially inflated these prices.

This compromise did not occur by accident. In a 1999 article, then-president of the Pharmaceutical Research and Manufacturers of America (PhRMA) Alan Holmer signaled support for a Medicare expansion, just not one that resulted in the government bargaining drug prices.

> "PhRMA supports expanding prescription drug coverage as part of a Medicare program that is modernized to allow beneficiaries to choose among qualified, private-sector health plans. These plans would rely on market competition, not government regulation or price controls, to improve quality, integrate care, and manage costs" (Holmer 1999).

This quote uses a clever sleight-of-hand, as preventing reimportation and government bargaining is the opposite of promoting competition. A 2004 article describing the dollar and personnel lobbying investments manufacturers made leading up to the MMA being signed into law suggests significant efforts were made in line with Holmer's stated preferences and likely were key in achieving a favorable agreement (PublicCitizen 2004).

In their efforts to influence the shape of the ACA, pharmaceuticals companies appear to have had two key concerns. The first was a single-payer system. This would have left the industry bargaining with the federal government as the sole insurer, likely resulting in much wider discounts than a predominantly private system. The second concern was, again, the re-importation of drugs. One article on the ACA negotiations quotes a lobbyist for PhRMA as saying, "'Confidential: WH is working on some very explicit language on importation to kill it in health reform. This has to stay quiet,' Bryant Hall — who was then the chief lobbyist at PhRMA — wrote to other pharmaceutical industry executives.'" (Haberkorn 2012). According to another article, then-CEO of PhRMA Billy Tauzin said, "'We had a choice [to] make sure it wasn't going to be a single-payer government system,' Tauzin told POLITICO, recalling PhRMA's thinking at the time. 'If we were not at the table, it would be likely we would become the meal.'" (Norman and Karlin-Smith 2016).

One of the tradeoffs pharmaceutical companies made in order to avoid these larger concerns was to accept expanded discounting within the 340B program. The ACA itself made

several new types of sites eligible the program, while the 2010 HRSA guidance allowing unlimited contract pharmacies was presumably also part of the discussions. Again, we see the pattern of give-and-take and distortions layered on top of distortions, making it difficult to assess the efficiency impact of any single program in isolation.

The second rationale for government intervention is equity. There can be cases where sacrificing efficiency can be desirable for overall social welfare if it leads to a more equitable division of resources. Equity is a subjective concept, and there is room for disagreement as to what amount of redistribution from drug companies to safety-net providers is the most equitable. One could argue in favor of such redistribution on the grounds that safety-net providers provide a public good. Additionally, the fact that drug manufacturers signed off on the policy changes that expanded the 340B program in return for other concessions could be seen as having equity implications.

Another relevant concept from economics is the take-up rate, or the percentage of eligible recipients enrolled in a public program. How to increase these rates is a frequent subject of study among economists interested in social programs (Ko and Moffitt, 2024). For example, the take-up rate of seniors eligible for the Supplemental Nutrition Assistance Program is around 50%, which is considered so unacceptably low that is has triggered substantial scholarly attention (Jones et al., 2022).

One could view the capture rate for the 340B program as being a type of take-up rate. Dickson et al. (2023b) estimate that the 340B Part D capture rate – the percentage of 340B-eligible drugs filled at 340B pharmacies – rose from 18.4% in 2013 to 49.9% in 2020. The number of retail contract pharmacies tripled from 2009-2011, again from 2011-2013, and saw a nearly 2.5 times increase from 2013-2022 (Lin et al. 2022; Nikpay et al. 2023; McGlave et al.

2024). If the capture rate and number of contract pharmacies grew proportionally, these numbers imply a pre-2010-HRSA-guidance capture rate of just 2%. A take-up rate of 2% is unfathomably low, 18% is still very low, and even 50% is low enough to warrant investigation and program modification. When viewed this way, it seems far more likely that the pre-HRSA-guidance level of 340B discounting was too low rather than the current rate being too high.

Accordingly, if manufacturers' single contract pharmacy policies return affected entities to pre-2010 capture rates, this would appear to work against program intent. Even if policymakers feel that the optimal rate is below 50%, they still may not wish to leave policy decisions in the hands of manufacturers. As profit maximizers, manufacturers are incentivized to minimize their costs, including 340B outlays, regardless of covered entity efforts toward program aims. In the absence of intervention, manufacturers have the incentive and discretion to make obtaining 340B discounts as difficult as possible. This would presumably lead to capture rates that are far lower than optimal.

The above discussion applies most directly to federal policy, as it considers the impacts on everyone involved, including drug companies, covered entities, and patients. The policy debate for states hinges only on those affected within their borders. For most states, this makes the analysis much simpler: the program provides an opportunity to bring out-of-state money into the state without taxpayers having to foot the bill. The only exception would be states with a major drug manufacturing industry, which is not the case with Kentucky. Accordingly, recent legislative activity in many states always points in the direction of protecting or expanding 340B rather than shrinking it. A large majority of states have protections against differential treatment by insurers and PBMs. Eight states have implemented protections for contract pharmacy networks, and many more are considering doing so. Neglecting to implement such protections

would lead to Kentucky behind other states in terms of drug prices and overall economic development.

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Table 1 – Summary of Results from Empirical Studies on Impacts of the 340B Program

	Anecdotal	Non-Causal	Causal
Panel A: Intended Effects			
Better access or reduced prices for low-income patients	17 yes	5 yes 2 no	
Increased charity care			1 yes
Increased uncompensated care		1 yes	2 no
Increase other beneficial community spending			1 no
Increase unprofitable service line provision			1 no 1 mixed
Increased oncology services			2 yes
Increased obstetric services			1 yes 1 no
Improved health			1 mixed
Reduced Part B drug spending			1 yes
Panel B: Unintended Effects			
Child sites or contract pharmacies located in relatively affluent areas		4 yes	
Increased biologic/brand name drugs or decreased biosimilars/generics		1 mixed 2 no	2 yes
Higher price markups		2 yes 1 no	
Manipulation of DSH percentages		1 yes	1 no
Increased vertical integration		1 yes	1 yes 1 no
Panel C: Other Effects			
Prices follow wholesale trend	1 yes		
Downward pressure on manufacturer prices		3 yes	
Growth in contract pharmacies		4 yes	
Increase in Part D capture rate		1 yes	
Reduced targeting efficiency after ACA Medicaid expansion			1 no

Notes: Numbers refer to the number of studies meeting the specified criteria. "Yes" means the study found evidence of the stated effect. "No" means it did not, but we caution that not finding evidence of an effect is not the same as finding conclusive evidence that there is no effect. "Mixed" means the study examined multiple outcomes and found "yes" for some and "no" for others.

State of Arkansas *As Engrossed: H4/15/21*
93rd General Assembly **A Bill**
Regular Session, 2021 HOUSE BILL 1881

By: Representatives M. Gray, Wardlaw, Murdock, V. Flowers
By: Senator Rapert

For An Act To Be Entitled

AN ACT TO ESTABLISH THE 340B DRUG PRICING NONDISCRIMINATION ACT; AND FOR OTHER PURPOSES.

Subtitle

TO ESTABLISH THE 340B DRUG PRICING NONDISCRIMINATION ACT.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:

SECTION 1. Arkansas Code Title 23, Chapter 92, is amended to add an additional subchapter to read as follows:

Subchapter 6 — 340B Drug Pricing Nondiscrimination Act

23-92-601. Title.

This subchapter shall be known and may be cited as the "340B Drug Pricing Nondiscrimination Act".

23-92-602. Definitions.

As used in this subchapter:

(1) "Patient" means an individual seeking medical diagnosis and treatment;

(2) "Pharmacy" means the same as defined in § 17-92-101;

(3) "Provider" means a licensed pharmacist as defined in § 17-92-101;

(4)(A) "Third party" means:

(i) A payor or the payor's intermediary; or

(ii) A pharmacy benefits manager.

(B) "Third party" does not include:

(i) The Arkansas Medicaid Program;

(ii) A risk-based provider organization as established under the Medicaid Provider-Led Organized Care Act, § 20-77-2701 et seq.; or

(iii) A self-insured governmental plan or a pharmacy benefits manager for a self-insured governmental plan; and

(5) "340B drug pricing" means the program established under section 602 of the Veterans Health Care Act of 1992, Pub. L. No. 102-585.

23-92-603. Third-party requirements.

A third party shall:

(1) Inform a patient that the patient is not required to use a mail-order pharmacy;

(2) Obtain a signed waiver from a patient before allowing the use of a mail-order pharmacy;

(3) Make drug formulary and coverage decisions based on the third party's normal course of business;

(4) Allow a patient the freedom to use any pharmacy or any provider the patient chooses, whether or not the pharmacy participates in 340B drug pricing; and

(5) Eliminate discriminatory contracting as it relates to:

(A) Transferring the benefit of 340B drug-pricing savings from one (1) entity, including critical access hospitals, federally qualified health centers, other hospitals, or 340B drug-pricing participants and their underserved patients, to another entity, including without limitation pharmacy benefits managers, private insurers, and managed care organizations;

(B) Pricing that occurs when offering a lower reimbursement for a drug purchased under 340B drug pricing than for the same drug not purchased under 340B drug pricing;

(C) Refusal to cover drugs purchased under 340B drug pricing;

(D) Refusal to allow 340B drug-pricing pharmacies to participate in networks; and

(E) Charging more than fair market value or seeking profit sharing in exchange for services involving 340B drug pricing.

23-92-604. Third party and pharmaceutical manufacturer — Prohibitions.

(a) A third party shall not:

(1) Coerce a patient into using a mail-order pharmacy;

(2) Require a patient to use a mail-order pharmacy;

(3) Discriminate, lower the reimbursement, or impose any separate terms upon a pharmacy in any other third party contract on the basis that a pharmacy participates in 340B drug pricing;

(4) Require a pharmacy to reverse, resubmit, or clarify a 340B drug-pricing claim after the initial adjudication unless these actions are in the normal course of pharmacy business and not related to 340B drug pricing;

(5) Require a billing modifier to indicate that the drug or claim is a 340B drug-pricing claim unless the drug or claim is being billed to the fee-for-service Arkansas Medicaid Program;

(6) Modify a patient's copayment on the basis of a pharmacy's participation in 340B drug pricing;

(7) Exclude a pharmacy from a network on the basis of the pharmacy's participation in 340B drug pricing;

(8) Establish or set network adequacy requirements based on 340B drug pricing participation by a provider or a pharmacy; or

(9) Prohibit an entity authorized to participate in 340B drug pricing or a pharmacy under contract with an entity authorized to participate in 340B drug pricing from participating in the third party's provider *network on the basis of participation in 340B drug pricing.*

(b) A third party that is a pharmacy benefits manager shall not base the drug formulary or drug coverage decisions upon the 340B drug-pricing status of a drug, including price or availability, or whether a dispensing pharmacy participates in 340B drug pricing.

(c) A pharmaceutical manufacturer shall not:

(1) Prohibit a pharmacy from contracting or participating with an entity authorized to participate in 340B drug pricing by denying access to drugs that are manufactured by the pharmaceutical manufacturer; or

(2) Deny or prohibit 340B drug pricing for an Arkansas-based community pharmacy that receives drugs purchased under a 340B drug pricing

contract pharmacy arrangement with an entity authorized to participate in 340B drug pricing.

23-92-605. Pharmacy claims.

All pharmacy claims processed by a pharmacy that participates in 340B drug pricing are final at the point of adjudication.

23-92-606. Rules.

The Insurance Commissioner shall promulgate rules to implement this subchapter.

/s/M. Gray

APPROVED: 5/3/21

By Senator Brodeur

10-01570A-24 20241608__

A bill to be entitled

An act relating to prohibitions related to 340B drugs; creating s. 626.8829, F.S.; defining terms; prohibiting certain actions by health insurance issuers, pharmacy benefit managers, or other third-party payors, or their agents, relating to reimbursement to a 340B entity for 340B drugs; providing applicability; prohibiting certain actions by manufacturers relating to interference with the acquisition of a 340B drug; prohibiting a manufacturer's interference with a pharmacy's right to contract with a 340B entity; providing that each commission of certain acts constitutes a violation of the Florida Deceptive and Unfair Trade Practices Act and subjects the violator to certain actions and penalties; providing that each commission of a prohibited act constitutes a violation of the Florida Deceptive and Unfair Trade Practices Act; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 626.8829, Florida Statutes, is created to read:

626.8829 Prohibitions related to 304B drugs.—

(1) As used in this subsection, the terms:

(a) "340B drug" means a drug that has been subject to any offer for reduced prices by a manufacturer pursuant to 42 U.S.C. s. 256b and is purchased by a covered entity as defined in 42

U.S.C. s. 256b(a)(4).

(b) "340B entity" means an entity participating or authorized to participate in the federal 340B Drug Discount Program, as described in 42 U.S.C. s. 256b, including its pharmacy, or any pharmacy contracted with the participating entity to dispense drugs purchased through the 340B Drug Discount Program.

(c) "Health insurance issuer" means an entity subject to the insurance laws and regulations of this state, or subject to the jurisdiction of the commissioner, which contracts or offers to contract, or enters into an agreement to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services, including a sickness and accident insurance company, a health maintenance organization, a preferred provider organization or any similar entity, or any other entity providing a plan of health insurance or health benefits.

(d) "Manufacturer" means any person that is a manufacturer of a prescription drug and that manufactures or distributes such prescription drug in this state.

(e) "Pharmacy" has the same meaning as in s. 465.003.

(f) "Pharmacy benefit manager" has the same meaning as in s. 626.88.

(2) With respect to reimbursement to a 340B entity for 340B drugs, a health insurance issuer, pharmacy benefit manager, or other third-party payor, or their agents, may not do any of the following:

(a) Reimburse a 340B entity for 340B drugs at a rate lower than that paid for the same drug to non-340B entities or entities owned or operated by the pharmacy benefit manager or

lower reimbursement for a claim on the basis that the claim is for a 340B drug.

(b) Impose any terms or conditions on any 340B entity which differ from such terms or conditions applied to non-340B entities on the basis that the entity participates in the federal 340B Drug Discount Program set forth in 42 U.S.C. s. 256b or that a drug is a 340B drug, including, but not limited to, any of the following terms or conditions related to:

1. Fees, charges, clawbacks, or other adjustments or assessments. For purposes of this subsection, the term "other adjustments" includes, but is not limited to, placing any additional requirements, restrictions, or unnecessary burdens on the 340B entity which result in administrative costs or fees to the 340B entity which are not placed on non-340B entities, including affiliate pharmacies of the health insurance issuer, pharmacy benefit manager, or other third-party payor.

2. Dispensation of fees that are less than such fees for non-340B entities.

3. Restrictions or requirements regarding participation in standard or preferred pharmacy networks.

4. Requirements relating to the frequency or scope of audits of inventory management systems.

5. Requirements that a claim for a drug include any identification, billing modifier, attestation, or other indication that a drug is a 340B drug in order to be processed or resubmitted unless it is required by the Centers for Medicare and Medicaid Services or the Agency for Health Care Administration for the administration of the Florida Medicaid program.

6. Any other restrictions, conditions, practices, or policies that are not imposed on non-340B entities.

(c) Require a 340B entity to reverse, resubmit, or clarify a claim after the initial adjudication unless these actions are in the normal course of pharmacy business and not related to 340B drug pricing.

(d) Base an action or contract requirement solely on the basis that the entity is a participant in the 340B drug discount program in such a manner that prevents or interferes with any patient's choice to receive such drugs from the 340B entity or its contracted pharmacy, including the creation of a restriction or additional charge on a patient who chooses to receive drugs from a 340B entity through direct dispensing, delivery, mail order, or administration of such drugs, regardless of the type of insurance coverage or medication. For purposes of this paragraph, it is considered a prohibited practice that prevents or interferes with a patient’s choice to receive drugs at a 340B entity if a health insurance issuer, pharmacy benefit manager, or other third-party payor places any additional requirements, restrictions, or unnecessary burdens on the 340B entity beyond that of any other pharmacy dispensing medications within the scope of Florida law, including, but not limited to, requiring a claim for a drug to include any identification, billing modifier, attestation, or other indication that a drug is a 340B drug in order to be processed or resubmitted unless it is required by the Centers for Medicare and Medicaid Services or the Agency for Health Care Administration in administration of the Florida Medicaid program.

(e) Require or compel the submission of ingredient costs or

pricing data pertaining to 340B drugs to any health insurance issuer, pharmacy benefit manager, or other third-party payor.

(f) Exclude any 340B entity from the health insurance issuer, pharmacy benefit manager, or other third-party payor network on the basis that the 340B entity dispenses drugs subject to an agreement under 42 U.S.C. s. 256b, or refuse to contract with a 340B entity for reasons other than those that apply equally to non-340B entities.

(3) Subsection (2) does not apply to the Florida Medicaid program as payor when Medicaid provides reimbursement for covered outpatient drugs as defined in 42 U.S.C. s. 1396r-8(k).

(4) A manufacturer may not deny, restrict, prohibit, or otherwise interfere with, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with a 340B entity and is authorized under such contract to receive and dispense 340B drugs on behalf of the covered entity unless such receipt is prohibited by the United States Department of Health and Human Services.

(5) A manufacturer may not interfere with a pharmacy's right to contract with a 340B entity.

(6) The commission of any act prohibited by this section is a deceptive and unfair trade practice, constitutes a violation of the Florida Deceptive and Unfair Trade Practices Act under part II of chapter 501, and subjects the violator to all actions, including, but not limited to, investigative demands, remedies, and penalties provided for in the Florida Deceptive and Unfair Trade Practices Act. Each commission of a prohibited act constitutes a violation of the Florida Deceptive and Unfair

Trade Practices Act.

Section 2. This act shall take effect July 1, 2024.