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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.

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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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References

Akscin, J., Barr, T. R., & Towle, E. L. (2007). Key practice indicators in office-based oncology practices: 2007 report on 2006 data. *Journal of Oncology Practice, 3*(4), 200–203. https://doi.org/10.1200/JOP.0743001

Alpert, A., Hsi, H., & Jacobson, M. (2017). Evaluating the role of payment policy in driving vertical integration in the oncology market. *Health Affairs, 36*(4), 680–688. https://doi.org/10.1377/hlthaff.2016.0830

American Medical Association. (2024). *Trends in health care spending.* https://www.ama-assn.org/about/research/trends-health-care-spending

Bidwal, M., Lor, K., Yu, J., & Ip, E. (2017). Evaluation of asthma medication adherence rates and strategies to improve adherence in the underserved population at a Federally Qualified Health Center. *Research in Social & Administrative Pharmacy, 13*(4), 759–766. https://doi.org/10.1016/j.sapharm.2016.07.007

Bond, A. M., Dean, E. B., & Desai, S. M. (2023). The role of financial incentives in biosimilar uptake in Medicare: Evidence from the 340B program. *Health Affairs, 42*(5), 632–641. https://doi.org/10.1377/hlthaff.2022.00812

Borusyak, K., Jaravel, X., & Spiess, J. (2024). Revisiting event-study designs: Robust and efficient estimation. *The Review of Economic Studies, 91*(6), 3253–3285. https://doi.org/10.1093/restud/rdae007

Burde, A., O'Connor, S., & Hachey, D. (2019). Community pharmacy enhanced dispensing model to improve medication access for rural patients living with HIV. *Innovations in Pharmacy, 10*(4), Article 2264. https://doi.org/10.24926/iip.v10i4.2264

Callaway, B., & Sant'Anna, P. (2021). Difference-in-differences with multiple time periods. *Journal of Econometrics, 225*(2), 200–230. https://doi.org/10.1016/j.jeconom.2020.12.001

Castellon, Y. M., Bazargan-Hejazi, S., Masatsugu, M., & Contreras, R. (2014). The impact of patient assistance programs and the 340B Drug Pricing Program on medication cost. *The American Journal of Managed Care, 20*(2), 146–150.

Center for Healthcare Quality and Payment Reform. (2025). *Rural hospitals at risk of closing.* https://chqpr.org/downloads/Rural_Hospitals_at_Risk_of_Closing.pdf

Centers for Medicare & Medicaid Services. (2004). *CMS increases payments to rural and small urban hospitals.* U.S. Department of Health and Human Services. https://www.cms.gov/newsroom/press-releases/cms-increases-payments-rural-and-small-urban-hospitals

Centers for Medicare & Medicaid Services. (2023). *Medicare program; Hospital outpatient prospective payment system: Remedy for the 340B-acquired drug payment policy for calendar years 2018-2022.* https://www.federalregister.gov/documents/2023/07/11/2023-14623/medicare-program-hospital-outpatient-prospective-payment-system-remedy-for-the-340b-acquired-drug

Centers for Medicare & Medicaid Services. (2024a). Acute inpatient PPS. U.S. Department of Health and Human Services. https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps

Centers for Medicare & Medicaid Services. (2024b). Disproportionate share hospital (DSH). U.S. Department of Health and Human Services. https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/disproportionate-share-hospital-dsh#:~:text=Under%20the%20primary%20method%20to,entitled%20to%20Medicare%20Part%20A

Centers for Medicare & Medicaid Services. (2024c). *MLN fact sheet: Medicare disproportionate share hospital.* U.S. Department of Health and Human Services. https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/disproportionate_share_hospital.pdf

Chang, J., Karaca-Mandic, P., Nikpay, S., & Jeffery, M. M. (2023). Association between new 340B program participation and commercial insurance spending on outpatient biologic oncology drugs. *JAMA Health Forum, 4*(6), e231485. https://doi.org/10.1001/jamahealthforum.2023.1485

Clark, B. L., Hou, J., Chou, C. H., Huang, E. S., & Conti, R. (2014). The 340B discount program: Outpatient prescription dispensing patterns through contract pharmacies in 2012. *Health Affairs, 33*(11), 2012–2017. https://doi.org/10.1377/hlthaff.2014.0833

Clifton, G. D., Byer, H., Heaton, K., Haberman, D. J., & Gill, H. (2003). Provision of pharmacy services to underserved populations via remote dispensing and two-way videoconferencing.

American Journal of Health-System Pharmacy, 60(24), 2577–2582. https://doi.org/10.1093/ajhp/60.24.2577

Conti, R. M., & Bach, P. B. (2014). The 340B drug discount program: Hospitals generate profits by expanding to reach more affluent communities. *Health Affairs, 33*(10), 1786–1792. https://doi.org/10.1377/hlthaff.2014.0540

Conti, R. M., Nikpay, S. S., & Buntin, M. B. (2019). Revenues and profits from Medicare patients in hospitals participating in the 340B Drug Discount Program, 2013-2016. *JAMA Network Open, 2*(10), e1914141. https://doi.org/10.1001/jamanetworkopen.2019.14141

de Chaisemartin, C., & D'Haultfœuille, X. (2020). Two-way fixed effects estimators with heterogeneous treatment effects. American Economic Review, 110(9), 2964–2996. https://doi.org/10.1257/aer.20181169

Dean, E. B., Johnson, P., & Bond, A. M. (2021). Physician, practice, and patient characteristics associated with biosimilar use in Medicare recipients. *JAMA Network Open, 4*(1), e2034776. https://doi.org/10.1001/jamanetworkopen.2020.34776

Desai, S., & McWilliams, J. M. (2018). Consequences of the 340B Drug Pricing Program. *The New England Journal of Medicine, 378*(6), 539–548. https://doi.org/10.1056/NEJMsa1706475

Desai, S. M., & McWilliams, J. M. (2021). 340B Drug Pricing Program and hospital provision of uncompensated care. *The American Journal of Managed Care, 27*(10), 432–437. https://doi.org/10.37765/ajmc.2021.88761

Dickson, S., & Reynolds, I. (2019). Estimated changes in manufacturer and health care organization revenue following list price reductions for hepatitis C treatments. *JAMA Network Open, 2*(7), e196541. https://doi.org/10.1001/jamanetworkopen.2019.6541

Dickson, S. (2020). Association Between the Percentage of US Drug Sales Subject to Inflation Penalties and the Extent of Drug Price Increases. *JAMA Network Open, 3*(9), e2016388. https://doi.org/10.1001/jamanetworkopen.2020.16388

Dickson, S., & James, K. (2023). Comparison of Generic Prescribing Patterns Among 340B-Eligible and Non-340B Prescribers in the Medicare Part D Program. *JAMA Health Forum, 4*(5), e231026. https://doi.org/10.1001/jamahealthforum.2023.1026

Dickson, S. R., Gabriel, N., Gellad, W. F., & Hernandez, I. (2023a). Assessment of Commercial and Mandatory Discounts in the Gross-to-Net Bubble for the Top Insulin Products From 2012 to 2019. *JAMA Network Open, 6*(6), e2318145. https://doi.org/10.1001/jamanetworkopen.2023.18145

Dickson, S., Gabriel, N., & Hernandez, I. (2023b). Trends in Proportion of Medicare Part D Claims Subject to 340B Discounts, 2013-2020. *JAMA Health Forum, 4*(11), e234091. https://doi.org/10.1001/jamahealthforum.2023.4091

Drug industry and HMOs deployed an army of nearly 1,000 lobbyists to push Medicare bill, report finds. (2004, September 7). *Public Citizen*. https://www.citizen.org/news/drug-industry-and-hmos-deployed-an-army-of-nearly-1000-lobbyists-to-push-medicare-bill-report-finds/

Endriukaitis, L. A., Hayes, G. L., & Mills, J. (2021). Economic Evaluation of Changes in Reimbursement for Medications Purchased Through the 340B Drug Pricing Program. *Hospital Pharmacy, 56*(4), 235–240. https://doi.org/10.1177/0018578719888907

Faraj, K. S., Oerline, M., Kaufman, S. R., Dall, C., Srivastava, A., Caram, M. E. V., Shahinian, V. B., & Hollenbeck, B. K. (2024). The 340B Program and High-Risk Prescribing of Oral Targeted Therapies for Advanced Prostate Cancer. *Urology Practice, 11*(6), 931–938. https://doi.org/10.1097/UPJ.0000000000000655

Fischer, D., Patel, A., Perotti, A., Bastow, S., Scarpelli, D., Lamb, M., Spiegel, T., Colgan, K., & Celmins, L. (2022). Initiation of a discharge pharmacy within a busy urban emergency department: The first year. *American Journal of Health-System Pharmacy: AJHP: Official Journal of the American Society of Health-System Pharmacists, 79*(17), 1438–1444. https://doi.org/10.1093/ajhp/zxac145

Gallegos, N., Fitzgerald, L., Versackas, A., Sherer, E., & Valdez, C. (2022). Improving Organizational Sustainability of an Urban Indian Health Clinic With an Innovative Pharmacy Model. *Journal of Primary Care & Community Health, 13*, 21501319211069750. https://doi.org/10.1177/21501319211069750

Genesis Healthcare Inc. v. Becerra, No. 4:19-cv-01531-RBH (D.S.C. 2023).

Goodman-Bacon, A. (2021). Difference-in-differences with variation in treatment timing. *Journal of Econometrics, 225*(2), 254–277. https://doi.org/10.1016/j.jeconom.2021.03.014

Government Accountability Office. (2011). *Drug discount program: Status of GAO recommendations to improve 340B drug pricing program oversight.* https://www.gao.gov/assets/gao-15-455t.pdf

Government Accountability Office. (2018). *Drug discount program: Federal oversight of compliance at 340B contract pharmacies needs improvement.* https://www.gao.gov/assets/d18480.pdf

Government Accountability Office. (2023). *340B drug discount program: Information about hospitals that received an eligibility exception as a result of COVID-19.* https://www.gao.gov/assets/gao-23-106095.pdf

Grimm, D., Trunk, S., Gayland, H., & Golden, S. (2024). The 340B 'Saga' Continues: As More States Pass 340B Contract Pharmacy Laws, More Lawsuits Follow. *ArentFox Schiff.* https://www.afslaw.com/perspectives/health-care-counsel-blog/the-340b-saga-continues-more-states-pass-340b-contract

Haberkorn, J. (2012, May 19). Report: W.H. pushed for PhRMA deal. *Politico*. https://www.politico.com/story/2012/05/report-wh-pushed-hard-for-phrma-health-reform-deal-076925

H.R. 1, 108th Cong. (2003-2004). *Medicare Prescription Drug, Improvement, and Modernization Act of 2003.* https://www.congress.gov/bill/108th-congress/house-bill/1

H.R. 2534, 118th Cong. (2023-2024). *PROTECT 340B Act of 2023.* https://www.congress.gov/bill/118th-congress/house-bill/2534

H.R. 3590, 111th Cong. (2009-2010). *Patient Protection and Affordable Care Act.* https://www.congress.gov/bill/111th-congress/house-bill/3590

H.R. 4710, 115th Cong. (2017-2018). *340B PAUSE Act.* https://www.congress.gov/bill/115th-congress/house-bill/4710

H.R. 5193, 102nd Cong. (1991-1992). *Veterans Health Care Act of 1992.* https://www.congress.gov/bill/102nd-congress/house-bill/5193

H.R. 7635, 118th Cong. (2023-2024). *The 340B PATIENTS Act of 2024.* https://www.congress.gov/bill/118th-congress/house-bill/7635

H.R. 8574, 118th Cong. (2023-2024). *340B ACCESS Act.* https://www.congress.gov/bill/118th-congress/house-bill/8574

Han, D. (2023). The impact of the 340B Drug Pricing Program on Critical Access Hospitals: Evidence from Medicare Part B. *Journal of Health Economics, 89*, 102754. https://doi.org/10.1016/j.jhealeco.2023.102754

Health Resources and Services Administration. (2010). *Notice regarding 340B drug pricing program-contract pharmacy services.* US Department of Health and Human Services. https://www.federalregister.gov/documents/2010/03/05/2010-4755/notice-regarding-340b-drug-pricing-program-contract-pharmacy-services

Health Resources and Services Administration. (2023). 2022 340B covered entity purchases. US Department of Health and Human Services. https://www.hrsa.gov/opa/updates/2022-340b-covered-entity-purchases

Health Resources and Services Administration. (2024). 2023 340B covered entity purchases. US Department of Health and Human Services. https://www.hrsa.gov/opa/updates/2023-340b-covered-entity-purchases

Health Resources and Services Administration. (2024). 340B Drug Pricing Program. US Department of Health and Human Services. https://www.hrsa.gov/opa

Health Resources and Services Administration. (n.d.). 340B Glossary. US Department of Health and Human Services. https://340bopais.hrsa.gov/help/Links/340B_Glossary.htm#:~:text=In%20contrast%2C%20hospital%20outpatient%20clinics,can%20begin%20using%20340B%20drugs

Holmer, A. F. (1999). Perspective: Covering prescription drugs under Medicare: For the good of the patients. *Health Affairs, 18*(4), 23–24. https://doi.org/10.1377/hlthaff.18.4.23

Horwitz, J. R. (2005). Making profits and providing care: Comparing nonprofit, for-profit, and government hospitals. *Health Affairs (Project Hope), 24*(3), 790–801. https://doi.org/10.1377/hlthaff.24.3.790

Hudd, T. R., & Tataronis, G. R. (2011). The impact of an urban telepharmacy on patient medication adherence in a federally qualified health center. *Journal of Pharmacy Technology*. https://doi.org/10.1177/875512251102700304

Ingmire, B. (2024). Deep dive: Why states are in the driver's seat on 340B and contract pharmacies. *MultiState*. https://www.multistate.us/insider/2024/8/29/deep-dive-why-states-are-in-the-drivers-seat-on-340b-and-contract-pharmacies

Jessop, A. B., Luu, J., Holbert, R., & Mazzella, S. (2022). Delivering care to a city's most vulnerable residents: A harm reduction organization and community pharmacy working together to reduce health disparities. *Journal of Health Care for the Poor and Underserved, 33*(4S), 202–208. https://doi.org/10.1353/hpu.2022.0169

Jones, E. A., Linas, B. P., Truong, V., Burgess, J. F., & Lasser, K. E. (2019). Budgetary impact analysis of a primary care-based hepatitis C treatment program: Effects of 340B Drug Pricing Program. *PLOS ONE, 14*(3), e0213745. https://doi.org/10.1371/journal.pone.0213745

Jones, J. W., Courtemanche, C., Denteh, A., Marton, J., & Tchernis, R. (2022). Do state Supplemental Nutrition Assistance Program policies influence program participation among seniors? *Applied Economic Perspectives and Policy*, *44*(2), 591-608.

Kentucky Hospital Association (2024). The 340B program is essential to the patients of Kentucky. https://www.kyha.com/advocacy/policy-issues/340b/the-340b-program-is-essential-to-the-patients-of-kentucky/

Knox, R. P., Wang, J., Feldman, W. B., Kesselheim, A. S., & Sarpatwari, A. (2023). Outcomes of the 340B drug pricing program. *JAMA Health Forum, 4*(11), e233716. https://doi.org/10.1001/jamahealthforum.2023.3716

Ko, W., & Moffitt, R. A. (2024). Take-up of social benefits. *Handbook of Labor, Human Resources and Population Economics*, 1-42.

Kozhimannil, K. B., Interrante, J. D., Admon, L. K., & Ibrahim, B. L. B. (2022). Rural hospital administrators' beliefs about safety, financial viability, and community need for offering obstetric care. *JAMA Health Forum, 3*(3), e220204. https://doi.org/10.1001/jamahealthforum.2022.0204

Lasser, K. E., Heinz, A., Battisti, L., Akoumianakis, A., Truong, V., Tsui, J., Ruiz, G., & Samet, J. H. (2017). A hepatitis C treatment program based in a safety-net hospital patient-centered medical home. *Annals of Family Medicine, 15*(3), 258–261. https://doi.org/10.1370/afm.2069

Lee, C. H., Chang, J., & McCombs, J. (2019). Specialty drug price trends in the Federal 340B Drug Discount Program. *Journal of Managed Care & Specialty Pharmacy, 25*(2), 178–187. https://doi.org/10.18553/jmcp.2019.25.2.178

Levengood, T. W., Conti, R. M., Cahill, S., & Cole, M. B. (2024). Assessing the impact of the 340B drug pricing program: A scoping review of the empirical, peer-reviewed literature. *The Milbank Quarterly, 102*(2), 429–462. https://doi.org/10.1111/1468-0009.12691

Lin, J. K., Li, P., Doshi, J. A., & Desai, S. M. (2022). Assessment of US pharmacies contracted with health care institutions under the 340B drug pricing program by neighborhood socioeconomic characteristics. *JAMA Health Forum, 3*(6), e221435. https://doi.org/10.1001/jamahealthforum.2022.1435

Lopata, E., Terrone, C., Gopalan, A., Ladikos, N., & Richardson, T. (2021). Meeting the affordability challenges posed by orphan drugs: A survey of payers, providers, and employers. *Journal of Managed Care & Specialty Pharmacy, 27*(6), 706–713. https://doi.org/10.18553/jmcp.2021.20553

Machta, R. M., Reschovsky, D., Jones, D. J., Kimmey, L., Furukawa, M. F., & Rich, E. C. (2020). Health system integration with physician specialties varies across markets and system types. *Health Services Research, 55*(Suppl 3), 1062–1072. https://doi.org/10.1111/1475-6773.13584

Malouin, R. A., Mckernan, L., Forsberg, A., Cheng, D., Drake, J., McLaughlin, K., & Trujillo, M. (2018). Impact of the 340B pharmacy program on services and supports for persons served by hemophilia treatment centers in the United States. *Maternal and Child Health Journal, 22*(9), 1240–1246. https://doi.org/10.1007/s10995-018-2545-7

Mansour, A. (2015). Built for the road ahead. *Healthcare Financial Management: Journal of the Healthcare Financial Management Association, 69*(10), 76–81.

Mascardo, L. A., Spading, K. A., & Abramowitz, P. W. (2012). Implementation of a comprehensive pharmaceutical care program for an underserved population. *American Journal of Health-System Pharmacy: AJHP: Official Journal of the American Society of Health-System Pharmacists, 69*(14), 1225–1230. https://doi.org/10.2146/ajhp110490

Masia, N., & Kuwonza, F. (2023). Income differences between locations of 340B entities and contract pharmacies. *The American Journal of Managed Care, 29*(6), e184–e188. https://doi.org/10.37765/ajmc.2023.89377

McGlave, C., Bruno, J. P., Watts, E., & Nikpay, S. (2024). 340B contract pharmacy growth by pharmacy ownership: 2009–2022. *Health Affairs Scholar, 2*(1). https://doi.org/10.1093/haschl/qxad075

Mulligan, K. (2021). The 340B drug pricing program: Background, ongoing challenges, and recent developments [White Paper]. University of Southern California Leonard D. Schaeffer Center for Health Policy and Economics. https://healthpolicy.usc.edu/wp-content/uploads/2022/07/USC_Schaeffer_340BDrugPricingProgram_WhitePaper.pdf

Mulligan, K., Romley, J. A., & Myerson, R. (2021). Access to the 340B Drug Pricing Program: Is there evidence of strategic hospital behavior? *BMC Research Notes, 14*(1), 228. https://doi.org/10.1186/s13104-021-05642-4

National Association of Community Health Centers. (2023). *340B Restrictions Summary Chart*. https://www.nachc.org/wp-content/uploads/2023/09/340B-restrictions-summary-chart.pdf

National Association of Community Health Centers. (2024). *32 State-Level Laws to Protect CHCs' 340B Savings*. https://www.nachc.org/wp-content/uploads/2024/01/05_03_24_nachc_state-level-340b-laws-and-legislation_tracker.pdf

Nikpay, S., Buntin, M., & Conti, R. M. (2018). Diversity of participants in the 340B drug pricing program for U.S. hospitals. *JAMA Internal Medicine, 178*(8), 1124. https://doi.org/10.1001/jamainternmed.2018.2015

Nikpay, S., Buntin, M. B., & Conti, R. M. (2020). Relationship between initiation of 340B participation and hospital safety-net engagement. *Health Services Research, 55*(2), 157–169. https://doi.org/10.1111/1475-6773.13278

Nikpay, S. (2022). The Medicaid windfall: Medicaid expansions and the target efficiency of hospital safety-net subsidies. *Journal of Public Economics, 208*, 104583. https://doi.org/10.1016/j.jpubeco.2021.104583

Nikpay, S., Gracia, G., Geressu, H., & Conti, R. (2022). Association of 340B contract pharmacy growth with county-level characteristics. *The American Journal of Managed Care, 28*(3), 133–136. https://doi.org/10.37765/ajmc.2022.88840

Nikpay, S., McGlave, C. C., Bruno, J. P., Yang, H., & Watts, E. (2023). Trends in 340B Drug Pricing Program contract growth among retail pharmacies from 2009 to 2022. *JAMA Health Forum, 4*(8), e232139. https://doi.org/10.1001/jamahealthforum.2023.2139

Nikpay, S. (2024). Characteristics of 340B hospitals receiving Medicare Part B repayments. *JAMA Health Forum, 5*(4), e235397. https://doi.org/10.1001/jamahealthforum.2023.5397

Nikpay, S., Bruno, J. P., & Carey, C. (2024). Recent court ruling could increase the size and administrative complexity of the 340B program. *Health Affairs Scholar, 2*(12), qxae157. https://doi.org/10.1093/haschl/qxae157

Norman, B., & Karlin-Smith, K. (2016, July 14). The one that got away: Obamacare and the drug industry. *Politico*. https://www.politico.com/story/2016/07/obamacare-prescription-drugs-pharma-225444

Novartis Pharmaceuticals Corporation v. Carole Johnson, No. 21-5299. (U.S. D.C. Cir. 2024).
Oliver, T. R., Lee, P. R., & Lipton, H. L. (2004). A political history of Medicare and prescription drug coverage. *The Milbank Quarterly, 82*(2), 283–354. https://doi.org/10.1111/j.0887-378X.2004.00311.x

Owsley, K. M., & Bradley, C. J. (2023). Access to oncology services in rural areas: Influence of the 340B drug pricing program. *Health Affairs (Project Hope), 42*(6), 785–794. https://doi.org/10.1377/hlthaff.2022.01640
Owsley, K. M., Hasnain-Wynia, R., Rooks, R. N., Tung, G. J., Mays, G. P., & Lindrooth, R. C. (2024). U.S. hospital service availability and new 340B program participation. *JAMA Health Forum, 5*(5), e240833. https://doi.org/10.1001/jamahealthforum.2024.0833

Owsley, K. M., & Karim, S. A. (2024). Community social vulnerability and the 340B drug pricing program: Evaluating predictors of 340B participation among critical access hospitals. *The Journal of Rural Health, 40*(4), 720–727. https://doi.org/10.1111/jrh.12833

Pharmaceutical Research and Manufacturers of America v. Alan McClain, No. 22-3675. (U.S. 8th Cir. 2024).

Pharmaceutical Research and Manufacturers of America v. Alan McClain, No. 22-3675. (Supreme Court of the United States 2024). https://www.supremecourt.gov/docket/docketfiles/html/public/24-118.html

Robbins, C., Stillwell, T., Wilson, S., & Fitzgerald, L. (2012). Formulary expansion to provide access to medications prescribed by a specialist in a low-income population. *Journal of Health Care for the Poor and Underserved, 23*(2), 834–841. https://doi.org/10.1353/hpu.2012.0053

Robinson, J. C., Whaley, C., & Dhruva, S. S. (2024). Hospital prices for physician-administered drugs for patients with private insurance. *The New England Journal of Medicine, 390*(4), 338–345. https://doi.org/10.1056/NEJMsa2306609

Rodis, J. L., Capesius, T. R., Rainey, J. T., Awad, M. H., & Fox, C. H. (2019). Pharmacists in federally qualified health centers: Models of care to improve chronic disease. *Preventing Chronic Disease, 16*, E153. https://doi.org/10.5888/pcd16.190163

S.2312 - 115th Congress (2017–2018): Helping Ensure Low-Income Patients Have Access to Care and Treatment. (2018, January 16). https://www.congress.gov/bill/115th-congress/senate-bill/2312

S.B. 27 – Kentucky General Assembly Regular Session 2024. (2024). *An Act Relating to Pharmaceutical Manufacturers*. https://apps.legislature.ky.gov/record/24rs/sb27.html

S.B. 50 – Kentucky General Assembly Regular Session 2020. (2020). *An Act Relating to Pharmacy Benefits in the Medicaid Program and Declaring an Emergency*. https://apps.legislature.ky.gov/record/20rs/sb50.html

S.B. 188 – Kentucky General Assembly Regular Session 2024. (2024). *An Act Relating to Patient Access to Pharmacy Benefits*. https://apps.legislature.ky.gov/record/24rs/sb188.html

Sanofi. (2020). *340B Program Integrity Initiative Notification*. https://www.rwc340b.org/wp-content/uploads/2020/12/Sanofi-340B-Program-Integrity-Initiative-Notification-7.2020.pdf

Sanofi Aventis U.S. LLC v. United States Department of Health and Human Services, Nos. 21-3167, 21-3379. (U.S. 3rd Cir. 2023).

Shi, L., Wharton, M. K., & Monnette, A. (2018). Ensuring access to prescription medications in the post-ACA healthcare access landscape: The essential role of FQHCs in the safety net for the underinsured. *The American Journal of Managed Care*, 24(5 Suppl), S67–S73.

Smith, K., Padmanabhan, P., Chen, A., Glied, S., & Desai, S. (2023). The impacts of the 340B Program on health care quality for low-income patients. *Health Services Research*, 58(5), 1089–1097. https://doi.org/10.1111/1475-6773.14204

Sun, L., & Abraham, S. (2021). Estimating dynamic treatment effects in event studies with heterogeneous treatment effects. *Journal of Econometrics, 225*(2), 175–199. https://doi.org/10.1016/j.jeconom.2020.09.006

Taliaferro, L. M., Dodson, S., Norton, M. C., & Ofei-Dodoo, S. (2023). Evaluation of 340B prescription assistance program on healthcare use in chronic obstructive pulmonary disease. *Exploratory Research in Clinical and Social Pharmacy*, 11, 100295. https://doi.org/10.1016/j.rcsop.2023.100295

Talwar, A., Kim, S., Yu, S., Samant, S., Tozan, Y., & Givi, B. (2023). Private payer-negotiated rates for FDA-approved head and neck cancer immunotherapy and chemotherapy agents. *Otolaryngology–Head and Neck Surgery: Official Journal of the American Academy of Otolaryngology-Head and Neck Surgery*, 169(4), 954–961. https://doi.org/10.1002/ohn.308

Tripp, A. S., Marrufo, G., Kornfield, T., Morley, M., Nichols, D., & Yeh, A. (2023). The 340B Program and health disparities among Medicare beneficiaries with chronic asthma. *Health Services Insights*, 16, 11786329231169257. https://doi.org/10.1177/11786329231169257

Tripp, A., Marrufo, G., Kornfield, T., Morley, M., Yeh, A., & Nichols, D. (2024). Expansion of the 340B Program's child sites and health disparities among Medicare beneficiaries with asthma. *Medical Research Archives*, 12(4). Knowledge Enterprise Journals. https://doi.org/10.18103/mra.v12i4.5295

Wagner, A. A., Whitner, J. B., Williams, A. C., Hirt, K. L., Miracle, T. L., & Valentino, A. S. (2023). Community health center 340B program: A qualitative study of the experiences of patients with diabetes. *Innovations in Pharmacy*, 14(3), 10.24926/iip.v14i3.5445. https://doi.org/10.24926/iip.v14i3.5445

Watts, E., McGlave, C., Quinones, N., Bruno, J. P., & Nikpay, S. (2024). 340B participation and safety net engagement among federally qualified health centers. *JAMA Health Forum*, 5(10), e243360. https://doi.org/10.1001/jamahealthforum.2024.3360

Wu, T., Williams, C., Vranek, K., & Mattingly, T. J., 2nd (2019). Using 340B drug discounts to provide a financially sustainable medication discharge service. *Research in Social & Administrative Pharmacy: RSAP*, 15(1), 114–116. https://doi.org/10.1016/j.sapharm.2018.03.065

Xiao, R., Ross, J. S., Gross, C. P., Dusetzina, S. B., McWilliams, J. M., Sethi, R. K. V., & Rathi, V. K. (2022). Hospital-administered cancer therapy prices for patients with private health insurance. *JAMA Internal Medicine*, 182(6), 603–611. https://doi.org/10.1001/jamainternmed.2022.1022

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.