

DISCUSSION PAPER SERIES

IZA DP No. 17880

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## ABSTRACT

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# What Economists Should Know about the 340B Drug Discounting Program\*

The 340B Drug Pricing Program was instituted to bolster the non-profit 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. Covered entities, most of which are hospitals, argue that discounts from the program are critical to their ability to provide charity care and unprofitable lines of service. At the same time, with 340B purchases now comprising over 13% of prescription drug sales, drug manufacturers argue that the program has grown beyond its original intent and led to important revenue losses. These manufacturers have responded to the rapid growth in the network of contract pharmacies by enacting restrictions on distribution that in turn led to a flurry of lawsuits and legislative activity. Given the 340B program's size, importance, and role in ongoing policy debates, it is perhaps surprising that it has received very little attention in economics journals. Our paper reviews the scholarly literature on the 340B program, which lies almost completely in public health and medical journals, with an eye for the gaps in this literature that economics research can help fill. In particular, economists' causal inference econometric toolkit and theoretical understanding of the role of government intervention can help improve our understanding of 340B's impacts and lead to more informed policy decisions.

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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 2024a). 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).<sup>1</sup>

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 effects that occur via provider responses to revenue generated and incentives created by the program.

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<sup>1</sup> 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,<sup>2</sup> or in some cases even close completely.<sup>3</sup> 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, this means the 340B program could be vital to ensuring adequate access to care.

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, they contend, 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 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 considering such laws.

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<sup>2</sup> According to Kozhimannil et al. (2022), around 40% of rural hospitals' obstetrics programs lose money.

<sup>3</sup> 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.

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 potentially divergent policy implications for states and the federal government. 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 policy considerations at the state level is considerably reduced given differing incentives at the state and federal level.

With these challenges in mind, there is no consensus that covered entities have exclusively embraced or abandoned program aims of expanding safety-net care. 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 generalizing from anecdote would be tenuous at best. 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 lower-cost biosimilar drugs in place of higher-cost biologics, 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 murkiness of the 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 covered entities. This introduces something of a continuum of governance considerations as one moves from the state to the federal level. States without a drug manufacturing presence are incentivized to maintain the inflow of 340B funds as the transfer is from out-of-state to in-state and is a clear net gain. Those with manufacturing interests must weigh the tradeoff of manufacturers' loss within their borders to the gain for covered entities from in-state and out-of-state transfers. When viewed from a national perspective, this is a more complicated issue. 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. Thus, the federal government must worry about defining the intent and adequate performance of the program as a complex whole, whereas states need not concern themselves with program impacts beyond their borders.

Our work builds upon prior reviews of the 340B literature by Levensgood 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. Throughout, we emphasize the role for economists in moving the literature forward, both through rigorous causal inference econometrics and a theory-informed perspective on welfare impacts of policy options.

## **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 2024a). 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 2024a). 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 low-income Medicare patients. 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 =  $2.5\% + [0.65 \times (DPP - 15\%)]$ ; if it were above, the formula changes to  $5.88\% + [0.825 \times (DPP - 20.2\%)]$ . 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 2024b). 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 3<sup>rd</sup> 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 (3<sup>rd</sup> 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 Lilly, 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 (3<sup>rd</sup> Circuit Court 2023).

In 2023 and 2024 respectively, the 3<sup>rd</sup> and D.C. Circuit Courts found that the law did not expressly prohibit manufacturer restrictions on distribution (3<sup>rd</sup> Circuit Court 2023; D.C. Circuit Court 2024). Also in 2024, however, the 8<sup>th</sup> Circuit Court found that Arkansas was not excluded from legislating such prohibitions, and the Supreme Court declined to review this decision (8<sup>th</sup> 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 4<sup>th</sup> 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 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 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 8<sup>th</sup> Circuit, the matter of states' 340B legislation could still go before the Supreme Court.

### **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 the dependent variable used 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 Levenson et al. (2024). We then utilized Google Scholar to identify additional studies not included by Knox et al. (2023) and Levenson et al. (2024), finding around twenty. In most cases, those studies were published after the time frame covered by those reviews.<sup>4</sup> Notably, of the dozens of published studies on the 340B program included in our review, only *two* were published in an economics journal (Han 2023; Nikpay 2022). This is in spite of the fact public policies related to health care finance are well within the domain of economics, as are several of the specific outcomes studied in the literature, such as prices, expenditures, and market concentration.

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. As we will see, although the 340B literature is large, few studies even attempt to identify causal effects. Economists are extensively trained in finding ways to identify causal effects using observational data and in evaluating the validity of the assumptions required for econometric techniques to successfully do so. Given the many open causal questions that remain in the 340B literature and the lack of obvious ways to answer these

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<sup>4</sup> Due to lags in the journal publication process, these prior reviews are not as up-to-date as their publication dates would suggest.

questions, increased attention from economists has the potential to add considerable value to the literature.

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 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.

The quasi-experimental econometric toolkit of economists is well suited to addressing these challenges with identifying causal effects. “Difference-in-differences” (DiD) and “fixed

effects” (FE) models account for underlying differences between treated and untreated groups if they are constant over time. 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.<sup>5</sup>

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 observations used for identification. For example, even if an RD approach successfully identifies

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<sup>5</sup> 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).

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. 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 rural and low-income 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, 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; Jones et al. 2019; Lasser et al. 2017; Mansour 2015; Mascardo 2012; Taliaferro et al. 2023; Wu 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 suggests that the program serves relatively disadvantaged patient populations but to an extent that has diminished over time. Other evidence indicates expanded medication access at FQHCs and cross-subsidized service provision (Clark et al. 2014; 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.

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 group is 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.<sup>6</sup> 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

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<sup>6</sup> The authors mention that the data source used for uncompensated care, HCRIS, experienced significant changes in how uncompensated care was reported in 2010, making values from 2009 and earlier incomparable to those after the change.

provision, and they both find null results. However, Nikpay et al. also find evidence of a sizeable increase in charity care provision, raising the question of how charity care could 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, 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

critical-access hospitals 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 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 – 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. 10 percentage points is a relatively wide bandwidth, as it means that comparisons are made of hospitals up to 20 percentage points apart. Such a wide bandwidth was presumably used because narrower bandwidths discarded too much identifying variation to obtain precise enough results to be informative. This illustrates the tradeoff between unbiasedness and efficiency that often plagues RD designs. An additional concern is that, if Mulligan et al. (2021) are correct that hospitals manipulate DSH scores around the cutoff to ensure 340B eligibility, being just below versus just above the cutoff is no longer good-as-random.

Smith et al.'s (2023) 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” paper mentioned earlier. The potential motive for avoiding the adoption of biosimilars 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 should not be wholly discarded. 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. Two “causal” studies provide evidence of sizeable increases in oncology service offerings. Evidence on provision of relatively unprofitable services such as obstetrics is mixed. This is consistent with some hospitals increasing these offerings, but not frequently enough to drive clearly measurable effects across a broad sample. With all that said, the small number of “causal” studies – each of which has limitations – means that the effect of 340B on service line provision remains an open question.

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 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 patient mix rather than a given patient's income. A hospital can see higher-income patients and still meet the DSH requirement. However, this does suggest a point of potential divergence as a hospital's DSH percentage, and therefore 340B eligibility, is determined by its inpatient mix, while outpatient prescriptions receive the 340B discount. If 340B hospitals are able to meaningfully change their outpatient mix to be higher paying while maintaining a qualifying inpatient mix, then this might support the implication that DSHs are pursuing higher-income patients, while presumably abandoning or ignoring low-income patients. However, it is a harder argument to make if more of both patient types are being served, even if the proportion is skewing toward higher income.

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. While non-causal evidence does not suggest this is the case for generics more generally, if 340B participation leads to expanded oncology services, but these are performed in a more expensive way, then low-income cancer patients being served may face unnecessarily higher costs.

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. Nonetheless, 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 modeling. However, it seems hard to argue that the 18% rate from 2013 noted by Dickson et al. (2023b) was adequate. We see little reason to believe that the means to regulate program size was intended to be via the capture rate, rather than eligibility criteria for covered entities and covered prescriptions.

To provide an imperfect but useful comparison, suppose the government aimed to control the size of the Supplemental Assistance Nutrition Program (SNAP) by targeting the percentage of eligible funds actually spent by recipients. Presumably, the intent is for 100% usage (or close to it) of the electronic benefit transfer provided to participants. An 18% usage rate would be considered extremely low and worthy of investigation into how to increase it, likely including considerations for expanding locations at which funds could be used. Even a 50% usage rate, like the 340B capture rate in 2020, would be considered low if viewed as a parallel to intended usage.

Regardless of what might be a reasonable capture rate, current program tension is centered around contract pharmacies because that is the lever manufacturers can pull to impact their 340B outlays without legislative reform. They can restrict distribution to contract pharmacies and or make their use more burdensome and costly. States, on the other hand, cannot modify or add language to a national program and are left largely reacting to the cost-reducing efforts of manufacturers wherever federal law is vague or silent. This introduces additional monetary and time costs into the program for all involved parties as state and manufacturer

policies are changed and challenged, leaving the 340B landscape a moving patchwork of legal rulings and reactive legislation.

In short, numerous empirical studies of varying rigor have aimed to assess various potential impacts of the 340B program. However, in our assessment, the body of causally interpretable evidence is insufficient to draw credible, generalizable conclusions about these impacts.

#### **IV. Insights from Economic Theory**

While Section III discussed strategies used to identify other possible effects of the 340B program, its clearest effect does not require sophisticated econometrics to observe: the redistribution of resources from drug manufacturers to qualifying health care providers. Is this redistribution desirable, and if so, when does it become excessive? Economic theory has much to offer in terms of providing a framework that can be used to analyze these questions. We provide a brief discussion below that we hope can stimulate more rigorous theoretical investigations in future research.

Economic theory posits two justifications for government intervention in markets. The first is to improve efficiency, which would only occur if the intervention corrects a market failure such as externalities or imperfect information. Since it is difficult to connect the 340B program to a specific market failure, at first glance one might deduce that 340B hurts efficiency.

Importantly, however, that logic only applies when an intervention is made in a market *that was previously efficient*. The market for health care bears little resemblance to the free market of economics textbooks. Dating back to Arrow (1963), economists have understood that there are several inherent inefficiencies in the health care sector, such as asymmetric information, adverse selection, and moral hazard. Additionally, strong special interests representing different aspects

of the sector exert considerable influence over public policy. The end result is a market plagued by both market and government failures, with regulations, taxes, and subsidies affecting 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.

While the distortions in health care are too numerous to fully dissect here, 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 Medicare 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 significant distortions in drug companies' favor and at least one against. By getting them to agree to 340B expansion, the government found a way to provide a revenue stream for 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 maintained higher 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 (Public Citizen 2004).

In their efforts to influence the shape of the ACA, pharmaceutical companies appear to have had two key concerns. The first was avoiding a monopsony market. 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. According to a news 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). 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).

This suggests that one of the tradeoffs pharmaceutical companies made to obtain and maintain favorable market distortions was to accept expanded discounting within the 340B program. In light of this, later complaints about the expanded program may then come across as less sympathetic.

Of course, hospitals also have a strong lobbying presence that seeks distortions in their favor. On one hand, they claim 340B funds are needed to expand or sustain important services to low-income populations. On the other hand, they also support market-distorting certificate-of-need (CON) laws that restrict the availability of such services (Mitchell 2024a; Mitchell 2024b).

Our point here is not to blame pharmaceutical companies or hospitals for acting in their self-interest, nor to assert that the cumulative impact of market and government failures is to favor one over the other. We are simply emphasizing that it is difficult to tell whether a program like 340B hurts or helps efficiency when so many other distortions in the market are present. Further investigation using the mathematical tools of economic theory may help resolve this issue or at least elucidate the assumptions under which the efficiency effects of 340B would be positive or negative.

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 that plays a major role in many health care policies such as public health insurance expansions. With regard to 340B, 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 help address health equity concerns for low-income populations unable to afford prevailing prices – though the extent to which 340B funds are used in this manner is an empirical question that warrants further causal investigation, as discussed in Section III.

An important caveat to the above discussion is that it applies most directly to federal policy. 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. Moreover, states naturally would not be inclined to leave decisions about contract pharmacy networks in the hands of pharmaceutical companies whose profits increase if these networks become smaller. 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.

#### **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 of covered entities' preference for biologics over biosimilars points towards possible misaligned incentives from the savings being proportional to drug cost.

Notably, virtually none of the studies on 340B's impacts have been published in economics journals despite numerous possible connections to economics. For instance, the program affects the prices paid by hospitals and possibly also consumers as well as the net revenues of drug manufacturers and hospitals. 340B has also led to concerns about market power, which is a core topic within industrial organization. Additionally, economic theory has the potential to provide insights about the welfare impacts of a program like 340B within the health care landscape that features numerous market and government failures as well as concerns about equity. Finally, wider use of the empirical tools of economics – namely, quasi-experimental econometric methods – has the potential to resolve important causal questions regarding the program's impacts.

While economists have been co-authors on 340B studies, the fact that these studies have scarcely touched the pages of economics journals has undoubtedly limited the diffusion of knowledge about the program within the profession. Our hope is that this review puts the 340B program on the radar of more economists, who can use their tools to increase the amount of credible evidence about its effects and ultimately steer ongoing federal and state policy debates in welfare-improving directions.

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

	Anecdotal	Non-Causal	Causal
<i>Panel A: Intended Effects</i>			
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
<i>Panel B: Unintended Effects</i>			
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
<i>Panel C: Other Effects</i>			
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.