Concerns Surrounding 340B Program Abuse and Impact on Patient Access to Provider-Administered Drugs

EXECUTIVE SUMMARY

Investigations into practices by nonprofit, tax-exempt hospitals have revealed that certain hospitals are increasingly displaying characteristics of for-profit corporations.1 2 3 4 These institutions may be utilizing tax savings and savings from other programs, such as the 340B drug discount, to drive profits and business practices rather than to subsidize charitable care, uncompensated care, and/or programs to improve access to care among vulnerable patient populations.

In the medical benefit drug landscape (i.e., provider-administered drugs), NICA is deeply concerned by a trend among nonprofit, tax-exempt DSHs participating in the 340B program. This concerning trend involves entities using the accumulated savings from 340B-discounted drugs (“340B revenue”) and tax savings to acquire community-based, physician-owned practices in specialties that administer a high volume of expensive, provider-administered drugs (e.g., oncology, rheumatology, gastroenterology, neurology). These practices are generally found in affluent communities with a large proportion of commercially insured patients.5 6 DSHs are operating in this way to expand their 340B market share and maximize the arbitrage opportunity that participating in the program provides.

This arbitrage opportunity, while not explicitly prohibited under 340B statute, is the result of several factors:

(1) Congress did not clearly identify its intent for the program and did not clearly identify the program’s parameters, leaving the 340B statute silent on many important program requirements;

(2) Congress did not establish any mechanisms to monitor or calculate program savings or specify how to be utilized across all covered entity types, resulting in a wide variation in how covered entities (mainly non-grantees) are utilizing program savings;

(3) the 340B statute neither defines “charity care”, nor does it require covered entities to report the level of charity care they provide, resulting in a lack of transparency into the level of charity care provided by covered entities compared to non-340B entities;

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2 Bob Herman, Hospitals are making a fortune on Wall Street, AXIOS (Dec. 2017), available at https://www.axios.com/hospitals-are-making-a-fortune-on-wall-street-2513530266.html
(4) the statute vaguely defines the eligibility criteria for what constitutes a 340B-eligible patient, providing ample room for interpretation which has resulted in increased risk of program abuse and significant variation across entities in whether patients are benefiting from the 340B program and which patient populations experience benefit; and,

(5) HRSA lacks sufficient authority to adequately oversee the program and clarify program requirements, including patient eligibility criteria, and lacks the capacity to audit a sufficient number of entities and lacks the authority to audit at a sufficient level.

Key Points

▪ Lack of transparency and reporting obligations relating to hospitals’ tax-exempt status and 340B savings may be allowing these savings to drive profits over public service.

▪ Nonprofit hospitals are increasingly displaying characteristics of for-profit hospitals.7

▪ Standalone hospitals are increasingly pursuing mergers/affiliations with other hospitals, hospital systems, outpatient provider groups, and physician-owned practices.8

▪ HRSA lacks sufficient authority to clarify program requirements and adequately oversee the program. Consequently, key aspects of the program have remained vague, resulting in variation in the way covered entities use the 340B program.9

▪ Given this restricted authority, HRSA can only conduct a narrow review of covered entities’ use of the program during the audit process.

▪ Medicaid eligibility expansion through the PPACA has increased the number of DSHs eligible for 340B, because program eligibility is based, in part, on the hospital’s Medicaid and low-income Medicare inpatients. HRSA’s limited oversight ability translates to inadequate program oversight.10

▪ There is a financial incentive for 340B hospitals to prescribe more, and more expensive drugs to Medicare Part B beneficiaries, compared to non-340B hospitals. Prescribing trends confirm this behavior.11

▪ There are undoubtedly good actors that are using the 340B program to help vulnerable patient populations get the care they need. However, it is uncertain whether all entities are.

▪ Congress did not clearly identify its intent for the program or the program’s parameters, leaving the statute silent on many important program requirements (e.g., patient eligibility).

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The resulting explosive growth in the 340B program has created significant market distortions as increased hospital participation has resulted in the majority of 340B drug spend funneling through hospitals.

As of 2015, 40% of all hospitals participated in the 340B program\textsuperscript{12}; and, as of Q1 2015, DSHs alone represented 78% of all 340B drug purchases.\textsuperscript{13}

340B DSHs assert that their ability to treat indigent, uninsured, and underinsured patients (i.e., charity care and uncompensated care) with outpatient drugs relies on 340B savings and that they would not be able to treat these vulnerable patient populations without their 340B revenue.

In 2017, total DSH margins through the 340B program were $14.5B, 50% of which ($7.2B) were from physician-administered drugs.\textsuperscript{14}

However, charity care and uncompensated care appear to be negatively correlated with 340B program growth. In 2016, overall hospital uncompensated care in the U.S. dropped 16% from 2012 levels—a historic low when measured as a percentage of hospital expenses.\textsuperscript{15}

\textbf{Congress did not establish any mechanisms to monitor or calculate program savings or specify how program savings are to be used. Consequently, there is great variation in how program savings are utilized across covered entities. Although, federal grantees are restricted in the way they can use program funds due to other federal grant requirements.}

As a result, the 340B statute does not require covered entities to report the level of charity care provided, so there is a lack of data and transparency on how much charity care is provided by covered entities.

In 2017, charity care represented one percent or less of patient costs at 37% of 340B hospitals\textsuperscript{16}, well below the national average for two-thirds of 340B hospitals.

For these reasons, the 340B program has expanded rapidly. DHSs represent over three-quarters of all 340B drug purchases. 340B hospitals are delivering more outpatient drugs, yet charity care has declined during periods of program expansion and over one-third of 340B hospitals provide less charity care than the national average.

Who is receiving these outpatient drugs? If these entities are not utilizing tax savings and 340B savings to serve vulnerable patient populations, how are these savings being utilized? Who is the 340B program really serving?

Alongside program growth, there has been an increase in consolidation of community-based private practices within specialties that administer a high volume of expensive outpatient drugs.\textsuperscript{17}


\textsuperscript{13} Medicare Payment Advisory Commission, Report to Congress: Overview of the 340B Drug Pricing Program (May 2015).


\textsuperscript{15} American Hospital Association Uncompensated Hospital Care Cost Fact Sheet. American Hospital Association. December 2017.


• 340B hospitals have a financial incentive to open child sites, or hospital off-site outpatient facilities, in areas that do not reflect the DSH percentage of the parent entity, thus enabling the hospital to expand their 340B market share by gaining access to a higher number of commercially-insured patients. As of October 2017, 70% of registered covered entities were child sites. As of 2015, 60% of oncology practices were vertically integrated (i.e., affiliated with a hospital through acquisition or contract). Approx. 51% of oncology practices and 30% of rheumatology, gastroenterology, and neurology practices that were independent in 2007 had integrated vertically by 2017.

• Perhaps more concerning is that 340B hospitals appear to be targeting practices in affluent communities with well-insured patients. These consolidation practices result in increased patient cost and, in some instances, negatively impacts the quality of patient care. Additionally, these market consolidations may increase private insurance premiums, as well as other patient costs.

• NICA has received numerous reports from patients and providers relating to vertical integration that has resulted in significant increases in patient cost, delayed and disrupted access to care.

• 340B hospitals appear to be administering more and more expensive 340B drugs to commercial patients, thereby capitalizing on the arbitrage opportunity and leveraging tax savings as well as 340B revenue to acquire physician practices—across specialties that administer a high volume of high-cost outpatient drugs—in affluent communities with a healthy proportion of commercially insured patients to expand their 340B market share and maximize financial gain, rather than advance their public service.

• In 2001, HRSA allowed a select number of 340B-covered entities to contract with multiple pharmacies, making way for national pharmacy chains (e.g., Walgreens, Walmart, CVS Health, etc.) to participate in the program. By 2010, HRSA allowed all covered entities to contract with as many pharmacies as they pleased. The expansion led to a 4,228% increase in the number of participating pharmacies from 2010 to 2020.

• 340B-covered entities may purchase certain products at $0.01 and still acquire the full reimbursement for the drug from Medicare Part D or private insurance plans. Through these practices and profit margins averaging 72% on 340B medicines, covered entities and contract pharmacies were able to obtain $13 billion in gross profits in 2018.

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18 340B Program Hospital Registration Instructions [PDF]. (2019, February 11). North Bethesda: Health Resources and Services Administration.


21 Nikpay SS, Richards MR, Penson D. Hospital-Physician Consolidation Accelerated In The Past Decade In Oncology, Cardiology. 2018; 37(7):1123-1127.


These behaviors do not align with the 340B program’s intent and are adversely impacting patients’ access to care in lower cost care settings, leaving our nation’s sickest and most vulnerable citizens without the care they need.

Judging the 340B program on outcomes, not intentions, reveals that the program appears to be a very expensive and inefficient way to help vulnerable patient populations afford the medicines they need.

The lack of transparency and reporting obligations combined with insufficient oversight and vague patient eligibility criteria have created a lot of room for interpretation. The more room for interpretation, the greater the risk that a program intended for good could be inadvertently abused. If there are bad actors that have willingly exploited these conditions to capitalize on the resulting arbitrage opportunity, is it safe to assume they are responsible stewards of their nonprofit tax savings?

### 340B Program: Overview

The Veterans Health Care Act of 1992 established the 340B Drug Pricing Program in section 340B of the Public Health Service (PHS) Act to address an unintended consequence created by the Medicaid Drug Rebate Program under the Omnibus Budget Reconciliation Act of 1990. The program was designed to improve access to medications for vulnerable patients by re-establishing a discount program for our nation’s safety-net providers. The program stated that in order to have their drugs covered by Medicaid, manufacturers must agree to sell covered outpatient drugs at or below statutorily defined discount prices (called “340B ceiling prices”) to covered entities.

Under the 340B program, covered entities can purchase outpatient drugs at steep discounts, between 20 and 50%, sell them to a “patient” (anyone that has received services from that covered entity), charge the patient’s payor for reimbursement well above the acquisition cost, and keep the difference. Current law or program guidance does not specify exactly how these savings should be allocated by covered entities. Essentially, 340B hospitals are able to sell all their 340B discounted drugs to commercially insured patients exclusively, bill the insurer for an enormous markup on the drug, and pocket the entire difference without sharing any of the savings with the patient, their insurer, or vulnerable (i.e., uninsured) patients being treated by the covered entity.

Additionally, the program does not address what eligible providers may charge, and many payors—including Medicare and, in some cases, Medicaid—reimburse at amounts that are much higher than the acquisition cost of the drugs. Under current law and program guidance, covered entities may generate revenue from the “spread” between the cost at which the drug was acquired and the price at which the drug is reimbursed above acquisition cost.

### Is the Program Aligned with Initial Intent?

Congress intended for the savings from these discounted prices to enable covered entities “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” In a 2013 letter to the administrator of HRSA, Senator Charles Grassley wrote “Hospitals can elect to sell all of their 340B drugs to only fully insured patients while not passing any of the deeply discounted prices to the most vulnerable, the uninsured. This is contrary to the purpose of the 340B program since much of the benefit of the discounted drugs flows to the covered entity rather than to the vulnerable patients that the program was designed to help.”
Essentially, 340B hospitals are not required to pass along their discounts to patients or insurers, nor are they required to demonstrate their investments in outpatient support programs for vulnerable patients. Consequently, these covered entities may not be using program savings to improve access to outpatient drugs for the vulnerable patient populations the program was intended to serve.

In 2012, one 340B entity reported five-year profits of $282 million accrued through its outpatient departments and affiliated clinics as a result of its participation in the 340B program. Another report suggested that profits generated through the prescribing of a single medical oncologist practicing at an outpatient clinic affiliated with a 340B hospital could reach $1 million per year by administering drugs obtained at 340B discounted prices to fully insured patients.

The 340B Program has seen rapid growth in recent years, averaging 21% annual growth in sales at the 340B price since 2010. In fact, the program has grown by 125% in the last three years (2014-2017). As the 340B program has grown, so has the proportion of drugs acquired at steeply discounted prices. Drug sales at the 340B price increased to almost $20 billion in 2017, representing almost 8% of the overall drug market in 2016. However, charity care and uncompensated care has not appeared to positively correlate with program growth. In 2016, overall hospital uncompensated care in the United States fell 16% from 2012 levels – a historic low when measured as a percentage of hospital expenses. Unfortunately, charity care represents 1% or less of patient costs at 37% of 340B hospitals, and charity care is below the national average for almost two-thirds of 340B hospitals. Perhaps more disconcerting is that uninsured patients may not be offered access to 340B discounts at DSHs’ contract pharmacies, which means these patients would pay the full retail price for a medicine a hospital purchased at a steep discount.

There are many covered entities that use their 340B revenue as the program intended to subsidize charity care, uncompensated care, and programs to improve access to health care for vulnerable patients. However, although well-intentioned, there is concern that limited program guidance and lack of standardized definitions, transparency and reporting obligations across all covered entities may have allowed the program to get off track by creating a very large regulatory-driven profit opportunity with strong incentives to maximize 340B market share to drive 340B revenues.

As a result, the program has seen explosive growth in recent years with the number of covered entities increasing significantly and the number of child sites and contract pharmacies increasing exponentially. Specifically, the number of contract pharmacies participating in the 340B program has grown by 4,228% from April 2010 to April 2020, and over 50% of the profits from 340B program participation is retained by three national pharmacies: Walgreens, Walmart and CVS Health, as well as Cigna’s Accredo specialty pharmacy. Economists, research organizations and advocacy groups are concerned that the program’s

32 340B Hospitals Continue to Expand: Growth and Distribution of Physician-Administered Drug Reimbursement Across Ten Therapeutic Areas. (Avalere Health analysis based on Medicare cost reports). Alliance for Integrity and Reform of 340B.
explosive growth has created distortions in the market, manifesting in three ways: (1) prescribing behavior moving toward more or more expensive drugs; (2) the cost of drugs shifting to other stakeholder groups; and, (3) provider consolidation that creates additional cost pressures.

**340B encourages covered entities to prescribe more or more expensive medications**

Under the 340B program, covered entities can sell drugs acquired through the program at steep discounts to all qualified patients, regardless of income and insurance status. As such, the more medications, and the more expensive the medications, acquired through the program at steep discounts and sold above acquisition cost, the greater the “spread” (i.e., margins) on these products.

Medicare Part B reimburses for outpatient drugs based on 106% of ASP (or 104.3% under sequestration). According to a 2015 report by the Government and Accountability Office (GAO), because 340B hospitals are able to acquire these drugs at significant discounts but get reimbursed at the same rate as non-340B hospitals and physician offices, there is a significant financial incentive at 340B hospitals to prescribe more and more expensive medications to Medicare patients than at non-340B hospitals.\(^{35}\)

Additionally, a 2015 report by the U.S. Health and Human Services’ Office of Inspector General (OIG) found that Medicare payments for 340B-purchased drugs accounted for almost 50% ($3.2 billion) of all Part B hospital outpatient drug expenses in 2013.\(^{36}\) In 2013, Part B paid covered entities a total of 58% more than the statutorily-defined 340B ceiling prices, which allowed these covered entities to realize $1.3 billion in profit on outpatient drugs alone. Compare this to roughly a 4% profit margin for independent physician offices and non-340B participants.

Additionally, according to a 2019 report by Berkeley Research Group DSH margins through the 340B program totaled $14.5B in 2017. 50% ($7.2B) were from physician-administered drugs (other than Medicare FFS), 29% ($4.3B) were from retail drugs, 12% ($1.7B) were Part B margin clawed back under Outpatient Prospective Payment System (OPPS), and 9% ($1.3B) were remaining Part B margin under OPPS.\(^{37}\)

If covered entities are unnecessarily prescribing more drugs or more expensive drugs, then total drug spend increases unnecessarily and the cost-burden for both patients and payors follows suit. Additionally, if payors determine that this increased financial risk must be balanced across its entire beneficiary portfolio in a subsequent plan year, the cost-burden may be shifted to all beneficiaries in the form of increased premiums and/or reduced coverage.

**340B program growth may be shifting drug costs to other stakeholder groups**

As the adage goes, there is no such thing as a free lunch. Government-mandated discounts must be paid for somehow. As pharmaceutical manufacturers face substantial and expanding demand for discounts on the acquisition prices of their drugs, they may be inclined to pass the increased cost-burden of these discounts onto payors.

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\(^{36}\) Part B Payments for 340B-Purchased Drugs. HHS Office of Inspector General. 2015

In a 2013 article published in the Journal of the American Medical Association, Conti and Bach stated that “drug manufacturers will likely seek to increase list prices even further to offset revenue losses incurred as a large number of drug sales become eligible for 340B discounts [and thus fewer drugs are sold at full price].”

Referencing a 1996 CBO report, Conti and Bach continued by noting that an analogous response was seen when Congress enacted mandatory rebates for the purchase of drugs for Medicaid-eligible patients. Additionally, in a 2016 article published in the New England Journal of Medicine, Conti and Rosenthal stated that “the scope of the 340B program is currently so vast for drugs that are commonly infused or injected into patients by physicians that their prices are probably driven up for all consumers.”

If the expansion of the 340B program has been a driver of increasing drug list prices, the cost-burden may be shifted to payors and patients. The resulting costs created by the program are ultimately integrated into the overall health care system, manifested through: (1) rising insurance premiums; (2) higher co-pays and deductibles; and, (3) rising medical costs in unrelated segments of the healthcare system.

340B program abuse has distorted the competitive landscape in favor of 340B hospitals, driving provider consolidation that creates additional cost pressures and impacts patients’ access to care

Independent, physician-owned practices, specifically office-based infusion providers, are forced to navigate a volatile reimbursement landscape, in which competition is significantly distorted in favor of hospitals. The atmosphere is becoming increasingly pressurized to operate on narrower and narrower margins. For example, independent physician-owned practices are not eligible for 340B discounts and are not exempt from taxation; however, 340B participants are eligible for steep discounts and many are exempt from federal, state, and local taxes. Additionally, independent physician offices are typically reimbursed based on an Average Sales Price (ASP) plus methodology through both commercial payors and Medicare, whereas many 340B hospitals are reimbursed based on a negotiated percentage of charges through commercial payors. Under this reimbursement methodology, hospitals are able to mark up the drug to a stratospheric charge, then discount this charge to a merely outrageous rate negotiated with the payor.

This price differential is creating a widening profit disparity between hospitals and independent physician practices that is distorting competition. The impact of site of care price variation is an important driver of health care spending. While patients may receive the same treatment in the office as they would in the hospital, insurers typically reimburse payments to hospital outpatient departments (HOPDs) at a higher rate than to physician offices. Hospitals justify this payment differential because they incur higher overhead costs. The Medicare Payment Advisory Commission (MedPAC) and critics argue that the value of the services provided should determine prices, rather than overhead. Commercial payors seem to agree as they struggle to transition their beneficiaries from hospital care

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settings to physician offices where the costs are lower, at least until those sites are acquired by a hospital.

Magellan Rx Management surveys payors annually to identify trends in medical pharmacy and publishes their findings in their annual Medical Pharmacy Trend Report. In the 2015 report, Magellan highlighted the historic trend of hospital-physician affiliation. Among the survey respondents, 90% indicated that they saw at least one in five of the independent, physician-owned oncology practices in their network be acquired by a hospital or health system in the last 10 years. Additionally, half of respondents saw at least one in three, and 20% saw over half of the independent, physician-owned oncology practices in their network absorbed by a hospital or health system in the last 10 years. However, oncology is not the only specialty in which respondents indicated seeing hospital-physician consolidation. For rheumatology practices, 81% of respondents saw at least one in five, 31% saw at least one in three, and 12% saw 41% of independent, physician-owned practices in their network be acquired by a hospital or health system in the last 10 years. For gastroenterology practices, 79% of respondents saw at least one in five, 35% saw at least one in three, and 21% saw over half of the independent, physician-owned practices in their network be acquired by a hospital or health system over the last 10 years. For neurology practices, 64% of respondents saw at least one in five and 27% saw at least one in three of their independent, physician-owned practices be acquired by a hospital or health system over the last 10 years.41

In Magellan’s 2015 report, they also presented the top perceived causes of consolidation provided by payor respondents. The top three reasons were: (1) increased hospital incentive to expand infusion centers (i.e., child sites) if they have access to 340B acquisition costs (57%); (2) increased hospital incentive to expand infusion centers because of reimbursement based on percentage of charges (47%); and, (3) substantial decreases over the last 10 years in physician office reimbursement for commercial payors to more closely reflect CMS rates (37%).

Furthermore, Vandervelde and Blalock, citing a 2017 Magellan report, confirm Conti and Bach (2013) findings that 340B drives care away from less expensive physician office settings to more expensive hospital settings.42

If the 340B program is creating incentives to geographically expand into affluent communities with well-insured patients, driving market consolidation through hospital-acquisition of lower cost, independent, physician-owned practices, the program may be influencing increases in cost of care and total spending on health care. Additionally, market consolidation may increase private insurance contracted rates, and thus private insurance premiums, and other patient costs.43

Policy options to refocus the 340B program
Judging the 340B program on outcomes, not intentions, reveals that the program appears to be a very expensive and inefficient way to help vulnerable patient populations afford the medicines they need. Was the program intended to allow tax-exempt hospitals to leverage one vulnerable patient population—Medicare patients—to generate enormous profit margins while possibly not using savings to treat the vulnerable patient populations the program was intended to help? Taxpayers would hope that Congress’ response is a resounding “no”.

If vulnerable patient populations may not be receiving discounted prices on the medications they desperately need, the entire premise of the program is violated. Additionally, if the 340B program may be distorting the market and creating unintended consequences, evaluating how the program is being used is imperative. However, the lack of standardized transparency and reporting obligations across all participating entities prevents HRSA and Congress from evaluating the program’s alignment with its intended purpose. The best politically feasible reform would return the scope of the 340B program to its original purpose of serving vulnerable patient populations, without disrupting operations for program participants that are using the program as it was intended.

To address the aforementioned concerns and market distortions, foundational policy options to refocus the 340B program without disrupting operations for participants that are using the program properly: (1) update the law governing the program so that it clearly defines who qualifies for the discounted drugs acquired through the 340B program; (2) establish standardized transparency and reporting obligations across all participating entity types to ensure that the program is helping improve medication and health care access for the vulnerable patient populations the program was intended to support; and, (3) adopt measures to ensure that 340B savings are passed onto these same patients, while filling their prescriptions at covered entities or contract pharmacies.

These changes would ensure that the subsidized drugs would only benefit the intended patients and prevent program exploitation as a profit opportunity. Non-340B patients may also benefit if drug prices no longer reflect the cross subsidies necessary to offset revenue loss caused by inappropriate expansion of the 340B program. Additionally, patients and insurers may benefit from the elimination of 340B-created incentives to over-prescribe expensive medications and indirectly benefit from slowing down consolidation of hospitals with community-based, physician-owned care settings and physicians.

**Conclusion**

The market distortions created by the opacity of the program and rapid expansion has potentially led to negative, unintended consequences for health care consumers and our nation’s sickest and most vulnerable citizens. Policymakers from both sides of the aisle should be able to align and agree that refocusing the program, eliminating potential abuse, and ensuring that the targeted vulnerable patient populations actually benefit from the program, are reforms worth passing with bipartisan support.