STATEMENT

on behalf of

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before the

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Subcommittee on Oversight and Investigations

on the topic of

Oversight of the 340B Drug Pricing Program

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Introduction

Chairman Griffith, Vice-Chair Lesko and Ranking Member Castor, I am Anthony DiGiorgio, assistant professor of neurological surgery and faculty at the Institute for Health Policy Studies at the University of California, San Francisco. I am honored to testify before the committee today on the 340B program. Today, I am here in my personal capacity and the views expressed are my own and do not necessarily reflect those of UCSF, it's department of neurological surgery or Institute for Health Policy Studies, Zuckerberg San Francisco General Hospital, or the Mercatus Center.

The 340B Drug Pricing Program was intended to benefit hospitals like mine by providing discounted medications to covered entities (CEs), allowing them to stretch scarce resources to help underserved communities. However, over the years, the program has grown to include thousands of hospitals, many of which are not fulfilling the program's original intent. Instead, large corporations are using 340B to increase their revenue, diverting funds from the populations that need them most.

In my testimony today, I will focus on:

1. The explosive growth of the 340B program
2. The negative effects resulting from abuse of this program
3. Potential areas for reform

340B Program's Growth and Its Consequences

The 340B program was originally created to stretch scarce resources by providing discounted medications to hospitals that serve a disproportionate share of low-income patients. The program allows hospitals to resell the drugs at an increased markup, keeping the revenue with no restrictions on where that revenue is spent. The profit potential is immense with difference between a drug's full costs and the 340B price discount, which can exceed 50% of list price. This potential for revenue has led to explosive growth of the 340B program. As of 2020, the annual sales of discounted drugs has reached $38 billion.[1]

There are several ways entities can become eligible for 340B. Most commonly, this is done by reaching a disproportionate share (DSH) percentage of 11.75%. For comparison, my hospital's DSH percentage is nearly 80%. There is evidence of strategic corporate behavior to meet, without exceeding, the minimum share of low-income patients to qualify for 340B.[2] Additionally, changes to legislation and rulemaking have allowed more lenient inclusion of child sites and contract pharmacies. This expansion allows well-resourced systems to exploit the potential for revenue by expanding into wealthy areas. Data shows that newer entrants to the 340B program spend less on uncompensated care and are more financially stable than the original entities for which the program was targeted.[3]

In contrast, safety-net hospitals like mine provide specialized services such as emergency psychiatric services, behavioral health, and high-risk obstetrics, which often lead to revenue loss but are essential to maintaining the safety net. These services, and the revenue loss, mean safety-net hospitals have a much narrower margin than non-safety-net hospitals.[4]

Program Abuse

Hospitals are not using 340B revenue to expand services for the poor. Instead, there's a lack of transparency about how these funds are utilized. They don't increase provision of uncompensated care,[5] and offset charity care by reducing other community benefit programs.[6] There is evidence that 340B hospitals devote fewer resources towards charitable care than comparable non-340B hospitals.[7] Ironically, while the 340B program has been expanding, charity care has been declining.[8]

Despite the growth of the 340B program, its benefits are not reaching the intended low-income patients. The discounts are not passed on to patients. These patients face high out-of-pocket costs since any copay is based on the sale price, not the discounted 340B price.

Hospitals are establishing child sites in affluent neighborhoods, prioritizing payer mix over serving low-income populations.[9] The proliferation of contract pharmacies has led to increased revenue generation without corresponding benefits to underserved patients.

Contract pharmacies are also expanding to wealthy areas,[10] and avoiding low income areas.[11] Contract pharmacies are dominated by large chains (71%) while they tended to be located furthest from the CEs compared to independent pharmacies.[12] Contract pharmacies are often far geographically removed from the CE. One study examined contract pharmacies associated with CEs in Arizona, finding them across 33 states, as far away as New Hampshire and Florida.[13]

The lack of a clear definition of what constitutes a 340B patient allows hospitals to exploit the program. Without a precise and enforceable definition, hospitals can broadly interpret the criteria to maximize eligibility and revenue. For example, the can claim 340B discounts for patients who have only a minimal interaction with the healthcare system. Combined with the child site proliferation, this loose definition fuels much of the unrestrained growth in the system.

Negative Effects of the 340B Program

Abuse of the 340B system has seen pharmaceutical companies try to claw back the benefits, such as restricting which medications can be distributed at off-site pharmacies.[14] These restrictions are certainly understandable given the abuses of the program, yet they have the unintended consequences of harming hospitals which really need the discount. Mass abuse of the program has weakened it for the patients it was intended to serve.

The program acts as a transfer of funds to CEs. It isn't just pharmaceutical companies that fund this transfer; although their lost revenues going to tax-exempt CEs does deprive the treasury, funds are also transferred from private insurance, Medicare and Medicaid. Private plans pay an average of 278% of the sale price of medications,[15] and the program incentivizes using higher priced drugs, as shown by shifts away from cheaper medications in 340B CEs.[16] Since the payers pay full price for the drug, and the program has superseded many rebates, self-insured employers spend an extra $5.2B in extra drug costs.[17] Medicare subsidizes the CEs with $3.7B in revenue off 340B drugs in 2016[18] and a GAO report found that Medicare drug spending is higher at 340B hospitals.[19] Even Medicaid transfers wealth to CEs when state programs forego the Medicaid Drug Rebate Program (MDRP) due to the prohibition on duplicate discounts.[20] A recent report out of the California Legislative Analysts Office found that Medicaid Managed Care Organizations (MCOs) often negotiated prices for 340B drugs that were much higher than what the state would pay under fee-for-service. By carving 340B drugs out of Medicaid MCOs, and reclaiming the MDRP, California will save millions of dollars.[21]

The 340B program incentivizes consolidation, giving a competitive edge to 340B hospitals over independent practices, who aren't eligible for the discount. This is part of the

destruction of independent physician practices.[22] There is evidence of consolidation from 340B in the cancer care arena.[23] Additionally, areas with higher overall healthcare consolidation see higher healthcare costs.[24]

Need for Reform

To restore the 340B program's integrity and ensure it serves its intended purpose, the following reforms are necessary:

1. **Change hospital eligibility:** The simplest way to curb the program abuses is to increase the DSH percentage required for eligibility. There is room to increase this far above the 11.75% that is required now. That number is arbitrary. DSH calculation for 340B should also include outpatient visits, incentivizing hospitals to create outpatient services for DSH patients instead of relying on inpatient numbers alone. These inpatient numbers skew higher to low-income patients since they lack access to outpatient services. It creates a vicious cycle. Counting outpatient visits towards 340B eligibility would help incentivize outpatient services which are tailored to low-income individuals. Furthermore, regulations should prohibit hospitals that engage in predatory behavior, such as aggressive debt collection on patients, from being eligible for the program.
2. **Increased Transparency**: Congress should require Hospitals disclose their 340B purchases and reimbursement along with how they use 340B savings. Reporting requirements could be as simple as spending on charity care or uncompensated care, keeping in mind safety-net hospitals don't have the extra resources to hire unnecessary administrative staff. Furthermore, mechanisms must be put in place to clearly delineate 340B drugs from those under MDRP.[20]
3. **Define Eligibility Criteria for Patients:** The patient must have an established relationship with the CE. This can and should include telehealth visits since patients without means often lack transportation options to make in-person visits. If the patient is established with one in-person visit (inpatient or outpatient) and continues to have ongoing care with the CE, they should continue to qualify.
4. **Ensure child sites meet the program requirements**: Child sites must meet the eligibility requirements of their parent hospitals. There are low-income people who live in wealthy areas, and we must maintain their access to these medications. However, if child sites are in wealthy areas, they should meet the same DSH threshold of the parent site. Again, this would help incentivize outpatient services for low-income patients.

5. **Limit contract pharmacies:** Congress must curb unconstrained contract pharmacy growth in geographically distant areas, while maintaining access to pharmaceuticals for underserved populations. In urban areas, a greater number of contract pharmacies should be allowed if they are geographically near the CE. Again, low-income patients are restricted in their ability to travel far to get medications. In rural areas, more use of distant pharmacies can be allowed. There are established methods to delineate a hospital referral region, and this can be used to restrict contract pharmacies' locations.[25]

6. **Direct Benefit to Patients**: The 340B benefits should follow the patient, akin to other social benefit programs. This approach would guarantee that low-income patients directly receive the discounts and support intended by the program and that some of the savings are passed on to patients themselves. Cost savings must be passed on to the patients, so that the 340B program goes from benefitting institutions to benefitting people.

Conclusion As a physician committed to serving vulnerable populations, I believe in the original mission of the 340B program. However, reforms are necessary to prevent abuse and ensure that the program benefits those it was designed to help. Many of the current rules are arbitrary, and new regulations should be based on empirical data and transparency. I urge Congress to consider these reforms to restore the 340B program's integrity and ensure it continues to support safety net hospitals in delivering affordable healthcare to those in need.

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