Reforming the 340B Drug Pricing Program and Ensuring Access to Affordable Medications

Testimony of:

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Summary of major points

1. Reform of the 340B Drug Pricing Program is needed.

- The program was created in 1992 to help safety net hospitals stretch scarce federal resources in providing care to underserved patient populations.
- The program allows qualifying entities to purchase drugs at discounts set by statute and sell these drugs at markups, retaining the difference between the drug's acquisition cost and sale price.
- The 340B program has grown substantially in recent years to include a broad range of federal grantees and hospitals.
    - More than 40% of acute care hospitals in the US now qualify.
    - Covered entities purchase over $65 billion worth of drugs each year.
- Program participants rely on 340B to expand offerings and fill budget gaps.
- However, 340B also incentivizes a set of behaviors that increases healthcare costs and misallocates resources away from facilities with the greatest need.

2. Congress should consider several measures to strengthen the 340B program.

- *Transparency*: More comprehensive reporting is needed regarding the magnitude and sources of 340B revenue and how money is allocated by covered entities.
- *Oversight*: The federal agency in charge of 340B should be given more resources and responsibility to monitor compliance with program regulations.
- *Expansion*: Congress should identify ways to ensure that new satellite clinics and contract pharmacies serve patients in need.
- *Debt collection*: Restrictions should be placed on 340B debt collection practices.
- *Community benefits*: Congress should further delineate standards expected for covered entities to provide community benefits (tailored to the type of entity).
- *Out-of-pocket costs*: Although 340B covered entities are under no legal obligation to pass on pharmaceutical savings to patients, Congress should consider ways of ensuring that more 340B covered entities help with patient cost-sharing.

3. The US pays the highest prices for prescription drugs in the world. The reforms outlined above, while important, will not lower these prices. Congress should couple 340B reform with other measures to reduce drug prices.

- *Price negotiation*: Lawmakers should seek to protect and expand price negotiation under the Inflation Reduction Act.
- *Patent abuses*: Congress should identify ways to combat pharmaceutical patent thickets and ease barriers to generic and biosimilar entry.

4. The healthcare safety net that 340B was designed to support is under threat.

- Millions of Americans will lose Medicaid coverage in the coming years because of recently passed legislation.
- Millions more could soon face higher premiums if tax credits for Affordable Care Act marketplace plans are allowed to expire.
- Recent cuts could have profound consequences for 340B clinics and hospitals. Efforts to reform 340B should be accompanied by measures to ensure that more Americans have access to health insurance coverage and affordable care.

Chair Cassidy, Ranking Member Sanders, and Members of the Committee:

My name is William Feldman. I am physician and health policy researcher at the University of California, Los Angeles David Geffen School of Medicine. My research focuses on pharmaceutical policy and outcomes and is funded by the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and non-profit foundations. I am honored to talk with you all today about the 340B Drug Pricing Program and, more generally, about improving healthcare in the United States. I applaud efforts by this committee to tackle 340B reform and will discuss several ideas for strengthening the program. I would also encourage lawmakers to pursue measures alongside 340B reform aimed at lowering drug prices in the US and ensuring that more Americans have access to health insurance coverage and affordable care. All views presented in this testimony are my own and do not necessarily represent those of my employer.

1. Background on the 340B Drug Pricing Program

The 340B Drug Pricing Program was created in 1992 to help safety net hospitals stretch scarce federal resources in providing care to underserved patient populations.[1, 2] The program allows qualified entities to purchase drugs at discounts set by statute and sell these drugs at markups, retaining the difference between the drug's acquisition cost and sale price (known as the "spread"). A hospital in the 340B program, for example, might purchase a clinician-administered drug like pembrolizumab (Keytruda) for $6,000 per infusion (a 50% discount off the Average Sales Price [ASP] of approximately $12,000[3]) and then sell the drug at a 200% markup for $24,000.[4-7] The hospital in this scenario would keep $18,000, which it could then spend on operations, including on losses associated with uncompensated care.

Two broad types of entities qualify for the 340B program: (1) federal grantees, which include federally qualified health centers (FQHCs), Ryan White HIV/AIDS programs, and other specialized clinics; and (2) hospitals, including children's hospitals, critical access hospitals, disproportionate share hospitals (DSHs), rural referral centers, and sole community hospitals.[8]

The 340B program has grown considerably since its inception, from fewer than 100 hospitals in 1993 to nearly 60,000 facilities (purchasing $66 billion worth of drugs) in 2023.[9-11] More than 40% of all acute care hospitals in the US now qualify.[1] Two particularly big drivers of 340B growth are "child sites" and contract pharmacies. A child site is a clinic affiliated with a 340B hospital that administers infused medications acquired at discounted prices, whether in the same building as the main hospital or more typically at a different location. Between 2013 and 2021, the number of child sites increased from 6,100 to 27,700.[11] By 2021, 340B hospitals had an average of 11 child sites (with 75% having at least 1), and these child sites represented more than half of all 340B facilities.

Like child sites, contract pharmacies enable 340B covered entities to earn revenue through pharmaceutical sales at offsite locations. However, in this case, the

arrangement is with third-party pharmacies rather than hospital-affiliated clinics. 340B covered entities may contract with pharmacies to dispense drugs (also acquired at 340B discounts) to patients treated by the covered entity. Before 2010, 340B hospitals could only contract with one outside pharmacy; now, they may contract with an unlimited number. Today, there are more 33,000 340B contract pharmacy locations in the US (which are predominately part of large pharmacy chains[12]), up from fewer than 1,300 in 2010.[9]

2. Benefits of the 340B program

The 340B program has long provided meaningful revenue for clinics and hospitals. FQHCs and other 340B federal grantees, which play an outsized role in supporting the healthcare safety net in our country, use this money to shore up limited budgets. FQHCs represent the largest share of 340B federal grantees and are located in urban and rural communities across the US, treating patients regardless of their medical condition or ability to pay. These clinics provide comprehensive services from obstetrics and cancer screening to addiction treatment and diabetes care.[13-15] Many FQHCs also help patients with transportation, food, and social services.[16] Although federal grantees represent around 40% of 340B facilities, they are responsible for just 13% of drug purchases.[11]

Hospitals, by contrast, account for 87% of drug purchases.[11] Many rely on 340B revenue to expand service offerings and cover shortfalls.[1] In 2022, according to the American Hospital Association, 340B hospitals provided approximately $100 billion in community benefits, including uncompensated care, medical education, financial assistance, and community-building activities.[17, 18] One survey study found that, after adjusting for differences in hospital size and ownership, 340B hospitals were more likely than non-340B hospitals to offer medication access services (e.g., help with prior authorizations) and provide treatment for drug and alcohol use disorders and HIV.[19]

3. Incentives in the 340B program

Whereas proponents of 340B see the program as a vital source of funding for clinics and hospitals in the US, critics argue that it has grown beyond what lawmakers intended and incentivizes a set of behaviors that increases costs for patients and payers and misallocates resources away from facilities with the greatest need. Seven features raise particular concern.

(1) High-priced drugs: Hospital revenue depends on the spread between 340B acquisition costs and sales prices, and 340B covered entities therefore earn more money when expensive medications are prescribed. Less expensive generic and biosimilars drugs, by contrast, generate smaller revenue streams. In a study of two widely-prescribed biologics, filgrastim (Neupogen) and infliximab (Remicade), 340B eligibility was associated with a 23% reduction in use of less costly biosimilar versions of these drugs compared to the more expensive originator biologic versions.[20]

(2) Hospital consolidation: The 340B program may also promote acquisitions of new clinics where high-cost therapies are administered. One study found that 340B eligibility was associated with 230% more hematologist-oncologists than expected in the absence of the program and 900% more ophthalmologists (two specialties that use a lot of expensive clinician-administered drugs).[21] Although hospital consolidation is driven by a number of factors, the 340B program may provide an extra reason for hospitals to acquire more clinics, which can contribute to anticompetitive market effects.

(3) Locating child sites and contract pharmacies in wealthy areas: 340B covered entities can increase revenue by locating child sites and contract pharmacies in wealthier areas with more commercially insured patients. My co-authors and I found that 340B DSHs have increasingly placed newly registered child sites and contract pharmacies in areas of lower socioeconomic deprivation and with higher rates of insurance and employment.[22] Several other studies similarly show that 340B hospitals have expanded into more affluent areas over time.[23-25]

(4) Misdirected redistribution: The allocation framework in 340B is not designed to ensure that clinics or hospitals with the greatest need receive the most funding. Instead, the covered entities that receive the most funding via the 340B program are those with the largest volume of medications (#1) prescribed by the highest-grossing specialties (#2) at locations with the most commercially insured patients (#3).

(5) Higher costs for payers: As hospitals drive greater volumes of medications through the 340B program, payers may miss out on rebates that would otherwise lower health care costs. The 340B program prohibits duplicate discounts, and many drugs have high rebates that offset payer-negotiated prices outside of 340B.[26] For example, discounts on inhalers for chronic obstructive pulmonary disease (COPD) in Medicare can exceed 50%;[27] each time a 340B contract pharmacy dispenses a $500 inhaler to a senior, Medicare could pay the full price (assuming no duplicate discounting), thus missing out on $250 that would have otherwise offset prescriptions drug costs. These high costs for payers, in turn, may contribute to higher premiums for beneficiaries.

(6) Questionable connection with uncompensated care: Several studies have raised questions about the relationship between 340B status and uncompensated care. One study, for example, found no association between new participation in the 340B program and increased provision of uncompensated care.[28] Another found that new participation in 340B was associated with an increase in charity care (by $0.9 million per hospital) but not an increase in the broader category of uncompensated care, which includes both charity care and uncollected debt.[29] The precise way that 340B revenue contributes to support for vulnerable patient populations at a given hospital can be difficult to discern, because the program does not impose substantial requirements on how 340B revenue is spent or how spending is reported at a granular level.

(7) Limited reductions in out-of-pocket costs for patients: The 340B program was not specifically designed to require that clinics or hospitals reduce cost-sharing for patients. Instead, clinics and hospitals may invest 340B revenue in other core

operations. A study of 340B contract pharmacies found that 1.4% of 340B-eligible pharmacy claims were linked to use of 340B discount cards that offset patient costs.[30]

4. The SUSTAIN 340B Act

A bipartisan working group of Senators, including some members of this committee, have recently circulated a framework for 340B reform known as the Supporting Underserved and Strengthening Transparency, Accountability, and Integrity Now and for the Future of 340B Act (SUSTAIN 340B).[31] SUSTAIN 340B focuses on improved transparency, more rigorous oversight, and limits on child sites and contract pharmacies. The draft framework proposes new requirements in some areas and solicits feedback in others. This framework is an excellent starting point for meaningful reform.

(1) Improved transparency: 340B covered entities would be required to disclose more comprehensive information about which patients receive drugs through the program, the magnitude and sources of revenue, and how money is allocated. A similar transparency law recently enacted in Minnesota highlights the promise of such reporting requirements.[32, 33] Because of this legislation, lawmakers in Minnesota were able to assess the magnitude of margins at 340B hospitals (42 cents in net revenue for every dollar charged to payers) and the amount earned by pharmacies and third-party administrators (TPAs) serving as intermediaries in the supply chain for drugs dispensed at 340B contract pharmacies (16% of gross revenue).[32, 33] Similar requirements applied nationwide could help lawmakers identify future targeted reforms to strengthen the 340B program.

However, when considering new transparency requirements, Congress must take care to ensure that they do not impose undue burden on covered entities, especially federal grantees such as FQHCs, which have limited resources to comply. The high reporting rate observed among covered entities in Minnesota during the first year of implementation (94%) suggests that reporting requirements can be both meaningful and manageable for covered entities. Even if transparency requirements were targeted only at hospitals, such efforts could generate insights for lawmakers given that the vast majority of 340B purchases are made through hospitals.

(2) Oversight: Under the SUSTAIN 340B Act, the Health Resources and Service Administration (HRSA) would also have more responsibility and financial resources to audit the program. To secure these financial resources, Congress would initiate user fees and set aside new appropriations.[31] The draft framework also proposes establishing a third-party clearinghouse to prevent duplicate discounts. More funding for HRSA could help strengthen oversight and improve the program.

(3) Limits on contract child sites and contract pharmacies: The SUSTAIN 340B Act also seeks to place limits on contract pharmacies and child sites. Key to any such reforms will be ensuring that child sites and contract pharmacies are situated in areas serving vulnerable patient populations and that enhanced access is accompanied by

measures to improve affordability for patients. Some argue that locating child sites and contract pharmacies in wealthier areas is a feature (rather than a bug) of the 340B program, because it allows covered entities to generate more revenue and therefore offset greater losses from uncompensated care. In my view, strengthening access to affordable care for underserved populations via child sites and contract pharmacies should be a core mission of 340B.

5. Other reform measures

I would encourage Congress to consider a few additional measures that enhance the covered entities' responsibility to promote 340B values.

(1) Limits on debt collection: Some 340B hospitals outsource debt collection to third-party agencies and have taken aggressive measures in recent years, including litigation, to collect debt from uninsured patients unable to afford care.[34] Congress could restrict the actions permitted by 340B debt collectors and require forgiving a specified amount of debt incurred each year by low-income patients (e.g., as a percentage of revenue earned in the 340B program).

(2) Setting standards for community benefits: Congress should outline a set of detailed standards for community benefits required of 340B hospitals. Many 340B hospitals already provide invaluable contributions to local communities, and not all 340B hospitals (e.g., sole community hospitals) should be expected to provide the same types of benefits as others (e.g., large, well-resourced DSHs). But Congress could adopt a set of measures aimed at ensuring hospital offerings that better reflect the mission of 340B.

(3) Reducing patient cost sharing: Although 340B covered entities are under no legal obligation to pass on pharmaceutical savings to patients, some clinics and hospitals do help defray out-of-pocket costs. I would encourage Congress to consider ways of ensuring that more 340B entities help with patient cost-sharing and that the 340B program helps address the problem of medication affordability in the US.

6. Broader drug pricing reform

The reforms outline above—centered on transparency, oversight, child sites and contract pharmacies, debt collection, community benefits, and patient cost sharing—could help strengthen the 340B program. However, none of these measures would lower pharmaceutical prices in our country. Brand-name drug prices in the US are by far the highest in the world, and any serious discussion of 340B should be accompanied by an equally serious discussion of how we can lower unreasonably high pharmaceutical prices.

Two sets of reforms, in particular, stand out as Congress considers its policy agenda over the coming year. The first is protecting and expanding the Inflation Reduction Act (IRA), which enabled Medicare to negotiate the prices for a limited set of prescription drugs and established out-of-pocket maximums for seniors. The pharmaceutical

industry has pushed to undue or weaken the IRA since it was first passed, and they have unfortunately made inroads. The One Big Beautiful Bill Act (OBBBA) will now exclude more high-revenue drugs from Medicare price negotiation than were originally excluded. The Congressional Budget Office released updated numbers this week showing that these new provisions will increase healthcare costs by approximately $8.8 billion over 10 years.[35] Rather than limit the IRA, Congress should find opportunities to protect and expand the law. My co-authors and I have found that biologics earn substantially more revenue than small-molecule drugs with similar development costs and yet are protected from Medicare price negotiation for an additional 4 years.[36, 37] Congress should shift the timeline for negotiating biologics earlier and consider extending negotiated prices to apply beyond Medicare to the private insurance market. Nearly all other high-income countries comparable to the US negotiate the prices for prescription drugs shortly after a drug is approved.[38] Rather than diminish the gains of the IRA, Congress should build upon them.

A second area ripe for reform is the pharmaceutical patent system. Brand-name firms continue to limit generic and biosimilar competition through extensive patent thickets that often cover trivial features of their products.[39-46] The Federal Trade Commission under both the Biden administration and the current Trump administration have pursued manufacturers for improperly listing patents with the Food and Drug Administration.[47-49] There is strong bipartisan support for reform aimed at removing barriers to generic and biosimilar entry.[39, 50] Such competition remains the key way to lower drug prices in the US for all payers and patients,[51, 52] and I would encourage Congress to move legislation that address pharmaceutical patent abuses.

7. Protecting the safety net

The 340B program was designed to support the health care safety net in the US. Good faith efforts at reform should be accompanied by measures to protect vulnerable patients in our country. Instead, the current administration has taken measures to gut key healthcare programs that benefit disadvantaged groups. The OBBBA alone will result in the loss of insurance coverage for approximately 10 million Americans.[53] The law will also result in millions of families losing access to Supplemental Nutrition Assistance Program (SNAP) benefits.[54] If Congress allows the enhanced premium tax credits of the Affordable Care Act (ACA) to expire this year, millions of Americans will see increased premiums. For the 24 million people enrolled in ACA marketplace plans in 2024, enhanced premium tax credits reduced annual premiums by an average of $705, bringing down payments to $888.[55] Cuts to the health care safety net only increase the burden on 340B clinics and hospitals, as they may be forced to devote more resources to uncompensated care in the coming years.

8. Conclusion

The 340B program needs reform. I would urge Congress to focus on 6 key areas to help strengthen the program: transparency, oversight, child sites and contract pharmacies, debt collection, community benefits, and patient cost-sharing. However, 340B reform

alone will not address our most pressing health care crises. Coupling 340B reform with measures to lower pharmaceutical prices and enhance insurance coverage is vital if we are to improve the health of patients in the US.

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